Tool Kit for Managing Attending Physicians in Post-Acute and Long-Term Care

AMDA – The Society for Post-Acute and Long-Term Care Medicine

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The Society for Post-Acute and Long-Term Care Medicine

TABLE OF CONTENTS

TABLE OF **CONTENTS** CONTINUED

INTRODUCTION TO THE TOOL KIT

AMDA's *Tool Kit for Managing Attending Physicians* is a guide for the medical director or administrator of nursing facilities. This tool kit is intended to help

- support a process to verify the qualifications of each attending physician who wishes to provide patient care in the facility and to make a decision to grant or deny the right to practice in the facility; and
- to develop and communicate to the community-based attending physicians the expectations that constitute acceptable medical practice and performance as a practitioner.

AMDA recognizes the differences in size, structure, and formality that exist in nursing homes. Therefore, this kit provides tools that address a range of needs from a very basic level of acknowledgment to the very structured level of a formal application and checklist validation of the attending physician's credentials.

The revision of the 501 Ftag in November 2005 emphasizes the medical director's role in coordination of care. While credentialing of community-based attending physicians is not required, it is a way to organize and manage these physicians. Credentialing can be very simple or complex and is not synonymous of privileging. The tools provided allow a medical director to develop an appropriate level of credentialing for the nursing facility and its staff.

This tool kit does not contain "fill in the blank" forms. Rather, the kit expresses AMDA's principles and includes several options for the facility, medical director, and attending physician to consider and to modify to fit their particular situation and state law. **This tool kit does not substitute for competent advice of qualified legal counsel.**

The pieces of the tool kit can be used alone or in conjunction with other pieces. For example, the Attending Physician Credentialing Application (Section 6) can be used alone or could be provided to the attending physician along with the Performance Responsibilities for Community-Based Attending Physicians (Section 4).

Before signing any agreement, attending physicians should always have draft contracts reviewed by counsel familiar with the unique requirements of health care contracting. Knowledgeable local counsel also should determine whether particular requirements of state law must be included in contracts.

THE CREDENTIALING PROCESS IN A NUTSHELL: A SELF-STUDY[1] TOOL FOR MEDICAL DIRECTORS

A Self-Study Checklist on the Credentialing Process

Initial Appointment Process:

1. Do you have written policies and procedures for the initial appointment process for community-based attending physicians?
2. Do you have a facility-specific written set of performance expectations and essential functions for attending physicians?[2]
3. Does each applicant wishing to practice in the facility submit:[3]
   - A written request for appointment?
   - A statement regarding his or her physical and mental health status?
   - Lack of impairment due to chemical dependency/substance abuse?
   - History of loss of license and/or felony convictions?
   - History of loss or limitation of privileges or disciplinary action?
   - Evidence of good standing to participate in federal and state health care programs?
   - An attestation to the correctness and completeness of his or her application?
   - Authorizations to release information from all primary sources?
4. For each applicant, do you obtain and verify from primary sources:[4]
   - Graduation from medical school and completion of residency, or board certification (if applicable)?
   - A current, valid license in the appropriate state?
   - A valid Drug Enforcement Administration (DEA) or Controlled Dangerous Substance (CDS) certificate?
   - Clinical privileges in good standing at community/transfer hospitals?
   - Work history?
   - References from appropriate individuals at the practitioner's previous practice settings?
   - Current malpractice insurance and adequacy (according to nursing home policy)?
   - Good standing to participate in all federal and state health care insurance programs?[5]
5. Do you have a procedure for notifying the physician or practitioner of the decision on initial application or periodic renewal?

Additional Steps to be Considered:

6. Does the governing body or administration approve all credentialing policies and procedures?
7. Do current medical staff bylaws, board bylaws, or facility policies and procedures describe the roles, responsibilities, functions, relationships, and authorities of the following in the credentialing process (as pertinent):
   - Governing Body
   - Administrator
   - Medical Director
   - Credentials Committee

- Corporate Medical Director
- Medical Staff Members

8. Is your credentialing process ongoing?
9. Do you follow the same credentialing procedures for all practitioners?
10. Do you apply credentialing criteria consistently?
11. Are your credentialing criteria objective and rational with respect to the nursing facility's quality-of-care, business, and compliance concerns?
12. Do you process applications within a reasonable time frame or the time frame specified in the medical staff policies and procedures (or bylaws)?
13. Do you have written procedures for:
    - Obtaining any missing or additionally required information from the applicant?
    - Closing an applicant's file if he/she does not submit complete information?
14. What body of your facility is charged with verifying physician credentials? Does it:
    - Review the Credentials Verification Organization's (CVO) materials?
    - Maintain written documentation specifying the relative responsibility and accountability of the CVO and internal credentials committee?
15. Does the Credentials Committee review requests for and make recommendations for temporary privileges?
16. Does the Credentials Committee make all recommendations on medical staff appointment and clinical privileges to the Administrator or management?
17. Does your nursing facility routinely consider the impact of credentialing decisions on:
    - Resident care?
    - Compliance?
    - The medical staff?
    - The nursing home?
18. Does your nursing facility grant the right to practice in the facility only to qualified individuals?[6]
19. Do you have a fair, written procedure that gives practitioners the opportunity to request reconsideration of adverse decisions about the right to practice in the facility?
20. Do you orient all new appointees to their roles and responsibilities?[7]
21. Do you complete a reappointment activity summary or profile for each physician upon reappointment?
22. Do you provide updates when performance expectations or regulations change?

Disciplinary Matters:

23. Do you have policies and procedures that address:
    - Impaired physicians?
    - Sexual harassment?
    - Unavailability or nonresponsiveness?
    - Noncompliance with regulations?
    - Reporting of elder abuse?
    - Conflict resolution within the staff that practices in the facility regarding any aspect of the credentialing process or a physician's performance in dispute?

24. Does your nursing facility:
    - Reduce, suspend, or terminate clinical privileges as necessary?
    - Report disciplinary actions to appropriate authorities?
    - Have a reconsideration process for practitioners who have been disciplined?
    - Inform practitioners of the procedure by which they may request reconsideration?

Documentation:

25. Do you store credentials files in a secure location?
26. Are credentials files easily accessible?
27. Do you have a policy and/or procedure controlling the confidentiality of credentials information?
28. Do you have a policy and/or procedure regarding access to and release of credentials information?

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[1] Material adapted from Greeley, H. *The Greeley Guide to Medical Staff Credentialing* (1999).

[2] See AMDA's *Sample Performance Requirements for Community-Based Attending Physicians* attached as p17.

[3] See AMDA's *Attending Physician Credentialing Application* attached as p23.

[4] See AMDA's *Credentials Verification Checklist* attached as p29.

[5] Information also may be requested from the following sources for each applicant: The National Practitioner Data Bank (NPDB); the State Board of Medical Examiners or Department of Professional Regulations; the American Medical Association (AMA) Masterfile; the American Board of Medical Specialties (ABMS); the American Board of Internal Medicine (ABIM); the Federation of State Medical Boards (FSMB); Office of the Inspector General List of Excluded Individuals.

[6] See AMDA's *Model Appointment Letter* attached as p31.

[7] An orientation package might include the names and contact information for key department heads, a listing of attending physicians on staff, or an e-mail listing for those who practice in the facility.

GUIDELINES FOR ORGANIZING THE MEDICAL STAFF AND PHYSICIAN SERVICES IN POST-ACUTE AND LONG-TERM CARE FACILITIES

Introduction

Although PA/LTC facilities are not required (by regulation) to have an "organized medical staff" or to credential attendings from the community, it is clear that facilities can use these tools to better organize their medical staff and to demonstrate oversight of community-based attendings. The following resources and information may be helpful.

I. A Medical Practice Agreement

At the most basic level, nursing facilities can create a document "Medical Practice Agreement for Long-Term Care Attending Physicians" to assist the medical director in fulfilling his or her regulatory responsibilities, including supervision of physician services in the medical care of residents. It is neither a credentialing process nor a set of official bylaws. It is simply a method by which attending physicians agree by personal signature to fulfill their regulatory obligations and give the medical director authority to carry out his responsibilities in regard to physician services. Any facility may utilize this document.

Physician Credentialing

A. What is Credentialing?

Facilities seeking JCAHO accreditation or those entering into managed care contracts (most third party payors utilize the same or similar standards as JCAHO) must comply with a process known as "physician credentialing." The concept of credentialing implies that the facility has formally verified and documented their medical staff's ability to provide appropriate care and services and granted them "privileges" to do so. At a minimum, the following physician credentialing information is required by JCAHO:

- Evidence of current license;
- Relevant training and/or experience;
- Current competence; and
- Health status.

Additional information may be requested or collected, such as:

- Proof of current malpractice insurance;
- Current DEA license; and
- Other information the facility deems appropriate.

Please refer to the JCAHO accreditation manual for more detail and instructions.

B. How is Credentialing Accomplished?

Credentialing information can be obtained in two ways: (1) through transfer of information from another JCAHO accredited institution (either a hospital or a long-term care facility); (2) through a formal, facility-based internal credentialing process. The only difference between the transfer method and internal credentialing is that if you receive all the pertinent physician information from another entity, you do not need to verify its authenticity (as the other entity has already done so). Formal verification of each item in the physician file is a

very time-consuming process. Therefore, we recommend you explore the first option as the preferred process.

1. Transfer of credential information from another healthcare organization
    a. **Transfer of credential information** is permissible when obtained from another accredited organization (JCAHO accredited hospital or LTC facility), or a hospital or another nursing facility (NF) that follows an established credentialing process.
    b. A **local governing body** should be established. This can be the Administrator if so designated in writing and if this individual's responsibilities include the duties of the governing body. A key responsibility is the granting of medical staff membership and clinical privileges.
    c. A **Medical Executive Committee** should be established. The medical director may function and perform the duties of the Medical Executive Committee.
    d. A written policy shall identify the **criteria for receiving and evaluating the credentialing information** from the transferring organization (obviously this will coincide with the agreed-upon process with the hospital or NF transferring to you, and may vary from facility to facility), and the **mechanism for communicating to the practitioner the granting or refusal of privileges.** Criteria should be designed to assure the governing body and the Medical Executive Committee that the patients will receive quality care.
    e. By utilizing the transfer process, a facility does not need to verify each credentialing item received.
    f. The **mechanism for appointment** (renewal/revision of clinical privileges) is approved **and implemented** by the Medical Executive Committee and the governing body.
    g. A written policy shall state **reappointment** will occur (at a minimum) every two years. Reappointment should be based on a reappraisal of the physician at the time of reappointment.
    h. Established criteria must be uniformly and consistently applied as reflected in each credentialing file.
2. Internal credentialing
    a. A **local governing body** should be established. This can be the Administrator if so designated in writing and if this individual's responsibilities include the duties of the governing body. A key responsibility is the granting of medical staff membership and clinical privileges.
    b. A **Medical Executive Committee** should be established. The medical director may function and perform the duties of the Medical Executive Committee.
    c. A written policy shall identify the **criteria for delineating and evaluating the necessary information** a practitioner must submit to the facility's governing body as well as the **mechanism for communicating to the practitioner the granting or refusal of privileges**. Criteria should be designed to assure the governing body and the Medical Executive Committee that the patients will receive quality care.
    d. The credential information must be verified for **authenticity and accuracy** by the governing body. For example, the board of licensure must be contacted to verify the current license is in effect and without restriction. It is not acceptable to verify credentials by making a copy of the information. Employment history must

be verified including relevant experience. It is not acceptable to confirm dates of employment only.

e. The **mechanism for appointment** (initial granting of clinical privileges) **and re-appointment** (renewal/revision of clinical privileges) is approved and implemented by the Medical Executive Committee and the governing body.

f. A written policy shall state **reappointment will occur (at a minimum) every two years.** Reappointment should be based on a reappraisal of the physician at the time of reappointment.

g. Established criteria must be **uniformly and consistently applied** as reflected in each credentialing file.

Many nursing facilities are moving to some form of credentialing to better manage attending staff. Medical directors may find the credentialing process a valuable tool for providing the coordination of medical care required of them under the 501 Ftag.

The tools included in this kit are provided for medical directors and nursing facilities to adapt to their needs.

Physician Privilege Request

Medical Care	Training/Experience	Privileges Granted
Skilled Nursing Facility Care		
_____ **Arthritis / Rheumatology** — Differential diagnosis, rheumatoid, osteoarthritis, gouty arthritis.		____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*
_____ **Cardiovascular** — Congestive heart failure - acute and chronic; coronary heart disease, with angina, infarction, or insufficiency; cardiac dysrhythmias; myocardial infarction, hypertension.		____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*
_____ **Gastrointestinal** — Differential diagnosis, peptic ulcer, ulcerative colitis, regional ileitis, obstruction, pancreatitis, malabsorption, cholecystitis.	.	____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*
_____ **Genitourinary** — Incontinence, cystitis, urethritis, nephritis, pyelonephritis, urosepsis.		____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*
_____ **Hematological** — Differential diagnosis, anemia, leukemia, thrombophiebitis, and DVT.		____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*

(continued)

Physician Privilege Request (continued)

_____ **Hepatic** — Differential diagnosis, cirrhosis, varices, hepatitis, jaundice.		____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*
_____ **Metabolic and Endocrine** — Differential diagnosis, diabetes mellitus, thyroid and parathyroid conditions, nutrition, technological feeding (tube feedings).		____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*
_____ **Infectious Diseases** — Differential diagnosis, viruses, bacterial including multiply-resistant organisms, T.B., fungal, isolation techniques.		____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*
_____ **Integument** — Rashes, vascular ulcers, pressure ulcers, wound care.		____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*
_____ **Neurologic** — Differential diagnosis, CVA — acute and rehab, Parkinsonism, Meningitis/Encephalitis, seizure disorders, dementia care, including Alzheimer's,		____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*
_____ **Pulmonary** — Differential diagnosis, pneumonia, bronchitis, COPO, pulmonary embolis, tracheostomy care, pulmonary hypertension, supplemental oxygen, asthma.	.	____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*
_____ **Other** — Collagen vascular diseases, pain management, immune disorders, allergy and atopy.	.	____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*
Subacute Program		
_____ **Dialysis/renal failure** — Managing patients with severe chronic renal failure; overseeing dialysis; managing complications of illness and dialysis.		____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*
_____ **Hyperalimentation (TPN)** — Managing those needing parenteral nutrition, adjusting mixture, laboratory monitoring.		____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*
_____ **Oncology** — Managing patients with cancer; prescribing and monitoring chemotherapy; pain management and rehabilitative care for patients with cancers; hospice care for terminally ill.		____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*

(continued)

Physician Privilege Request (continued)

_____ **Psychiatric care** — Managing major depression, organic psychosis, complex or fluctuating behavioral, cognitive, or mood disturbances.		____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*
_____ **Rehabilitation** — Managing patients with injuries, stroke, fractures, general deconditioning. Ordering physical therapy, occupational therapy, speech-language pathology services, neuropsychological services for patents with such disabilities as head and spinal cord.	.	____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*
_____ **Ventilator Care** — Weaning patients from ventilator, rehabilitation of those with COPD, management of complications of COPD.		____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*
_____ **Wound management** — Pressure sores, vascular ulcers, postoperative wound care.	.	____ No conditions ____ Conditional ____ *With consultation* ____ *Other:*

PERFORMANCE RESPONSIBILITIES FOR COMMUNITY-BASED ATTENDING PHYSICIANS

A Proposed List of the Facility's Expectations for the Community-Based Attending Physician

[NAME OF FACILITY]

Sample Performance Responsibilities for Community-Based Attending Physicians

Provide competent, safe medical care to patients under your care consistent with relevant age-appropriate medical and/or geriatric principles;

Ensure that all orders are related to medically necessary items and services;

Provide physician input and medical decision support to the clinical staff and management of the Facility;

Conduct physician rounds and timely physician visits for all of your patients and complete appropriate documentation in each resident's clinical record in accordance with your patients' problems, needs and responses to therapies, and with applicable regulatory requirements;

Coordinate, through oral and/or written communication, medical plans of care and treatment between the Facility staff, your patient's consulting physicians, and other health care providers or consultants;

Ensure 24-hour availability of physician services by providing on-call and telephone access or designating an alternative qualified attending physician staff member of this facility to do so;

Participate, as needed, in level of care assessments, certifications of medical necessity and placement recommendations for your patients who reside or seek admission to the Facility;

Maintain the relevant clinical competencies in the provision of medical care to residents of nursing homes;

Maintain confidentiality of resident-specific and facility information;

Provide all services in compliance with federal and state laws and regulations governing the provision of physician services and reimbursement for services to residents in nursing facilities;

Advise the medical director and facility Administration of current medical issues affecting the residents of this Facility;

Participate, as needed, in matters of peer review, compliance and quality assurance for the Facility.

Maintain current professional licenses and certifications to practice medicine and to prescribe controlled substances in the [State or Commonwealth];

Make application and maintain privileges at [transfer agreement] Hospital or establish an admitting coverage relationship with another physician or group;

Obtain and maintain levels of professional liability insurance acceptable to facility Administration, including sufficient continuity of coverage for "claims made" policies;

Maintain good standing to participate in all federal and state health care programs;

Provide complete financial disclosure to facility Administration regarding relevant financial interests in designated health services to which residents of this facility may be referred;

Assume full responsibility to continuously update your credentials file with the most recent information available and to immediately provide written notice to the Administrator and Medical Director of any change in credentials or standing to practice medicine under state or federal law.

[ADD OR DELETE EXPECTATIONS AS SPECIFIED FOR THIS FACILITY]

CREDENTIALING OVERVIEW

An Educational Overview Summarizing the Credentialing Issues and Process

Several trends in today's nursing facility practice environment suggest that all nursing facilities should establish clear policies and procedures to gather, validate and review the credentials of community-based physicians who wish to admit residents to the facility and to decide whether to grant the right to practice in the facility. AMDA believes that nursing facilities also should have well-defined roles and responsibilities for the attending physicians and give notice of the reasonable performance standards expected of all physicians that admit patients to the nursing facility.

This tool kit is designed to assist the Medical Director and his or her nursing facility in achieving two objectives:

1. Support a process to verify the qualifications of each attending physician who wishes to provide patient care in the facility and to make a decision to grant or deny the right to practice in the facility;

2. Develop and communicate to the community-based attending physicians the expectations and standards that constitute acceptable medical practice at the facility.

An organized medical staff is not a requirement for regulatory compliance or accreditation in nursing facilities. Structured medical staffs with written by laws and formal procedures are the exception rather than the rule. Physicians and nursing facility administrators need to have mutually accepted and understood expectations. The Medical Director often acts as mediator and problem solver. In such cases, the existence of reasonable, written rules and regulations, and policies and procedures consistently applied to all attending physicians helps achieve fair resolution of the problem and protects the attending physician, the Medical Director, and the facility. AMDA does not recommend any particular arrangement, but its members recognize the need to address the issue of physician staffs by shared and agreed upon expectations.

Additionally, recent developments in the nursing facility practice setting indicate an increasing need for more, rather than less, medical staff structure. The recent revision of the 501 FTag (including changes in delivery of services such as managed care, new regulations and survey procedures, compliance guidelines from the Office of the Inspector General, and increasing exposure to civil liability) calls for more attention to oversight but does not require credentialing. For example, the new long term survey *Investigative Protocol on Abuse Prohibition* imposes new standards on the selection of all personnel in nursing facilities, arguably including all contractors and attending physicians. Some state laws may impose similar requirements for background checks. Similarly, the March 16, 2000 *Compliance Program Guidance for Nursing Facilities*[1] published by the Department of Health and Human Services Inspector General requires facilities to verify all physicians' good standing to participate in state and federal healthcare programs and obtain assurances from the physicians that they will comply with the facility's standards of conduct for regulatory compliance.

These influences in the practice environment have the cumulative effect of increased performance expectations and legal exposure for the physician and the facility alike. For example, there is a disturbing trend toward suing medical directors and other physicians

practicing in long-term care; these suits may focus on the credentialing process. Thus, nursing facilities, their Medical Directors and the attending physicians alike are well-served by having a basic credentialing process in place.

As a practical matter there are many approaches to medical staff organization and credentialing in nursing facilities. The vast majority of facilities operate with an "open" medical staff model. Generally, a community-based physician who wants to admit an individual to the facility is welcomed and encouraged to do so. There is no organized medical staff with formal medical staff bylaws or even written medical staff policies and procedures. In very informal nursing facilities, there may or may not be a process in place to validate even the physician's current license and Drug Enforcement Administration (DEA) authorization status.

Some facilities have developed "closed" medical staff models that limit participation of community physicians to selected physicians or a group practice. Other nursing facilities, such as those accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), must have a systemic process in place to credential licensed independent practitioners as a condition of accreditation. A few nursing facilities, usually large institutions, employ physicians full- or part-time to serve as the attending physician for the residents. Physicians directly employed by the nursing facility usually have a formal job description and sign an employment agreement that says what the nursing facility and the physician can expect from the working relationship. Employment relationships like these are subject to many legal requirements such as those under the Americans with Disabilities Act.[2] These requirements will be reflected in job descriptions and employment agreements.

While there is no generally accepted formula to developing an internal facility-based credentialing process,[3] at a minimum, the nursing facility Administrator and Medical Director should establish:

(1) Written performance expectations for community-based physicians and other independently licensed professionals (e.g., nurse practitioners, physician assistants, podiatrists, ophthalmologists) that may practice at the facility;

(2) List of credentials that must be submitted and verified prior to admitting patients to the facility;

(3) Procedures for requesting information from the physician or a transferring hospital, including authorizations for release of information from third parties; and

(4) Procedures for verifying the information and notifying the physician or practitioner of the decision on initial application or periodic renewal.

The list of credentials should represent the minimum objective criteria applicable to all attending physicians in order to maintain quality of care and regulatory compliance. Criteria must be relevant to the role of attending physician. Continuing Medical Education (CME) is another indicator of whether the physician is keeping current on clinical information. The nursing facility must apply all criteria consistently and uniformly to all applicants and members of the attending physician staff.

Performance expectations and credentialing procedures must be facility-specific and responsive to the needs of the residents, the facility and the attending physicians. For example, a nursing facility with a specialized subacute unit may want to establish a more extensive review process including privileging (authorization to provide specialized resident care and treatment services) to ensure evidence of specific clinical skills before authorizing a physician to admit to the subacute unit. Nursing facilities that are accredited by a private accrediting body such as JCAHO or CARF will want to tailor their procedures to meet those standards as well.

Typical steps include:

Pre-application – The community-based physician expresses interest and receives information from the nursing facility about the minimum objective criteria for attending staff membership.

Application – The physician submits information and authorizations to release information in compliance with the attending staff application procedure.

Primary Source Verification – Review of completed application and related documents including contact with primary sources of all credentials to ensure authenticity and current validity (this is primarily applicable to JCAHO-accredited sites).4

Review and Action – Decision to grant or deny medical staff membership made by appropriate authority and communicated to the physician.

Renewal and Reappointment – Periodic review of all current credentials information including significant changes since initial appointment. Determination and communication of decision to physician.

Most physicians are familiar with the credentialing and privileging process in use by hospitals accredited by JCAHO. Administrators frequently assume that if a physician is on staff at a local hospital, the hospital must have verified his or her credentials. Consistent with JCAHO standards, credentials information may be transferred from another accredited organization, but must be reviewed and assessed by the nursing facility credentialing body.[5]

It is advisable for the facility to keep a credentials file on each attending physician with documentation of verification and renewal information. All initial and renewal credentialing decisions should be made in writing and maintained as part of each physician's record.

The organization's performance expectations and procedures should also place an affirmative obligation on the attending physician to provide the Medical Director or Administrator with updated or new information about license, provider status, insurance or any other relevant change in status. Such updated or new information should also become part of the physician's permanent file.

The materials that follow are intended to guide you through the process of developing and implementing a basic credentialing system that defines the responsibilities and expectations for community-based attending physicians in your nursing facility. The enclosed model documents are intended to provide practical guidelines for physicians and nursing facilities in the area of attending physician relationships. They are not an exhaustive review of each legal, regulatory, or operational issue that may apply. The model documents and AMDA policy are intended to be educational and do not constitute legal advice. The models must be amended, with the advice of qualified counsel, to reflect individual facts and circumstances and the legal requirements of your state.

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1 See OIG's *Compliance Program Guidance for Nursing Facilities* included as p83.

2 Consult knowledgeable counsel regarding the applicability of the Americans with Disabilities Act to non-employed physicians who are members of the nursing facility's attending medical staff.

3 Some organizations may outsource this function to a centralized Credentials Verification Organization (CVO). In this case, the facility retains the duty to review and evaluate the factual information obtained from an external agency against the facility's standards for those who practice in the facility.

4 See AMDA's introductory document *The Credentialing Process in a Nutshell,* p7 and AMDA's *Primary Source Verification Resources*, p101 for a list of potential resources for verification.

5 Joint Commission on Accreditation of Healthcare Organizations, *Comprehensive Accreditation Standards for Long Term Care.* Standard HR.4.10, pages HR. 14-15, MC 50-51 (2005 - 2006).

ATTENDING PHYSICIAN CREDENTIALING APPLICATION[1]

A letter outlining the facility's expectations of the attending physician, including a checklist validation of the attending physician's credentials, could come from the medical director or facility's administrator

Dear Doctor _____:

[Name of facility] is a long-term care facility licensed in [State] to provide nursing home care and skilled nursing services [and assisted living or other license categories] and certified to participate in the federal Medicare and Medicaid programs. We welcome your interest and willingness to help meet the medical needs of the people in our community.

All physicians who wish to participate as Attending Physicians at [Name of facility] shall submit their required credentials for verification and sign a statement of intent to comply with all policies and procedures of [Name of facility] and all laws and regulations that govern the provision of appropriate medical care and medically necessary items and services in facilities such as ours. This legal and regulatory foundation is set forth in the federal Medicare and Medicaid laws and regulations including the Requirements of Participation for nursing facilities and relevant state laws and regulations.[2] These performance requirements and expected standards of conduct are part of our ongoing efforts to provide quality care and to comply with the relevant laws and regulations. All Attending Physicians must agree to comply with them.

To be considered as an Attending Physician, please submit for our verification your written evidence of the following credentials:

Education:

▶ Graduated from approved school of medicine:

_____

Name of accredited medical school from where you graduated

_____

Institution | Address | Telephone

_____

Degree | Dates Attended | Date of Graduation

▶ Satisfactory completion of residency/fellowships in appropriate specialty;

_____

Institution | Address | Telephone

_____

Department Head | Dates

Institution Address Telephone

Department Head Dates

Certificate/Licenses:

Social Security number _____

Licensed to practice medicine in [State or Commonwealth]

Original date of issue _____

Expiration date _____

State and/or license number _____

Current DEA number _____

Original date of issue _____

Expiration date _____

UPIN _____

Board certified in _____

Date of initial certification _____

or,

Date of certification examination _____

Professional Work History:

▶ Teaching appointments:

Institution Address Telephone

Department Head Dates

▶ Staff privileges at accredited community hospitals:

Institution Address Telephone

Department Head Dates

Institution Address Telephone

Department Head Dates

Other Professional Work History:

Affiliation_____

Institution Address Telephone

Department Head Dates

Have any of your state licenses to practice ever been denied, investigated, relinquished, limited, or revoked?

☐ YES. Please provide details on separate sheets and attach.

☐ NO.

Have you ever been suspended, sanctioned, restricted or otherwise sanctioned in any federal or state health care program (e.g., Medicare, Medicaid, VA, CHAMPUS) or restricted from participation in any private health insurance program?

☐ YES. Please provide details on separate sheet and attach.

☐ NO.

Have your employment, medical staff appointment or privileges ever been refused, revoked, denied or limited?

☐ YES. Please provide details on separate sheet and attach.

☐ NO.

Professional Liability Coverage:

A current certificate of insurance in amounts and with a carrier acceptable to the Governing Body (as specified herein).

☐ Certificate attached. Note: Filling this is unnecessary if a copy of the certificate is attached.

Carrier	Level of Coverage	Policy #

Effective Dates

Professional References:

Please list at least two personal references with first-hand knowledge of your experience in a skilled nursing facility as consultant, attending physician, advisory physician:

Name	Address	Telephone
Name	Address	Telephone

I acknowledge my responsibility to continuously update this credentials file by providing to the Administrator or Medical Director the most recent information available.

If my medical license or other legal credential authorizing my practice or my ability to participate in any federally funded health care program is limited or restricted in any way by any authorizing body, I shall give written notice to the Administrator of this facility as soon as practicable. I understand that any affiliation with or services provided in this facility that are within the scope of the limitations imposed on me shall automatically be restricted in the same manner.

I understand that this position requires freedom from illegal use of drugs, and freedom from use and effects of use of drugs and alcohol in the workplace.

I also understand that persons who have been found guilty by a court of law of a program related crime, including but not limited to, abusing, neglecting or mistreating individuals in a health care related setting are ineligible for this position.

Authorization to Release Information:

I represent that the information provided or attached to this application is accurate to the best of my knowledge. I understand that any misstatement, omission, or misrepresentation, whether intentional or not, will be cause for immediate rejection, termination or denial of appointment or reappointment to this medical staff.

I authorize [Name of facility] and its authorized representatives to contact and to consult with any third party who may have information bearing on my professional credentials, clinical competence and qualifications to serve as a member of the medical staff at this nursing

facility. This authorization includes the right to inspect or obtain any documents, recommendations, reports, statements or disclosures relevant to my appointment to this medical staff. I expressly authorize said third parties to release this information to the nursing facility and its authorized representatives upon written request.

By my signature below, I accept the terms and conditions described above and submit this application for consideration of the governing body.

_____

Physician's Signature Date

For Nursing Facility Use Only

Credentials application complete _____

Date

Validation and Acceptance:

_____

Administrator or Governing Body Representative Date

_____

Medical Director Date

[1] This tool kit piece is one option and can be modified.

[2] The Medicare and other laws and regulations are not the sole basis for physician performance requirements; they are one foundation. The standards of appropriate geriatric medical practice are at least as important, if not more so, as a foundation.

CREDENTIALS VERIFICATION CHECKLIST[1]

A form to document the validation of information given by the attending physician to the nursing facility's credentialing body

Physician: _____ SSN: _____

UPIN: _____

Initial Authorization:

Submission of credentials and supporting documentation [Date]

Review and validation of credentials [Date]

Action by Governing Body [Date]

Reauthorization: _____

Education:

Graduation from approved school of medicine

Validation from primary institution _____

Date _____

Residency in appropriate specialty

Validation from primary institution _____

Date _____

Certificate/Licenses:

Licensed without restriction to practice medicine in

[State or Commonwealth]

Validation from the licensing agency _____

Date _____

Current valid authorization to use or prescribe any controlled substance

DEA # _____

Source of validation _____

Date _____

Board certification in _____ (if required by Facility);

Validation from medical specialty board _____

Date _____

Membership and clinical privileges at an accredited hospital

Validation from hospital(s) _____

Date _____

Good standing to participate in all state and federal health care programs[2]

Source of validation _____

Date _____

Insurance Requirements:

Physicians must obtain and maintain professional liability insurance in such amounts and coverages and underwritten by an insurer as are acceptable to the governing body or management. If the policy is a "claims made" policy the physician must provide evidence of adequate continuity of coverage.

Source of validation _____

Date _____

Work Experience & Clinical Competence:

Experience in a skilled nursing facility as consultant, attending physician, advisory physician or governing body member

Source of validation _____

Date _____

Letters of personal recommendation from peers with first-hand knowledge of the physician's clinical competence, technical skills, knowledge of applicable laws and regulations, ethical performance and professional responsibility

Source of validation _____

Date _____

Minimum ___ CME credits annually in relevant topic areas

Source of validation _____

Date _____

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[1] The use of a credentialing process may be construed as having an organized medical staff to which certain duties and responsibilities attach. The facility should consult qualified local counsel for legal advice specific to their state.

[2] Federal health care programs include Medicare and Medicaid as well as CHAMPUS and Veterans Affairs.

MODEL APPOINTMENT LETTER

A Letter Acknowledging the Agreement between the Attending Physician and the Facility

(Date, Day, Year)

John Smith, MD, CMD
123 Main Street
Anytown, PA 12345

RE: Medical Staff Membership

Dear Doctor _____:

You have indicated your interest in becoming a member of the medical staff of [Facility]. Our Credentials Committee[1] consisting of _____, Medical Director; _____, Administrator and _____ [Others] have evaluated the credentials you submitted in compliance with the medical staff policies of this facility and have found them to be satisfactory.

By your signature on this letter of understanding, you acknowledge receipt of the performance requirements expected of all physicians of [Facility], and you agree to abide by the terms and conditions of this appointment as set forth in the following attachments. These attachments are incorporated by reference and made part of this letter of understanding.

We welcome you as a practitioner in this facility and look forward to a long and satisfactory professional relationship.

Sincerely,

_____

[signature]

[1] The membership of the Credentials Committee may vary from facility to facility. The letter should be amended to reflect the committee membership of your facility.

ACKNOWLEDGMENT DOCUMENTS FOR ATTENDING PHYSICIANS

A Listing of Proposed Facility Documents, Suggested Readings, and References

By your signature below, you acknowledge receipt and acceptance of the following documents:

- Facility mission statement and philosophy
- Facility standards of conduct related to compliance with applicable laws and regulations
- Performance requirements/rules and regulations for attending physicians
- Medical staff policies and procedures[1]
- Facility policies and procedures relevant to resident care
- Suggested guidelines for physician notification of clinical problems in nursing facility residents
- AMDA Code of Ethics[2]
- Selected bibliography for nursing facility physicians and medical directors
- *Synopsis of Federal Regulations in the Nursing Facilities*[3]
- Other facility specific documents

You agree to continuously update your credentials file in the facility with the most recent information available.

You further acknowledge that the terms and conditions established by [Facility] to grant attending physician status are based on resident care considerations, applicable laws and regulations and facility-specific policies and procedures, and you agree to comply fully with them.

_____ [Physician]

_____ [Date]

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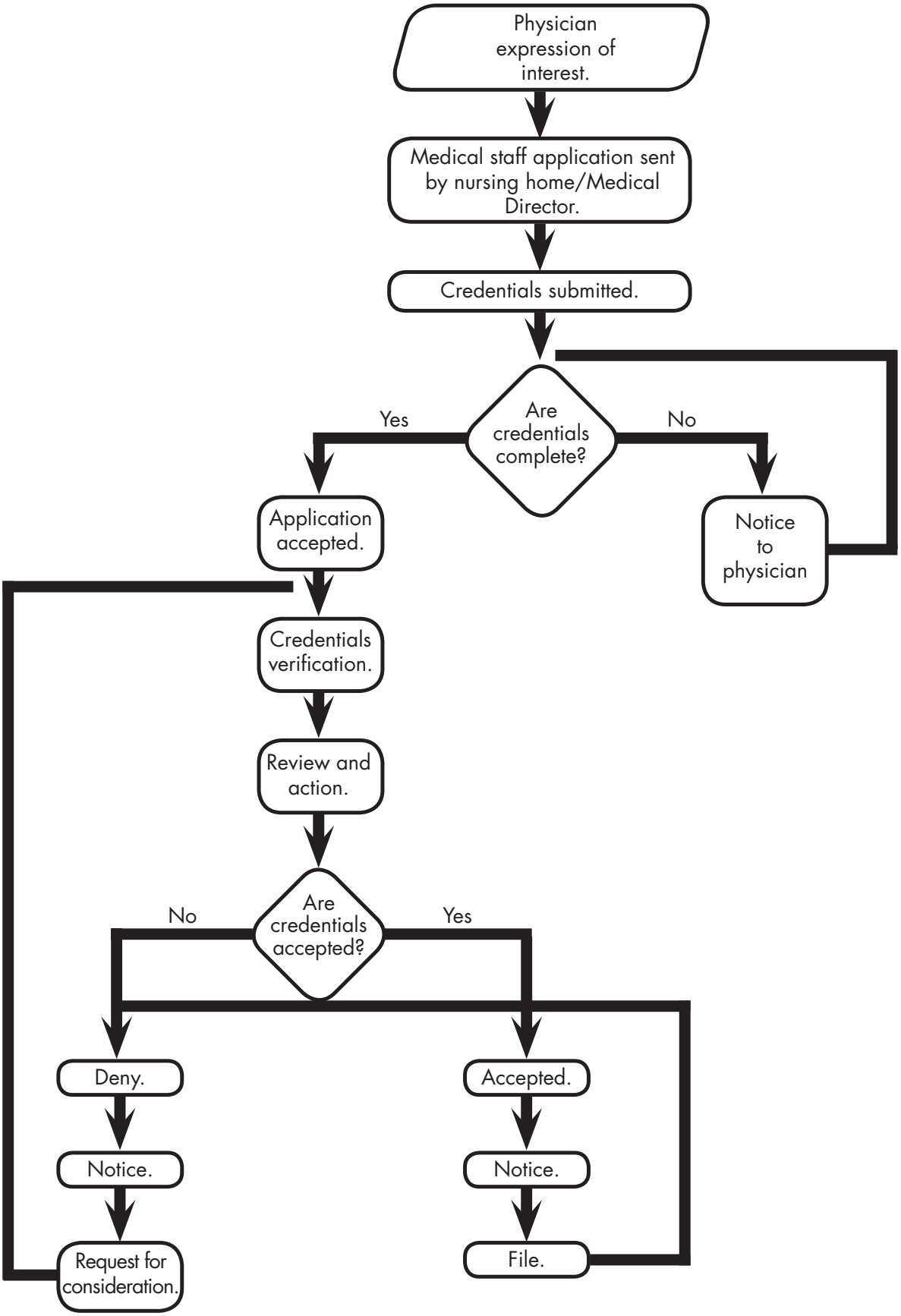
[1] See AMDA's *Guidelines for Organizing the Medical Staff and Physician Services In Long-Term Care Facilities* as p11.

[2] See AMDA's Code of Ethics included as p45.

[3] See AMDA's *Synopsis of Federal Regulations in the Nursing Facility* included as p81.

CREDENTIALING PROCESS FLOWCHART



GUIDELINES FOR PHYSICIAN PRACTICE AND PERFORMANCE[1]

What You May Expect From the Facility	What We Expect From You
General Approaches — We will solicit and consider your input regarding various aspects of care and operations. — We will provide fair interventions and dispute resolution. — We will expect and encourage appropriate professional conduct from all individuals and disciplines who work here. — You will receive feedback regarding the results of investigations. — We will be mindful of issues related to physician liability and legal exposure.	— Consider yourself part of a team approach to management of individuals with complex multi-dimensional problems. — Treat the other staff as colleagues with major responsibilities and essential roles. — Resolve problems appropriately and professionally. — Use the medical director as a resource to deal with disagreements and problems that arise between you and others. — Don't say, write, or do things that increase the facility's risk or legal liability or exposure. — Don't overuse the fear of legal liability as a reason to justify not wishing to follow appropriate protocols or documentation requirements.
Admissions — We will notify you of a new admission. — You will be asked to verify orders and to address any issues such as defining medical condition and prognosis that are needed to support care continuity. — You will be informed of conditions such medical instability, significant new medical condition, or problems that cannot be handled readily by phone, that may require your on-site presence.	— See a new admission in a timely fashion if the patient is at all unstable, has a significant new medical condition, or presents with problems that cannot be handled readily by phone. — For admissions, provide needed information regarding a resident's current status, recent history, and medications and treatments, to enable safe, effective continuity of care. — Provide appropriate certifications to support a designated or desired level of care for a new admission. — Authorize admission orders in a timely fashion. — Provide appropriate information in a transfer or discharge summary to enable continuing care and appropriate regulatory compliance.
Transferring a patient to another physician — We will inform you if a patient/family member wishes to transfer the care to another physician. — We will inform you when a receiving physician has formally accepted the care of that patient.	— Continue to care for a pending transfer until another physician has accepted the patient. — Once you have accepted a patient, you must continue to care for that patient until the patient is discharged or until another physician has formally agreed to assume the care. — Before accepting a managed care patient, make sure you know that you are acceptable to that payer.

(continued)

[1] Authored by Steven A. Levenson, MD, CMD

What You May Expect From the Facility	What We Expect From You
Discharges and transfers — We will inform you of pending discharges and transfers. — We will inform you of what is needed from you to facilitate the discharge or transfer.	— Provide a pertinent medical discharge summary at the time of transfer for those who are transferred to other settings, and in a timely fashion. — Ensure that there is a legitimate medical reason for discharges or transfers.
Patient visits — Forms, orders, and other documentation which you need to review or sign will be made available in an appropriate place for your visit. — Issues that you need to address will be clarified as much as possible and left in a readily identifiable location. — Whenever possible, and depending partially on when you visit, someone will try to answer questions and discuss the residents under your care. — We will give you a single reminder that a routine visit is due.	— Visit each newly admitted resident at least once every 30 days for the first 90 days after admission, and at least once every 60 days thereafter (or have an appropriately supervised NP or PA make alternate visits). — You can make your visits at any reasonable hour, as long as it does not conflict with residents' sleep or activity schedules. — Try to visit when nurses who know the patients/residents can review them with you. — Get an update on each patient's condition by seeing the patient, talking with the staff, and reviewing relevant documentation. — If you visit during the evenings or other times when the primary nurses are not present, review and respond to any information, test results, or questions regarding the individual's care that may have been left for you. — At each visit, review issues requiring a physician's expertise, including the patient's current condition, the status of any acute episodes of illness since the last visit, and other actual or high risk potential medical problems that may affect the individual's functional or physical status. — At each visit, write a progress note relevant to significant ongoing, active, or potential problems, including reasons for changing or maintaining current treatments or medications, and a plan to address potential or actual high risk situations. — Answer questions that other staff ask about medical issues relevant to their role in providing the care or answering patient and family questions (e.g., ethical issues).

(continued)

What You May Expect From the Facility	What We Expect From You
Coverages — We will follow the contact instructions and coverage schedule provided. — We will notify you of any problems with backup/ covering physicians.	— Have your office keep the facility informed about your current address, phone, fax, and beeper numbers. — Have your office keep the facility informed about the phone, fax, and beeper numbers of those physicians or group practices that cover for you at various times. — Have your office give the facility a written copy of your contact instructions and coverage schedule. — Have your office update the facility about any changes in the above. — Provide your covering physicians with information about long-term care and explain how they can be most helpful while they are covering for you. — Respond within ½ hour to emergency notification, by the end of the next office day to routine phone or fax notification, and as requested to other special situations. — Help address any problems with your backup physician coverage. — Inform covering physicians about patients/residents with active acute conditions or potential problems that they may need to manage during their coverage time.
Patient care — We will provide as much information as possible about each patient. — Other disciplines will perform accurate, timely assessments. — The facility will explain its available programs and services. — The nursing staff will contact you when a patient has a significant condition change or symptoms requiring discussion with, or assessment by, a physician. — The medical director may periodically provide articles or other information about the management of various medical conditions, treatments, and other aspects of the care of the frail elderly. — The facility will provide copies or pertinent summaries of its clinical protocols and guidelines. — We will clarify expectations of physicians in managing various medical conditions and problems.	— Perform accurate, timely medical assessments. — Help define and describe patient problems accurately and completely. — Clarify and verify diagnoses. — Help staff understand how diagnoses relate to problems — Evaluate a patient's current condition and help establish a realistic prognosis and care goals. — Help the staff determine the appropriate services and programs, consistent with diagnoses, condition and prognosis. — Clarify the medical care plan and goals for staff, residents and families. — Manage chronic illnesses to maximize function and personal comfort. — Help ensure that treatments are medically necessary and negative outcomes are medically unavoidable. — Communicate with the medical director if you have questions about current or proposed care regarding a patient.

(continued)

What You May Expect From the Facility	What We Expect From You
Physician orders — We will provide as much pertinent information as possible before asking for orders to deal with a symptom, problem, or medical condition. — We may suggest alternatives based on efficacy, side effects, risk factors, and costs.	— Follow the protocol for the new admission order sheets. — All orders should be based on applying geriatrics principles. — Take into account factors such as efficacy, side effects, risk factors, and costs when giving medical orders. — Always consider medications as a potential source of a patient's problems, complications, and new symptoms.
Testing — We will schedule and help arrange for necessary tests, consultations, or evaluations. — We will triage test results and notify you based on their urgency and the patient's condition.	— Order appropriate tests, consultations, or evaluations to determine improvement potential and effectiveness of treatments. — Explain enough about the reasons for ordering tests, consultations, or evaluations so that consultants, technicians, etc. understand why they are doing them and can do them correctly. — Order lab testing only for specific monitoring, not as a routine periodic screening. — Respond to notification of test results in a timely fashion, based an the patient's condition and the significance of the results. — Try to refrain from treating numbers (pulse oximetry, WBC, etc.) unless there is some suspected or definite clinical condition or risk associated. — If an abnormal test result does not indicate a clinically significant condition or a need to treat or to change current treatment, explain this so that it can be documented adequately.
Condition changes — Nursing staff will triage condition changes as a basis for discussing them with the physician. — Nursing staff will assess possible reversible causes of various signs and symptoms. — Nursing staff will provide pertinent current and historical information about the patient.	— Manage acute illness or significant condition change as aggressively as indicated by an individual's goals, condition, and prognosis. — Consider and document possible reversible medical causes (e.g., medications, infection) of declines in quality of life and daily function before attributing such declines to irreversible problems such as dementia, aging, or progression of existing diseases. — Assess the degree of medical instability and other pertinent factors before deciding to transfer a patient to the hospital.

(continued)

What You May Expect From the Facility	What We Expect From You
Medications — The nursing staff will ask you to provide a reason or problem for any medication order without one. — The medical director or nurse may ask you to consider tapering, stopping, or changing certain medications or certain doses, especially if symptoms have stabilized or subsided, or the medication may be causing side effects or complications. — The medical director or nurse may ask you to document clinical justifications for medications that must be continued for long periods or in high doses, or that cannot be tapered, especially for those in certain high-risk categories. — The consultant pharmacist may make recommendations about various aspects of medications, based on established guidelines.	— Be continuously alert to the possibility of an adverse drug reaction (ADR) in anyone with new or non-specific symptoms or a significant condition change, regardless of underlying diagnoses or the duration of using a medication. — Try to target medications to identified causes and significant symptoms, and resist prescribing them for any new symptom or nursing call. — Ensure that a clear reason or problem accompanies each medication order to clarify why the individual needs that medication. — On admission and during follow-up visits, consider the necessity of each medication, and whether it could be given less often or in a smaller dose. — Try to taper or discontinue medications that are no longer needed or which lack clear medical justification for continuing them. — Periodically document clinical justifications for medications that must be continued for long periods or in high doses, or that cannot be tapered. — Try to minimize multiple medications for the same problem. — Acknowledge pharmacist reviewer comments on medication use, even when changes are not indicated.
Managing psychiatric problems — Accurately assess and describe a patient's condition and symptoms, to help define the problem and identify possible causes.	— Always be alert to the presence of delirium, which often has an identifiable medical cause. — Remain involved in managing a patient's behavioral issues even if there is a psychiatric consultation, to ensure that any recommendations are pertinent to the medical condition and compatible with other medications.

(continued)

What You May Expect From the Facility	What We Expect From You
Ethical issues — Other staff will help clarify a patient's advance directives and other care instructions that might influence the aggressive management of medical conditions. — We will inform you of how relevant laws and regulations imp act the management of ethical issues in nursing facility residents. — We will prepare and clarify related documents or forms needing a physician's certification, signature, or review. — We will help transfer a patient to another physician if you decide that you do not wish to continue providing care because of a difference in opinion about treatment decisions.	— Be aware of current laws and regulations, and of the current standard of practice supporting the appropriate withholding or withdrawing of medical treatments when indicated. — As needed, help the staff decide the extent of a patient's decision making capacity (DMC) and their ability to exercise personal rights. — As needed, order tests, treatments, or services that might enhance or maintain a resident's decision-making capacity and quality of life. — Help identify treatable medical problems that may compromise a patient's mental status or DMC — Help identify individuals for whom aggressive medical interventions are not indicated. — Recognize the rights of competent individuals, or substitute decision makers acting for them, to restrict or refuse medical treatment. — Help the staff manage ethical issues consistent with patient wishes and relevant laws and regulations. — Incorporate the wishes and values of residents and families into medical decision making. — As needed, help patients formulate advance directives or help families identify relevant care instructions on their behalf. — Document your discussions with a patient or family about withholding or withdrawing treatment. — Help ensure that medical orders are clear and consistent with patient and substitute decision maker choices. — Ensure that individuals with limitations on medical treatment have appropriate comfort and supportive care measures. — Provide signatures or other documentation needed to comply with state laws and regulations regarding management of ethics issues. — Help patients and families understand the benefits and risks of giving or withholding specific medical treatments.

(continued)

What You May Expect From the Facility	What We Expect From You
Documentation and medical records — We will inform you of desired and required documentation.	— Document enough in progress notes to explain decisions to treat or not treat certain conditions or abnormalities; or, provide enough information to enable a nurse to document this appropriately. — When you are not present, explain enough to a nurse or another individual to enable them to document adequately. — Ensure that the history and physical contains enough information to allow care to proceed safely and effectively. — Use standard or approved abbreviations or other documentation shortcuts, and do not use those that are ambiguous or cannot be readily understood. — For a new admission, provide a history and physical with the appropriate content, and in the necessary time frame. — All documentation must be legible.

AMDA CODE OF ETHICS

AMDA — The Society for Post-Acute and Long-Term Care Medicine Endorses the Following Code of Ethics

AMDA is dedicated to the delivery of competent, comprehensive and compassionate medical care to all people residing in post-acute and long-term care facilities. To further these goals, all member of this Association:

- Shall uphold the ethics of the medical profession in all aspects of the care rendered.
- Shall be an advocate for all persons who reside in the facility.
- Shall strive to advance personal and professional knowledge, including the area of medical direction.
- Shall continue to study, apply and advance scientific knowledge.
- Shall do their utmost to serve as a model of personal and professional integrity and skills.
- Shall respect the law while recognizing the responsibility to seek changes in the law for the best interests of the people entrusted to their care.
- Shall work diligently with all professional colleagues to create a milieu that fosters the highest attainable degree of care.
- Shall always place the competent, compassionate care of all their patients above any financial reward or inducements.
- Shall recognize a responsibility to participate in those activities that contribute to an improved community.
- Shall respect the individual's rights to autonomy in decision making.

ROLES AND RESPONSIBILITIES OF THE MEDICAL DIRECTOR IN THE NURSING HOME

American Medical Directors Association White Paper Resolution A-11

SUBJECT:	White Paper on the Nursing Home Medical Director: Leader and Manager *Updates Resolution A06*
INTRODUCED BY:	Role of Medical Director Ad Hoc Workgroup
INTRODUCED IN:	March 2011

Introduction

In 1974, in response to identified quality of care problems, Medicare regulations first required a physician to serve as medical director in skilled nursing facilities and to be responsible for the medical care provided in those facilities. Following the passage of the Nursing Home Reform Act in 1987, AMDA—The Society for Post-Acute and Long-Term Care Medicine (AMDA) House of Delegates, in March 1991, approved the *Role and Responsibilities of the Medical Director in the Nursing Home,* a document setting forth AMDA's vision for nursing facility medical directors. It outlines the medical director's roles in nursing facilities and is the foundation for:

- AMDA's Certified Medical Director credentials;
- AMDA's *Model Medical Director Agreement and Supplemental Materials: Medical Director of a Nursing Facility* and;
- Resolutions on medical direction in other post-acute and long-term care settings.

Since 1991, the post-acute and long-term care field has been affected by changes in medical knowledge, clinical complexity of patients, societal attitudes, legal influences, demographics and patient mix, reimbursement, and shifts in the scope of care in various settings. Increasingly, medical directors are held accountable by state legislators, regulators, and the judicial system for their clinical and administrative roles in these diverse facilities. At least one state[1] has enacted legislation outlining the specific regulatory responsibilities and educational pre-requisites for medical directors, and other states may follow its lead.

The 2001 Institute of Medicine report *Improving the Quality of Long Term Care* urges facilities to give medical directors greater authority and hold them more accountable for medical services. The report further states, nursing homes should develop structures and processes that enable and require a more focused and dedicated medical staff responsible for patient care. These organizational structures should include credentialing, peer review, and accountability to the medical director (Institute of Medicine 2001, 140). These developments required AMDA to revise and update its 1991 document to develop a clearer vision for enhanced medical director responsibilities.

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[1] The State of Maryland enacted this legislation. *Code of Maryland Regulations. 10.07.02.11 .11 Medical Director Qualifications.*

In April 2002, AMDA convened a panel to review the document in the context of changes within post-acute and long-term care. Their work product outlined the medical director's major roles in the facility and was geared toward ensuring that appropriate care is provided to an increasingly complex, frail, and medically challenging population. These concepts were considered when the Centers for Medicare & Medicaid Services revised the Surveyor Guidance related to F-Tag 501 (Medical Director) in 2005. This AMDA policy statement has therefore been updated to be congruent with current regulatory requirements and their related interpretive guidelines, and as such reflect the current roles and responsibilities of the medical director.

AMDA's Core Curriculum Faculty has further developed and teaches the roles, functions and tasks of the medical director. The functions and tasks were last updated in 2009 to include person-directed care. This current document has been revised in late 2010 for presentation to the AMDA Board of Directors and the AMDA House of Delegates at the March 2011 meeting in Tampa, Florida. It is AMDA's most recent position statement to harmonize the leadership role and management responsibilities of today's medical director.

Certified Medical Director (CMD)

The mission of the American Medical Directors Certification Program (AMDCP) is to recognize and advance physician leadership and excellence in medical direction throughout the post-acute and long-term care continuum via certification. The Certified Medical Director in Long Term Care (AMDA CMD) recognizes the dual clinical and managerial roles of the medical director. The CMD credential reinforces the leadership role of the medical director in promoting quality care and offers an indicator of professional competence to post-acute and long-term care providers, government, quality assurance agencies, consumers, and the general public.

The Assistant or Associate Medical Director

Due to the expanded role of medical director, some facilities or organizations have identified a need for an assistant or associate medical director. The assistant or associate medical director should be a physician who has comparable knowledge and skills to those of the medical director.

Roles, Functions, and Tasks

The position of the nursing home Medical Director can be identified in terms of the Role, Functions, and Tasks hierarchy.

- Roles: the set of behaviors that an individual within an organization is expected to perform and feels obligated to perform.
- Functions: the major domains of activity within a role.
- Tasks: the specific activities that are undertaken to carry out those functions.

Roles

In defining the role of the medical director, and ultimately the foundation for the individual medical director agreement, it is important to begin with a framework that identifies core principles. This framework is based on functions related to providing high quality of care to the individuals served. These functions include providing input into the clinical policies governing the organization or facility, supervising the medical staff, reviewing and participating in quality assurance activities, and directly overseeing clinical safety and risk management.

The medical director is involved at all levels of individualized patient care and supervision, and for all persons served by the facility. The medical director serves as the clinician

who oversees and guides the care that is provided, a leader to help define a vision of quality improvement, an operations consultant to address day-to-day aspects of organizational function, and a direct supervisor of the medical practitioners who provide the direct patient care.

AMDA has identified four key roles of the post-acute and long-term care medical director, as follows.

Role 1—Physician Leadership

The medical director serves as the physician responsible for the overall care and clinical practice carried out at the facility.

Role 2—Patient Care-Clinical Leadership

The medical director applies clinical and administrative skills to guide the facility in providing care.

Role 3 — Quality of Care

The medical director helps the facility develop and manage both quality and safety initiatives, including risk management.

Role 4 — Education, Information, and Communication

The medical director provides information that helps others (including facility staff, practitioners, and those in the community) understand and provide care.

Functions and Tasks

Although individual job duties will vary among organizations, there are basic, universally relevant functions that are embedded in the overarching roles. The functions represent the foundation for developing the individual medical director's tasks. The relevance and nature of some tasks may vary; for example, due to different patient populations, facility requirements, or state or local regulations. Therefore, it is useful to divide tasks related to various functions into 1) essential tasks that all medical directors should perform (Tier 1) and 2) tasks that, while desirable, may vary in importance depending on a medical director's situation or setting (Tier 2). The manner in which different medical directors perform various tasks (regardless of whether a task is essential or optional) may vary.

Function 1 — Administrative

The medical director participates in administrative decision making and recommends and approves relevant policies and procedures.

Function 2 — Professional Services

The medical director organizes and coordinates physician services and the services provided by other professionals as they relate to patient care.

Function 3 — Quality Assurance and Performance Improvement

The medical director participates in the process to ensure the quality of medical care and medically related care, including whether it is effective, efficient, safe, timely, patient-centered, and equitable.

Function 4 — Education

The medical director participates in developing and disseminating key information and education.

Function 5 — Employee Health

The medical director participates in the surveillance and promotion of employee health, safety, and welfare.

Function 6 — Community

The medical director helps articulate the post-acute and long-term care facility's mission to the community.

Function 7 — Rights of Individuals

The medical director participates in establishing policies and procedures for assuring that the rights of individuals (patients, staff, practitioners, and community) are respected.

Function 8 — Social, Regulatory, Political, and Economic Factors

The medical director acquires and applies knowledge of social, regulatory, political, and economic factors that relate to patient care and related services.

Function 9 — Person-Directed Care

The medical director supports and promotes person-directed care.

Tasks

The tasks are listed as they relate to the nine functions and are divided into two tiers.

- Tier 1 — essential, universally applicable tasks
- Tier 2 — tasks that may vary with the individual's situation, availability, facility needs, and so on.

Function 1 — Administrative

Tier 1

Task 1

The medical director communicates regularly with the administrator, the director of nursing, and other key decision makers in the nursing home and provides leadership needed to achieve medical care goals.

Task 2

The medical director participates in the development and periodic evaluation of care-related policies and procedures.

Task 3

The medical director guides and advises the facility's committees related to quality assurance / performance improvement, pharmacy, infection control, safety, and medical care.

Task 4

The medical director participates in licensure and compliance surveys and interacts with outside regulatory agencies.

Task 5

The medical director informs medical staff about relevant policies and procedures, including updates.

Task 6

The medical director collaborates with the administrator to identify a job description that clearly defines the medical director's roles and functions in the facility.

Tier 2

Task 7

The medical director stays informed about factors that affect post-acute and long-term care and incorporates relevant information about social, medical, and fiscal issues into policies and procedures.

Task 8

The medical director helps the facility develop or incorporate policies and procedures and utilize pertinent strategies to effect and manage change.

Function 2 -Professional Services

Tier 1

Task1

The medical director organizes, coordinates, and monitors the activities of the medical staff and helps ensure that the quality and appropriateness of services meets community standards.

Task 2

The medical director helps the facility arrange for the availability of qualified medical consultative staff and oversees their performance.

Task 3

The medical director assures coverage for medical emergencies and participates in decisions about the facility's emergency equipment, medications, and supplies.

Task 4

The medical director collaborates with the DON and other clinical managers to help ensure that practitioners in the facility have adequate support from staff to assess and manage the patients (e.g., when they are making patient rounds or responding to calls about changes in condition).

Task 5

The medical director develops and periodically reviews and revises, as indicated, policies that govern practitioners in the facility other than physicians, including physician assistants and nurse practitioners; and guides the facility regarding the professional qualifications of other staff related to clinical decision making and the provision of direct care.

Task 6

The medical director guides the administrator in documenting the credentials of the facility's practitioners.

Task 7

The medical director collaborates with the facility to hold practitioners accountable for their performance and practice, including corrective actions as needed.

Tier 2

Task 8

The medical director develops and periodically reviews and updates, as needed, key documents governing physician services, such as by-laws or rules and regulations.

Task 9

The medical director helps the facility establish affiliation agreements with other health care organizations and helps the facility establish effective outside relationships; for example, with regulatory agencies, various professional groups, insurers, ambulance companies, and emergency medical systems.

Task 10

The medical director helps support the care-related activities of the interdisciplinary team.

Task 11

The medical director helps the facility ensure that its medical records systems meet the needs of patients and practitioners.

Task 12

The medical director helps the facility ensure adequate documentation of patient care and related information.

Task 13

The medical director advises the facility on interacting with utilization review organizations.

Task 14

The medical director develops policies and procedures related to activities of health care trainees within the facility (e.g., physicians in residency programs, medical students).

Task 15

The medical director advises the facility about the appropriateness of admissions and transfers, including related orders and the facility's case mix.

Task 16

The medical director advises and supports the practitioners and the facility regarding family issues; for example, concerns about the appropriateness and timeliness of the care.

Function 3 — Quality Assurance and Performance Improvement

Tier 1

Task 1

The medical director participates in monitoring and improving the facility's care through a quality assurance and performance improvement program that encourages self-evaluation, anticipates and plans for change, and meets regulatory requirements.

Task 2

The medical director applies knowledge of state and national standards for nursing home care to help the facility meet applicable standards of care.

Task 3

The medical director monitors physician performance and practice.

Task 4

The medical director helps ensure that the facility's quality assurance and performance improvement program addresses issues that are germane to the quality of patient care and facility services.

Task 5

The medical director helps the facility use the results of its quality assurance and performance improvement program findings, as appropriate, to update and improve its policies, procedures, and practices.

Task 6

The medical director participates in quality review of care, including (but not limited to) areas covered by regulation (e.g., monitoring medications, laboratory monitoring).

Tier 2

Task 7

The medical director helps the facility interpret and disseminate information gained from the quality assurance and performance improvement program in a form that is useful to patients, family members, staff members, attending physicians, and others as appropriate.

Task 8

The medical director helps the facility consider the feasibility and appropriateness of any proposed research projects and helps ensure that they meet pertinent standards and contain appropriate safeguards.

Task 9

The medical director periodically reviews admission, transfers, and discharges of patients.

Task 10

The medical director helps the facility identify private and public funding for research activities.

Task 11

The medical director provides medical leadership for research and development activities in post-acute and long-term care.

Task 12

The medical director includes physician input in identifying and applying quality assurance standards.

Function 4 — Education

Tier 1

Task 1

The medical director sustains his or her professional development through self-directed and continuing education.

Task 2

The medical director helps the facility educate and train its staff in areas that are relevant to providing high quality patient care.

Task 3

The medical director serves as a resource regarding geriatric medicine and other care-related topics, and helps the staff and practitioner identify and access relevant educational resources (e.g., books, periodicals, articles).

Task 4

The medical director informs attending physicians about policies and procedures and state and federal regulations, including updates.

Tier 2

Task 5

The medical director participates in the development, organization, and delivery of education programs for patients and patients' families, board members, and the community at large.

Task 6

The medical director encourages the facility to support staff membership in professional organizations.

Task 7

The medical director contributes to facility publications, as appropriate.

Task 8

The medical director supports educational opportunities within the nursing home for trainees in the health care professions.

Function 5 — Employee Health

Tier 1

Task 1

The medical director helps the facility foster a sense of self-worth and professionalism among employees.

Task 2

The medical director advises the facility about infectious disease issues related to employees.

Tier 2

Task 3

The medical director helps the facility identify, evaluate, and address situations that increase the risk of employee injury and illness.

Task 4

The medical director helps the facility implement a program to identify job requirements and assess employee capabilities relative to those requirements.

Task 5

The medical director advises the facility's safety committee, in areas where medical expertise is helpful.

Task 6

The medical director advises the facility on establishing and implementing employee wellness programs (e.g., weight reduction, stress reduction, cholesterol reduction, blood pressure reduction, nutrition, exercise).

Task 7

The medical director guides the facility in developing and implementing programs for employees experiencing physical, social, or psychological problems.

Task 8

The medical director advises the facility on policies related to the health and safety of staff, visitors, and volunteers.

Task 9

The medical director advises the facility on preventing and managing employee injuries.

Function 6 — Community

Tier 1

Task 1

The medical director helps the facility identify and utilize collaborative approaches to health care, including integration with community resources and services.

Tier 2

Task 2

The medical director acts as an advocate for the facility, encourages and facilitates community involvement in the activities of the facility, and helps the facility educate the community about its capabilities and services.

Task 3

The medical director participates in the activities of geriatrics and post-acute and long-term care committees of medical organizations and identifies issues and seeks solutions to problems that involve other institutions and programs.

Task 4

The medical director participates in health care planning in the community, including innovative cost-effective alternative health care programs for post-acute and long-term care.

Task 5

The medical director serves as a mentor to physicians-in-training within the facility.

Task 6

The medical director helps the facility address and communicate regarding situations that have brought the facility to the attention of the public and/or the media.

Task 7

The medical director meets with other post-acute and long-term care professionals in the community as appropriate.

Function 7 — Rights of Individuals

Tier 1

Task 1

The medical director helps the facility ensure that its policies and practices reflect and respect resident rights, including the opportunity for self-determination; e.g., via tools such as living wills and durable powers of attorney.

Task 2

The medical director helps the facility ensure that the ethical and legal rights of residents (including those who lack decision-making capacity, regardless of whether they have been deemed legally incompetent) are respected. This includes the right of residents to request practitioners to limit, withhold, or withdraw treatment(s).

Task 3

The medical director helps the facility accommodate patients' choice of an attending physician.

Tier 2

Task 4

The medical director participates in the activities of the institutional biomedical ethics committee and identifies community resources that can assist in resolving ethical and legal issues.

Task 5

The medical director helps the facility establish a system for identifying and reporting abuse, as well as criteria for identifying potential abuse among both residents and staff.

Task 6

The medical director helps the facility identify and use available community resources to help address ethical issues (e.g., ombudsman, health department, ministerial association).

Task 7

The medical director participates, when necessary, in family meetings and similar activities to help the facility and attending physicians promote and protect resident rights.

Function 8 — Social, Regulatory, Political, and Economic Factors

Tier 1

Task 1

The medical director helps the facility identify and provide care that is consistent with applicable social, regulatory, political, and economic policies and expectations.

Task 2

The medical director helps the facility identify, interpret, and comply with relevant State and Federal laws and regulations.

Tier 2

Task 3

The medical director seeks and disseminates information about aging, post-acute and long-term care, and geriatric medicine to the facility's practitioners, staff and residents.

Task 4

The medical director helps the facility make decisions about resource allocation including financial considerations that affect medical care (e.g., use of formularies, contracts, appropriate use of lab tests).

Task 5

The medical director participates in the facility budget process to help the facility allocate sufficient resources for essential medical functions and patient care activities.

Task 6

The medical director provides feedback, as appropriate, to legislators and public policy makers about existing and proposed laws and regulations.

Function 9 — Person-Directed Care

In addition to the following tasks, many of the tasks covered under the other functions relate directly or indirectly to the provision of person-directed care.

Tier 1

Task 1

The medical director oversees clinical and administrative staff, to help maintain and improve the quality of care including the success of person-directed care and patient and family satisfaction with all aspects of the care.

Task 2

The medical director guides the physicians and other health care professionals and staff to provide person-directed care that meets relevant clinical standards.

Task 3

The medical director collaborates with facility leadership to create a person-directed care environment while maintaining standards of care.

Tier 2

Task 4

The medical director helps the facility encourage active resident participation in, and promotes the incorporation of resident preferences and goals into development of, a person-directed plan of care.

Task 5

The medical director helps the facility develop, implement, and review policies and procedures that ensure residents are offered choices that promote comfort and dignity (e.g., choices regarding awakening, sleep, and medication administration times, discussions of risks/benefits regarding therapeutic diets, medications and treatments).

Task 6

The medical director collaborates with the interdisciplinary team (IDT), families, and allied services within and outside of the organization to encourage planning, implementing, and evaluating clinical services to maximize resident choice, quality of life, and quality of care.

Appendix I- Break down of the numbers of tasks (Tier 1 and 2) for each function

Function	Tier 1 Tasks	Tier 2 Tasks
1	6	2
2	7	9
3	6	6
4	4	4
5	2	7
6	1	6
7	4	4
8	2	4
9	3	3
TOTAL	35 (44%)	45 (56%)

ROLE OF THE ATTENDING PHYSICIAN IN THE NURSING HOME

Position Statement E03

Introduction

AMDA was founded on the premise that physician involvement in post-acute and long-term care is essential to the delivery of quality post-acute and long-term care. Attending physicians should lead the clinical decision-making for patients under their care. They can provide a high level of knowledge, skill, and experience needed in caring for a medically complex population in a climate of high public expectations and stringent regulatory requirements.

In 1991, the House of Delegates passed Resolution B91, Role of the Attending Physician in the Nursing Home. It reflected AMDA's recognition that the nursing home reforms mandated by OBRA '87 required increased levels of physician participation and medical director oversight in nursing homes.

In 2001, AMDA decided to clarify the principles outlined in its 1991 policy statement and reaffirmed by various reports such as the Institute of Medicine's *Improving the Quality of Long Term Care.* Like anyone, physicians need clearly stated expectations in order to fulfill their responsibilities. These revisions reflect essential functions and tasks that physicians should perform and cannot readily delegate to others. Although various factors make physician adherence challenging, AMDA believes that attending physicians should work with medical directors to address the obstacles, not cite them as a reason to avoid responsibility.

1. **Responsibility For Initial Patient Care.** The attending physician should:
   - Assess a new admission in a timely fashion (based on a joint physician-facility-developed protocol, and depending on the individual's medical stability, recent and previous medical history, presence of significant or previously unidentified medical conditions, or problems that cannot be handled readily by phone);
   - Seek, provide, and analyze needed information regarding a patient's current status, recent history, and medications and treatments, to enable safe, effective continuing care and appropriate regulatory compliance;
   - Provide appropriate information and documentation to support the facility in determining the level of care for a new admission;
   - Authorize admission orders in a timely manner, based on a joint physician-facility-developed protocol, to enable the nursing facility to provide safe, appropriate, and timely care; and
   - For a patient who is to be transferred to the care of another health care practitioner, continue to provide all necessary medical care and services pending transfer until another physician has accepted responsibility for the patient.
2. **Support Patient Discharges and Transfers.** The attending physician should:
   - Follow-up with a physician or another health care practitioner at a receiving hospital as needed after the transfer of an acutely ill or unstable patient;
   - Provide whatever documentation or other information may be needed at the time of transfer to enable care continuity at a receiving facility and to allow the nursing facility to meet its legal, regulatory, and clinical responsibilities for a discharged individual; and
   - Provide pertinent medical discharge information within 30 days of discharge or transfer of the patient.

3. **Make Periodic, Pertinent On-Site Visits to Patients.** The attending physician should:
   - Visits patients in a timely fashion, based on a joint physician-facility-developed protocol, consistent with applicable state and federal regulations, depending on the patient's medical stability, recent and previous medical history, presence of significant or previously unidentified medical conditions, or problems that cannot be handled readily by phone;
   - Maintain progress notes that cover pertinent aspects of the patient's condition and current status and goals. Periodically, the physician's documentation should review and approve a patient's program of care.
   - Determine progress of each patient's condition at the time of a visit by evaluating the patient, talking with staff as needed, talking with responsible parties/family as indicated, and reviewing relevant information, as needed;
   - Respond to issues requiring a physician's expertise, including the patient's current condition, the status of any acute episodes of illness since the last visit, test results, other actual or high risk potential medical problems that are affecting the individual's functional, physical, or cognitive status, and staff, patient, or family questions regarding the individual's care and treatments; and
   - At each visit, provide a legible progress note in a timely manner for placement on the chart (timely to be defined by a joint physician-facility protocol). Over time, these progress notes should address relevant information about significant ongoing, active, or potential problems, including reasons for changing or maintaining current treatments or medications, and a plan to address relevant medical issues.
4. **Ensure Adequate Ongoing Coverage.** The attending physician should:
   - Designate an alternate physician or appropriately supervised midlevel practitioner who will respond in an appropriate, timely manner in case the attending physician is unavailable;
   - Update the facility about his or her current office address, phone, fax, and pager numbers to enable appropriate, timely communications, as well as the current office address, phone, fax and pager numbers of designated alternate physicians or an appropriately supervised midlevel practitioner;
   - Help ensure that alternate covering practitioners provide adequate, timely support while covering and intervene with them when informed of problems regarding such coverage;
   - Adequately notify the facility of extended periods of being unavailable and of coverage arranged during such periods
   - Adequately inform alternate covering practitioners about patients with active acute conditions or potential problems that may need medical follow-up during their on-call time.
5. **Provide Appropriate Care to Patients.** The attending physician should:
   - Perform accurate, timely, relevant medical assessments;
   - Properly define and describe patient symptoms and problems, clarify and verify diagnoses, relate diagnoses to patient problems, and help establish a realistic prognosis and care goals;
   - In consultation with the facility's staff, determine appropriate services and programs for a patient, consistent with diagnoses, condition, prognosis, and patient wishes, focusing on helping patients attain their highest practicable level of functioning in the least restrictive environment;

- In consultation with facility staff, ensure that treatments, including rehabilitative efforts, are medically necessary and appropriate in accordance with relevant medical principles and regulatory requirements;
- Respond in an appropriate time frame (based on a joint physician-facility-developed protocol) to emergency and routine notification, to enable the facility to meet its clinical and regulatory obligations;
- Respond to notification of laboratory and other diagnostic test results in a timely manner, based on a protocol developed jointly by the physicians and the facility, considering the patient's condition and the clinical significance of the results;
- Analyze the significance of abnormal test results that may reflect important changes in the patient's status and explain the medical rationale for subsequent interventions or decisions not to intervene based on those results when the basis for such decisions is not otherwise readily apparent;
- Respond promptly to notification of, and assess and manage adequately, reported acute and other significant clinical condition changes in patients;
- In consultation with the facility staff, manage and document ethics issues consistent with relevant laws and regulations and with patients' wishes, including advising patients and families about formulating advance directives or other care instructions and helping identify individuals for whom aggressive medical interventions may not be indicated; and
- Provide orders that ensure individuals have appropriate comfort and supportive care measures as needed; for example, when experiencing significant pain or in palliative or end-of-life situations;
- Periodically review all medications and monitor both for continued need based on validated diagnosis or problems and for possible adverse drug reactions. The medication review should consider observations and concerns offered by nurses, consultant pharmacists and others regarding beneficial and possible adverse impacts of medications on the patient.

6. **Provide Appropriate, Timely Medical Orders and Documentation.** The attending physician should:
   - Provide timely medical orders based on an appropriate patient assessment, review of relevant pre- and post-admission information, and age-related and other pertinent risks of various medications and treatments;
   - Provide sufficiently clear, legible written medication orders to avoid misinterpretation and potential medication errors, such orders to include pertinent information such as the medication strength and formulation (if alternate forms available); route of administration; frequency and, if applicable, timing of administration; and the reason for which the medication is being given;
   - Verify the accuracy of verbal orders at the time they are given and authenticate, sign and date them in a timely fashion, no later than the next visit to the patient.
   - Provide documentation required to explain medical decisions, that promotes effective care, and allows a nursing facility to comply with relevant legal and regulatory requirements
   - Complete death certificates in a timely fashion, including all information required of a physician.
7. **Follow Other Principles of Appropriate Conduct.** The attending physician should:
   - Abide by pertinent facility and medical policies and procedures
   - Maintain a courteous and professional level of interaction with facility staff, patients, family/significant others, facility employees, and management

- Work with the medical director to help the facility provide high quality care
- Keep the well-being of patients/residents as the principal consideration in all activities and interactions.
- Be alert to, and report to the medical director — and other appropriate individuals as named through facility protocol — any observed or suspected violations of patient/resident rights, including abuse or neglect, in accordance with facility policies and procedures.

RESULTS: Passed by HOD.

WHITE PAPER ON DETERMINATION AND DOCUMENTATION OF MEDICAL NECESSITY IN POST-ACUTE AND LONG-TERM CARE FACILITIES

Published October 1999; Revised August 2001

SECTION I:
Determination of "medical necessity" in nursing facility care

Although a final definition and determination of "medical necessity" still is an unrealized goal of the medical, insurance, regulatory and legislative community, the American Medical Directors Association believes that the attending physician's decision and documentation should be held paramount. A working definition of "medical necessity" that could be accepted is:

Evaluation and management services, diagnostic tests and procedures, treatments, medical/surgical procedures, equipment or supplies that in the judgment of the attending physician (or physician extender [NP or PA] when permitted by federal and state statue) are required to professionally assess, plan, manage and monitor the health care of a resident or patient in the facility within the parameters of generally accepted principles of medical practice.

The physician must be prepared to justify that the service or intervention is sound clinical practice and that it reflects reasonable and realistic goals and expected outcomes. The physician also must be willing to address and defend a rationale in relation to pre-morbid function, excess disability, and the expected positive outcome of any prescribed intervention. However, explanations of the above need not be explicitly documented in detail prospectively in the clinical record.

SECTION II:
Dispute resolution:

Since the attending physician and medical director bears the ultimate responsibility of the care plan and medication or therapeutic device he or she has prescribed, that treatment should be considered "medically necessary" unless and until an insurer, a regulatory agency or another physician actually assumes the responsibility and liability for superseding the physician's care. In addition, "an insurer may be able to set aside the decision of the treating physician only if the insurer can show that the proposed treatment conflicts with clinical standards of care or that there is substantial scientific evidence, regardless of clinical practices, that the proposed care would be unsafe or ineffective or that an alternative course care of treatment would lead to an equally good outcome. By substantial evidence, we mean a sizable number of studies published in peer-reviewed journals that meet professionally recognized standards of validity and replicability and that are free of conflicts of interest."[1] "Given the enormous power of the payor to influence appropriate medical care by the denial of services", such criteria would prompt insurers to act reasonably and responsibly. AMDA also supports patient and physician access to a speedy, external review process when "medical necessity" is challenged — to ensure impartiality and nondiscrimination based on coverage criteria.

SECTION III:
Determination and documentation of medical necessity for primary care services:

Medical necessity for a visit by a primary care provider may be, but is not limited to, the following:

- one physician visit to a nursing facility in a calendar month on the presumption that such a visit is "medically necessary" for a person whose condition requires him or her to reside in a facility providing round the clock nursing care — (Non-skilled);
- one physician visit/week on the presumption that such a visit is medically necessary for a person whose condition requires him or her to be receiving sub-acute care — (Skilled);
- the initial nursing facility admission evaluation;
- patient instability or change in condition that the physician documents is significant enough to require a timely medical or mental status evaluation and/or physical examination to establish the appropriate treatment intervention and/or change in care plan — (Skilled or Non-skilled);
- therapeutic issues that the physician documents require a timely follow-up evaluation to assess effectiveness of therapy or treatment — including recent surgical or invasive diagnostic procedures, pressure ulcer evaluation, psychotropic medication regimens, or (for the terminally ill) comfort measures;
- regulatory requirements, including, when warranted, the need for more frequent evaluations and examinations to assist in time-delineated assessments associated with the Prospective Payment System or other regulatory or payor requirements;
- medical conditions — including delirium, dementia, or changes in mental status — manifesting with behavioral symptoms that are primarily organic in nature and that require timely evaluation. (Physician documentation of these conditions and symptoms precludes down-coding to a psychiatric visit.); and
- nursing, rehabilitation, managed care, patient, or family request to address a documented medical issue of concern that requires a physical (or mental status) examination to the concern.

Note: The above list is not exclusive and there may be other times when a medically necessary visit is required. The physician still bears the burden of documenting the need for any and all visits and that documentation needs to support the intensity of coding.

SECTION IV:
Consultation and specialist services

Consultations or specialist services should be considered "medically necessary" when they address a documented diagnostic or therapeutic question for which the attending physician determines he or she needs the assistance or second opinion of a specialist (by a record review and a physical and/or cognitive examination) to address the concern.

When ordering consultation services, the following elements need to be considered:

- A consultant should possess and additional knowledge base and/or skills clearly outside the skill/knowledge base of that primary care attending physician unless the consultation is for a second opinion.
- The service requested must be appropriate for the specific individual.
- The service will affect the resident/patient assessment, diagnosis or care planning or treatment.

Diagnostic services

Diagnostic studies are medically necessary if they are procedures (including clinical laboratory studies) that would be considered commonly accepted medical mechanisms to assess a medical condition, determine therapeutic intervention, establish the effectiveness of a treatment, or monitor a therapeutic range.

When ordering diagnostic services, the following elements need to be considered:

- Will the assessment, management, or monitoring of the individual's health care be affected by the service?
- Is the service appropriate? That is, does the individual wish to receive the service? Will the individual quality of life be affected by the service and its anticipated consequences?
- Can the individual tolerate the service and its consequences safely?

Therapeutic modalities:

Medications & Therapeutics are medically necessary if they are:

...treatments that are commonly accepted to be medically appropriate interventions for health problems identified and documented by the physician. If the medication or therapy is unusual or substantially more costly than the most commonly accepted intervention, the physician must document the rationale for the deviation from the community norm.

Factors the physician or other (ordering licensed practitioner) may consider regarding the "medical necessity" of an intervention, include:

- The physician believes there is potential for significant improvement in the level of function of the patient;
- The physician can document the goals and objectives of the therapy to the patient or surrogate decision maker, i.e. the potential benefits of therapy;
- The physician can document risks that may be avoided by skilled therapy intervention;

Factors that may make the use of skilled therapy services (e.g. physical therapy, occupational therapy, speech therapy) more appropriate than unlicensed rehabilitative services (e.g. rehab aides/technicians or nursing staff), include:

- The presence of comorbidities which require a skilled/licensed professional to adequately plan therapy and monitor the ongoing response to the intervention.
- If the physician determines that a therapy is unusual or more costly than the most commonly accepted intervention, the physician must be willing to document the rationale for the deviation from the norm. Alternatively, more costly therapeutic services may be justified if they improve the quality of life or functional status of the patient in a significant, otherwise unobtainable way.

Note: In all of the following, the regulatory requirement regarding "highest practicable level of function" must be taken into consideration when ordering evaluations and treatments. It will be in the physician's purview to balance this mandate with the clinical status of the patient when determining medical necessity.

Rehabilitation evaluations and treatments can be considered medically necessary if there is:

...medical provider affirms the documentation stating the rationale of how the intervention will provide the patient with an added quality to their life, a higher level of independence, or will prevent unnecessary debility or decline.

Hearing and vision evaluations and treatments can be considered medically necessary if there is:

...a regulatory requirement for the evaluation and the medical provider and/or the evaluator can document a justification that the evaluation and treatment that has a reasonable potential to provide the patient with an added quality to their life or, a higher level of independence or has reasonable potential to prevent unnecessary debility or decline.

Dental services can be considered medically necessary if:

...the care assists patients maintain their health through optimal nutrition, hygiene, or comfort.

Supplies/DME can be considered medically justified if there is:

...a medical provider affirms the documented therapeutic advantage (superceding any intermediary decision) to the use of supplies or equipment in the care regimen that will assist the patient heal or regain function more quickly, safely, or cost effectively.

[1] Rosenbaum, Frankford, Moore, and Borzi. Sounding Board: Who Should Determine When Health Care is Medically Necessary 1999. NEJM. 1999; 340:229-232

NEW CHANGES TO PHYSICIAN SELF-REFERRAL REGULATIONS

New regulations by the Centers for Medicare and Medicaid (CMS) revise current requirements implement prohibitions on physician self-referrals to Designated Health Services (DHS). The first regulation is the third phase of regulations to implement the self-referral law (commonly known as the Stark Law, after its sponsor, Congressman Pete Stark (D-CA). The regulations are likely to be known as "Stark Phase III". CMS promulgated additional changes in the 2008 Medicare physician fee schedule.

Stark Phase III

The Stark Phase III regulation was published September 5, 2007 and became effective December 4, 2007. Key changes include:

- Fair Market Value: The regulation eliminates a prior safe harbor for hourly rates for physicians under personal service contracts (which are used for many medical directors' employment contracts). The regulations had formerly established a "safe harbor" that included two methodologies for calculating hourly rates that would be deemed "fair market value". One methodology tied the hourly rate to that of emergency room physician services in the area, and the other required averaging at least four of several specified salary surveys. The fair market value requirement remains in place, although without the safe harbor. CMS intends to scrutinize arrangements for fair market value, and notes that wage surveys remain a recognized method for determining fair market values. CMS also recognized that rates paid for clinical work and for administrative work may differ. The fair market value exception will also apply to compensation paid by a physician to a DHS entity.
- "Stand in the Shoes": A physician is deemed to "stand in the shoes" of his or her physician organization and may not take advantage of the indirect compensation exception. A physician who stands in the shoes of his or her organization is deemed to have the same compensation with the DHS entity that the physician organization has with the entity. As a result, many compensation arrangements that were formerly considered indirect compensation arrangements may now be considered as direct compensation arrangements that must comply with an applicable exception for direct compensation arrangements. CMS has delayed the implementation of this provision for only academic medical centers and integrated health care systems until 12/4/08.
- A "grandfathering" provision allows arrangements that relied on the indirect compensation exception that are currently in place to remain valid during the current term of the contract.
- Shared Space: For physicians whose practices use the in-office ancillary services exception to provide DHS, the services must be provided in the office or must be based on a clock time basis, rather than a per-click basis.
- Independent Contractors: Independent contractors who wish to qualify as a physician in a group practice must have a direct contractual agreement with the group and perform services on the premises of the group practice.

- Physician Recruitment: CMS has modified its blanket prohibition on non-competition restrictions on physicians who left a practice by including a list of allowable restrictions. Group practices which receive economic assistance for recruitment of a physician must meet new accounting rules.
- Productivity bonuses: Productivity bonuses, but not profit sharing, are allowed for income directly derived from DHS referrals that are "incident to" the physician's services. The regulation clarifies that the definition of "incident to" includes both services and supplies such as drugs.
- Holdovers: Month-to-month payments may be made after the expiration of a rental agreement or a personal services arrangement for up to six months if the terms and conditions of the agreement do not change.
- Amendments: Amendments to compensation agreements covered under Stark regulations are permitted if the economic terms of the agreement are materially unchanged by the amendment.

Other regulatory provision relate to academic medical centers, amendments to agreements, holdover payments, non-monetary compensation, compliance training and professional courtesy. These will be summarized on the AMDA Legal web site.

2008 Medicare Physician Fee Schedule

In the July 2, 2007, proposed Medicare Physician Fee Schedule, the Centers for Medicare and Medicaid (CMS) proposed numerous changes to the physician self-referral or Stark regulations, as well as limitations on the use of the in-office ancillary services exception. In the end, CMS deferred most of the changes, and included only one revision in the final Fee Schedule, published December 1.

- Anti-Markup Provisions for Diagnostic Tests: Medicare regulations currently prohibit the markup of the technical component (TC) of certain diagnostic tests that are performed by outside suppliers and billed to Medicare by a different individual or entity. Medicare program instructions also limit who may bill for the professional component (PC, which is the interpretation) of diagnostic tests. In the 2008 Medicare Physician Fee Schedule, CMS imposes anti-markup restriction on the technical component (TC) and professional component (PC) of diagnostic tests (other than clinical lab tests) that are ordered by the billing supplier, if the TC or PC is purchased by the billing supplier, or the TC or PC is performed outside of the office of the billing supplier. The changes are intended to address CMS' concerns regarding physician group practices or other suppliers purchasing or otherwise contracting for the provision of diagnostic testing services and then realizing a profit when billing Medicare. This change will take effect Jan. 1, 2008.

Some of these changes, particularly for physicians with office practices, may require review of current contracts for compliance with the new regulations. Regulatory requirements for compliance with the Stark Law are complex. Physicians are urged to contact lawyers with experience in health care fraud and abuse to help them determine whether a proposed activity would violate the Stark Law or whether an exception is available

STARK LAW QUESTIONS AND ANSWERS

These Stark Law Questions & Answers are intended to be used by the reader for general informational purposes only. Due to the highly complex nature of the Stark Law, they should not be used as a substitute for professional legal advice. Your specific questions on Stark Law as they relate to your own practice are best answered on an individual basis by legal counsel specializing in health care law.

1. What is the Stark Law?

Generally speaking, the Stark Law, which is located in Section 1877 of the Social Security Act, prohibits a physician from referring Medicare or Medicaid program patients for certain "designated health services" to an entity with which the physician or an immediate family member has a "financial relationship."

2. What are the "designated health services"?

The "designated health services" covered by the Stark Law include:

a. clinical laboratory services
b. physical therapy, occupational therapy, and speech language pathology services
c. radiology and certain other imaging services
d. radiation therapy services and supplies
e. durable medical equipment and supplies;
f. parenteral and enteral nutrients, equipment, and supplies
g. prosthetics, orthotics, and prosthetic devices and supplies
h. home health services
i. outpatient prescription drugs
j. inpatient and outpatient hospital services

Additionally, in final regulations released on November 21, 2005, the Centers for Medicare and Medicaid Services (CMS) announced its decision to make nuclear medicine a "designated health service" under the Stark Law.

3. What is a "financial relationship"?

Under the Stark Law, a "financial relationship" can be either (a) a direct or indirect "ownership or investment interest" in the entity that furnishes designated health services or (b) a "compensation arrangement" between the physician and the entity. Therefore, unless a Stark exception is fully satisfied, a physician who is part owner of a rehabilitation clinic may not refer a Medicare or Medicaid patient to the clinic for rehabilitation services and the clinic may not bill for those services. Likewise, if a physician is compensated as a medical director by a SNF, the SNF may not bill the Medicare or Medicaid program for designated health services referred by that physician unless the medical director arrangement meets a Stark exception (see question #5 on Stark Law exceptions). If there are a number of "financial relationships" between a physician and an entity, each relationship must meet a Stark exception in order for the physician to appropriately refer patients to that facility for designated health services.

4. What is considered a "referral" under the Stark Law?

The Stark Law defines the term "referral" much more broadly than the generally accepted definition in the standard physician-patient relationship. Under the Stark Law, a "referral" can include (a) a physician's request for, ordering of, or certifying or recertifying the need for, any "designated health service" reimbursable under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by that other physician or under the physician's supervision; or (b) a physician's request that includes the provision of any designated health service, the establishment of a plan of care that includes the provision of a designated health service, or the certifying or recertifying of the need for such a designated health service. However, a "referral" does *not* include services personally performed or provided by the referring physician.

5. What are the Stark Law exceptions?

Stark Law contains approximately 35 exceptions that describe acceptable financial relationships that allow a physician to refer to an entity for the provision of designated health services. The first group of exceptions can be applied to either "ownership or investment interests" or "compensation arrangements." The second group of exceptions apply only to "ownership or investment interests." The third group of exceptions apply only to "compensation arrangements." Some commonly applied exceptions to the Stark Law include the exceptions for (a) in-office ancillary services, (b) bona fide employment relationships, (c) physician recruitment, and (d) physicians practicing in rural areas and locations designated as Health Professional Shortage Areas. It is important to remember that even these exceptions only apply in limited circumstances. For example, the Stark Law exception that covers a medical director agreement with a skilled nursing facility would not cover the medical director's ownership of that facility. A separate Stark law exception would need to be satisfied. Physicians should consult a lawyer to help determine which exception fits their proposed financial relationships.

Additional information on Stark Law exceptions may be found by visiting the CMS website at http://new.cms.hhs.gov/MedlearnProducts/40_PhysSelfReferral.asp, or by referring to the Code of Federal Regulations at 42 CFR §411.355 through 42 CFR §411.357.

6. If one exception to the Stark Law is satisfied, is an entire arrangement between a physician and an entity protected?

Not necessarily. A Stark exception has to be satisfied for *each* financial relationship between a physician and an entity that will receive referrals for "designated health services." It's also important to note that the Stark Law applies to both direct *and indirect* financial relationships. So a medical director agreement with a physician's practice entity, rather than the physician individually, is considered a "financial relationship" with the physician under the Stark Law.

7. Can a physician who has a financial relationship with a facility avoid implicating the Stark Law if the facility only accepts Medicaid patients, and does not bill Medicare?

No. The Stark Law applies to referrals for "designated health services" reimbursable by either the Medicare or *Medicaid* programs. CMS will not reimburse for the federal share of Medicaid to any entity that provides a designated health service prohibited by Stark Law, unless a Stark exception is fully satisfied. The physician who made the Medicaid patient referral would be subject to the Stark Law as well.

8. Does the Stark Law apply to Hospital-based SNFs only, or to any SNF receiving CMS funding?

The Stark Law applies to *any* SNF that provides "designated health services" reimbursable by the Medicare or Medicaid programs, whether that SNF is hospital-based or a stand-alone facility.

9. Isn't there a special rule involving what constitutes a "designated health service" when a SNF is involved?

Yes. When determining whether a particular service constitutes a "designated health service" in the SNF setting, the Stark Law excludes items or services that Medicare pays for on a "per diem" basis as part of a composite rate (e.g., the Part A "RUG rate"). Thus, if an item or service that would otherwise be a "designated health service" is included as part of the SNF per diem rate, it is not considered a "designated health service" for Stark Law purposes. Importantly, however, if a SNF furnishes "designated health services" that are not covered under the composite rate, such as therapy services furnished under Medicare Part B, these services *would* be "designated health services" covered by the Stark Law.

10. Is a medical director of a SNF required to meet a Stark Law exception for the referral of one of his or her patients to the SNF for the provision of non-per-diem services?

Very likely. As mentioned above, "per diem" items or services that are covered as part of a composite rate are not considered "designated health services" for the purposes of the Stark Law. Items or services that are *not* paid for as part of a composite rate (i.e., "non-per-diem" services) are subject to the Stark Law if those items or services fall into one of the "designated health services" categories.

11. Then what difference does the "per-diem" issue make?

Not much, probably. Almost all SNFs that participate in the Medicare and Medicaid programs provide both "per diem" and "non-per-diem" reimbursed items or services. It is highly unlikely that a physician would be affiliated with a SNF that provides items and services *solely* reimbursed on a "per diem" basis. It would be very difficult — if not impossible — for a physician to keep track of the reimbursement status of his or her patients as they wind their way through the complex government reimbursement system. A physician with a "financial relationship" with a SNF should assume that at least some his or her patients will receive "designated health services" from that SNF during the course of their stay. Therefore, a physician with a "financial relationship" with a SNF should plan on qualifying for an exception to the Stark Law if the physician is planning on referring his or her patients to the facility for items or services that might be subject to the Stark Law.

12. When given an opportunity to become a medical director of a nursing facility, what precautions should a physician consider with respect to the Stark Law?

Because Stark is a strict liability law, a physician who cannot meet a Stark exception commits a violation of the law simply by engaging in a prohibited referral, regardless of his or her intent or lack of knowledge of the law. A medical director candidate for a SNF should become familiar with the various "designated health services" the SNF might provide. The prospective medical director should also become familiar with what constitutes a "referral," since the Stark Law defines the term so broadly. The good news for medical directors is that the Stark Law provides a "personal services exception" that many medical director arrangements should be able to satisfy. A medical director agreement must meet all of the elements of the personal services exception in order for it not to violate the Stark Law.

13. What are the requirements for "personal services exception" to the Stark Law?

Generally speaking, for the personal services exception to be satisfied an agreement for a physician's services must:

1. be in writing, be signed by the parties to the agreement, and specify the services covered by the agreement;
2. cover *all* of the services to be furnished by the physician under the arrangement;
3. cover aggregate services that do not exceed those that are reasonable and necessary for the legitimate purposes of the arrangement;
4. be for a term of at least one year;
5. provide for compensation to be set in advance, not to exceed "fair market value," and (except in the case of a permissible physician incentive plan) not be determined by the volume or value of any referrals or other business generated between the parties; and
6. not involve counseling or promotion of a business arrangement or other activity that violates any state or federal law, such as the federal Anti-kickback Statute.

14. Since the Stark Law requires that a medical director's compensation should not exceed "fair market value," what is "fair market value"?

The Stark Law defines "fair market value" as "the value in arm's length transactions, consistent with the general market value." "General market value" means "the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to an agreement who are not otherwise in a position to generate business for the other party" at the time of the agreement.

Prior regulations had included a "safe harbor" for establishing fair market value by comparison to either the average hourly rate for emergency room physicians or the hourly rate based on salary surveys for physicians in the same specialty. In December, 2007, those safe harbors were eliminated, although the fair market value requirement remains in place.

Elimination of the safe harbor should not be construed as an indication that CMS will not scrutinize the fair market value of arrangements. CMS noted in the preamble to the regulation that, "Nothing precludes parties from calculating fair market value using any commercially reasonable methodology that is appropriate under the circumstances and otherwise fits the definition." CMS also observed that, "Reference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating fair market value. Ultimately the appropriate method for determining fair market value for purposes of the physician self-referral law will depend on the nature of the transaction, its location, and other factors. …" An important clarification for medical directors is language in the preamble that the fair market value of administrative services may differ from the fair market value of clinical services. (72 Fed. Reg. 51011, Sept. 5, 2007)

15. Under the Stark Law, may a physician become an owner or co-owner of a SNF where he or she is a medical director?

A physician may perform duties as a medical director at a facility he or she co-owns, but the physician must find a Stark Law exception for both the medical director arrangement and the physician's ownership interest in the facility itself. The medical director arrangement should be crafted to satisfy the "personal services exception," discussed above. Finding an exception for the physician's ownership interest in the facility could prove much more difficult. Unfortunately, there are very few exceptions for a physician's ownership interest in a nursing facility, such as a SNF. Unless the facility is in a rural area or a Health Professional

Shortage Area, the physician's options appear to be limited. Any physician considering investing in a nursing facility should immediately consult an attorney to analyze how the Stark Law will impact the proposed arrangement.

16. What are the penalties for violating the Stark Law?

A physician who violates the law is subject not only to substantial monetary penalties, but also to exclusion from participation in Medicare, Medicaid, and other government healthcare programs. Regulators may impose a broad range of penalties for violations of the Stark Law. Civil penalties include: (1) repayment of all amounts billed to the Medicare and Medicaid program that violate the Stark Law; (2) civil monetary penalties up to $100,000 if an arrangement is found to have as its principal purpose the intent to ensure physician referrals; or (3) exclusion from the Medicare and Medicaid programs. In addition, the U.S. Department of Justice has asserted that filing a Medicare or Medicaid claim in violation of the Stark Law constitutes a "false claim," which could trigger liability under the federal False Claims Act. If that weren't enough, many states have adopted "mini" Stark Laws, which prohibit self-referrals for items and services reimbursable by *any payor,* not just the Medicare or Medicaid programs.

17. If a physician commits an error and violates Stark Law without intent to do so, will he or she be penalized?

Yes. Stark is a strict liability law and may be violated regardless of the physician's good intentions to benefit patient care or improve patient access to health care resources. Penalties for violations of the Stark Law may be greatly increased if the intent of the arrangement is to secure patient referrals in violation of the federal Anti-kickback Statute or the federal False Claims Act. Physicians are urged to contact their lawyers to help them determine whether a proposed activity would violate the Stark Law or whether an exception is available. In addition, physicians may request a determination from CMS through the advisory opinion process outlined in the Stark Law regulations. Finally, a physician who discovers that he or she inadvertently violated the Stark Law should consult legal counsel on how to address the matter.

GUIDANCE ON STARK LAW-RELATED ISSUES

The final "Stark II" regulation regarding physician referrals to health services in which the physician has a financial relationship, has raised some questions among AMDA members. AMDA members have asked about the interpretation of "fair market value" of payment for their services, which is a requirement for several exceptions to the Stark non-referral requirements. Another issue of concern has been how the limit of $300.00 in non-monetary compensation impacts the ability of a nursing facility to pay for AMDA dues and continuing medical education. The regulations were published in March 2004 and became effective on July 26, 2004. We have asked for a legal opinion on these issues, which is published below.

In general, what restrictions does the Stark Law place on physician referrals?

The Stark Law prohibits a physician from referring a Medicare patient for any "designated health service" ("DHS") to an entity with which the physician (or an immediate family member) has a financial relationship (i.e., an ownership or compensation arrangement), unless an exception applies. Furthermore, an entity that receives a prohibited referral cannot bill the Medicare program for that service.

What are the designated health services to which the Stark Law applies?

The eleven categories of DHS covered by the Stark Law, as defined in the statute and implementing regulations (42 C.F.R. § 411.351), are as follows:

1. clinical laboratory services;
2. physical therapy services, including speech-language pathology services;
3. occupational therapy services;
4. radiology and certain other imaging services;
5. radiation therapy services and supplies;
6. durable medical equipment and supplies;
7. parenteral and enteral nutrients, equipment, and supplies;
8. prosthetics, orthotics, and prosthetic devices and supplies;
9. home health services and supplies;
10. outpatient prescription drugs; and
11. inpatient and outpatient hospital services.

A related definitional point should be kept in mind when determining whether a particular service constitutes a DHS in the skilled nursing facility ("SNF") setting. The Stark definition of DHS *excludes* services that Medicare pays for as part of a composite rate, such as what otherwise would be a DHS service included as part of the SNF per diem rate. If, on the other hand, a SNF furnishes a DHS services that is *not* paid for as part of the composite rate, such as therapy services furnished under a consolidated billing arrangement or DHS services furnished on an outpatient basis, these services *would* be Stark-covered DHS.

Do the Stark Law's restrictions on financial relationships between physicians and entities that provide "designated health services" ("DHS") apply to a medical director whose responsibilities entail providing solely medical direction services (e.g., resident care policy

implementation and medical care coordination) to the facility, rather than making any referrals to the facility?

If the physician serving as the medical director does not make any referrals for DHS to the nursing facility, then the Stark law would not apply. In assessing this type of situation, however, it is imperative that the parties understand accurately the scope and meaning of the term "referral" as used in the Stark law. That term's meaning under Stark is broader than the more generally understood notion of a "referral" in the health care industry context (e.g., sending a patient to a particular provider for treatment).

The Stark II regulations1 define the term "referral" to mean either of the following (paraphrased and summarized):

1. A physician's request for, ordering of, or certifying the need for any DHS for which payment may be made under Medicare Part B, including a request for a consultation by another physician.
2. A physician's (i) request that includes the provision of any DHS for which payment may be made under Medicare, (ii) establishment of a plan of care that includes a DHS, or (iii) the certification of the need for such a DHS.

Further, the Stark regulations include as a "referring physician" both a physician who makes a referral himself or herself, or who directs or controls another person or entity's referral. For these purposes, a referring physician and a professional corporation of which he or she is the sole owner are considered one-and-the-same.

There are several exceptions to this definition of "referral," including any DHS personally performed by the referring physician and requests for certain specialty consultations (e.g., certain pathology and radiology services). These physician activities will *not* be considered "referrals" under Stark. In addition, as discussed in Question 2 above, even if there are referrals, most inpatient services provided in an SNF and included in its Medicare per diem rate will *not* be considered to be DHS. Therefore, if there are referrals, then a follow-up assessment must be made to see if those referrals will constitute DHS in the post-acute and long-term care provider context in which the patient is being treated. If there are no referrals under the Stark law's definition of that term, or if these are referrals but they are *not* for DHS in the relevant provider context, then the Stark law's restrictions would not apply.

In sum, if a medical director does not make referrals for DHS to the nursing facility, then the Stark law does not apply. However, a careful determination must be made to ensure the absence of such "referrals," as that term is used in the Stark law and regulations. If the medical director is not the attending physician for any residents and strictly limits his or her services in the nursing facility setting to the type of resident care policy implementation and clinical coordination that typify a medical director's duties in that role, the Stark law probably will not be implicated.

In many cases, a facility's medical director may also be the attending physician for one or more facility residents. If that physician wants to make a DHS referral to the facility for any of his/her patients, a Stark exception would be needed to permit that referral and the subsequent billing of the Medicare program for the service. One of three Stark exceptions would most likely be needed to protect referrals/orders by a physician who has a medical director agreement with the facility: the personal services exception (applicable to independent contractors), the *bona fide* employment exception, or the fair market value exception. In each case, the exception would require, among other things, that the medical director's fee must not exceed fair market value ("FMV").

Doesn't the final Stark II (Phase II) rule have a formula to determine the FMV for payments to physicians that uses a fee average derived from a half-dozen national fee surveys for physicians? What if using that formula results in what many physicians would consider to be a less than fair market value fee in their communities; for example, $78 per hour for physicians specializing in geriatrics? Being restricted by the Stark law to a fee at that level could make it very difficult for a facility to recruit a qualified medical director in many areas of the country, and, in some instances, medical directors currently have contracts where the hourly fee exceeds $78. Do those contracts have to be changed to meet the FMV formula in the Stark regulations?

This question raises several points about the Stark exceptions for contracts between a physician and entities (including post-acute and long-term care facilities) to which the physician refers patients for DHS. However, it also highlights the need for clarification about the FMV formula in the final Stark II regulations.

As the question suggests, it is correct that a medical director agreement constitutes a compensation arrangement between the referring physician and the facility that needs to be protected by a Stark exception — likely one of the exceptions for compensation arrangements mentioned above. Each of these exceptions requires payments consistent with a FMV payment rate. Although the final regulations do include a formula for determining FMV payments to physicians with contracts providing for hourly payment provisions (i.e., the formula does *not* apply to flat-fee, annual payment formulae), the formula is *not* mandatory; rather, it is a voluntary safe harbor, compliance with which will be deemed to be a FMV payment rate. More specifically, under the safe harbor, a physician's hourly compensation rate will be considered to be fair market value under *either* of two methodologies. The first methodology requires that the hourly rate be less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, as long as there are at least three hospitals providing emergency room services in the market. The second methodology protects a rate that is consistent with the average fiftieth percentile salary for the physician's specialty in any four of six identified physician compensation surveys, divided by 2000 hours to arrive at an hourly rate. Where the survey does not have data for the particular physician's specialty, the salary for general practice is used.

CMS emphasizes that compliance with the safe harbor is entirely voluntary, and parties may establish fair market value using other methods, although they continue to bear the burden to demonstrate that their rates are fair market value. If the parties to an agreement do not follow the safe harbor methodology for showing a FMV payment rate, they need to take careful and thorough steps to document that the hourly payment (or any other payment rate) for a physician's personal service is a FMV rate in the market (e.g., consistent with the rate a party would pay as a result of *bona fide,* arm's length bargaining between well-informed parties who are not in a position to make referrals or otherwise generate business for the other party).

Does the Stark law's $300 annual limit on an entity's payment of non-monetary compensation (i.e., items or services other than cash or cash equivalents) to a referring physician mean that a nursing facility may no longer be willing (or able) to include AMDA dues or meetings in a (referring) medical director's compensation package?

No, not necessarily. Although it is true that the "non-monetary compensation up to $300" Stark exception does limit the ability of a facility receiving DHS referrals from the physician to pay for things like AMDA dues, association meetings, and Continuing Medical Education ("CME") under that exception, other exceptions also could be available to protect these types of payments. For example, if the facility has a medical director agreement with the referring physician, payment for these types of expenses on the physician's behalf could be

commercially reasonable and might well fit within an overall FMV compensation package under the personal services or FMV exceptions. Moreover, if the content of the CME program involves compliance training, another Stark exception may be available to cover the cost of a local compliance program. If, however, no separate Stark exception is available, then such non-monetary compensation from a facility to a referring physician must be carefully tracked to ensure it does not exceed the annual $300 limit (which will be inflation indexed) for non-monetary compensation.

Reference

1. The Centers for Medicare & Medicaid Services ("CMS") issued on March 26, 2004 the interim final Stark II (Phase II) rule with comment period. 69 Fed. Reg. 16,054 (2004). This rule became effective on July 26, 2004.

Links to CMS Resources

1. Federal Register. Friday, March 26, 2004. Part III Department of Health and Human Services. Centers for Medicare & Medicaid Services. 42 CFR Parts 411 and 424. Medicare Programs; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II); Interim Final Rule. (http://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/downloads/cms1810ifc.pdf)

2. CMS Physician Self-Referral Educational Resource Web Guide (https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html?redirect=/physicianselfreferral/)

AMDA'S MODEL MEDICAL DIRECTOR AGREEMENT WITH NURSING FACILITY

To download a word format version AMDA's Model Medical Director Agreement and Supplemental Materials visit:

http://www.amda.com/resources/modelagreement.docx

AMDA'S SYNOPSIS OF FEDERAL REGULATIONS IN THE NURSING FACILITY

To access the most updated version of AMDA's Synopsis of Federal Regulations in the Nursing Facility — Implications for Attending Physicians & Medical Directors visit:

http://www.amda.com/resources/synopsis.pdf

OFFICE OF INSPECTOR GENERAL'S FINAL COMPLIANCE PROGRAM GUIDANCE FOR NURSING FACILITIES

See following pages reproduced directly from Federal Register.

56832 Federal Register / Vol. 73, No. 190 / Tuesday, September 30, 2008 / Notices

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 facsim to Professional and Scientific Asso (PSA), the logistical support contra for the meeting, at fax number (70 234–1701. Individuals without ac the Internet who wish to register r call Sowjanya Kotakonda with PS (703) 234–1737. Individuals who attend the meeting and need spec assistance, such as sign language interpretation or other reasonable accommodations, should notify t 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]

BILLING CODE 4165–15–P

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

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

Full-sized page reproductions from the published *Federal Register* appear on the next 17 pages.

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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.

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Dated: September 23, 2008.

Elizabeth M. Duke,

Administrator.

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

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Supplemental Compliance Program Guidance for Nursing Facilities

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

ACTION: Notice.

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

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

Background

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

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

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

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

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

OIG Supplemental Compliance Program Guidance for Nursing Facilities

This document is organized in the following manner:

I. Introduction

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

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

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

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

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

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

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

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

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

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

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

A. Benefits of a Compliance Program

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

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

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

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

B. Application of Compliance Program Guidance

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

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

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

II. Reimbursement Overview

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

A. Medicare

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

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

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

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

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

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

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

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

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

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

B. Medicaid

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

III. Fraud and Abuse Risk Areas

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

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

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

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

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

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

[12] *Id.*

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

[14] *See id.*

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

[16] *See id.*

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

[18] *Id.*

[19] *Id.*

[20] *Id.*

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

[22] *Id.*

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

[24] Id.

[25] *Id.*

[26] *Id.*

[27] *Id.*

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

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

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

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

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

A. Quality of Care

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

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

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

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

1. Sufficient Staffing

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

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

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

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

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

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

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

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

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

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

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

2. Comprehensive Resident Care Plans

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

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

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

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

3. Medication Management

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

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

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

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

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

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

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

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

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

[44] 42 CFR 483.40(a).

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

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

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

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

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

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

4. Appropriate Use of Psychotropic Medications

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

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

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

5. Resident Safety

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

(a) Promoting Resident Safety

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

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

[50] 42 CFR 483.60(c).

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

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

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

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

[55] 42 CFR 483.13(a).

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

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

[58] 42 CFR 483.60(c).

[59] 42 CFR 483.20(k).

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

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

[62] *See id.*

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

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

[65] *Id.*

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

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

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

(b) Resident Interactions

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

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

(c) Staff Screening

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

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

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

B. Submission of Accurate Claims

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

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

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

1. Proper Reporting of Resident Case-Mix by SNFs

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

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

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

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

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

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

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

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

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

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

2. Therapy Services

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

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

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

3. Screening for Excluded Individuals and Entities

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

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

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

4. Restorative and Personal Care Services

Facilities must ensure that residents receive appropriate restorative and

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

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

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

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

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

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

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

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

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

[83] *Id.*

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

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

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

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

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

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

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

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

C. The Federal Anti-Kickback Statute

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

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

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

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

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

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

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

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

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

Nursing facilities that have identified potentially problematic arrangements or

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

[90] *Id.*

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

[92] 42 U.S.C. 1320a–7b(b).

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

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

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

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

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

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

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

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

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

1. Free Goods and Services

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

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

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

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

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

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

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

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

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

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

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

2. Services Contracts

(a) Non-Physician Services

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

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

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

(b) Physician Services

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

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

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

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

[99] 42 CFR 1001.952(d).

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

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

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

3. Discounts

(a) Price Reductions

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

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

(b) Swapping

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

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

4. Hospices

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

[102] 42 CFR 1001.952(d).

[103] 42 CFR 1001.952(j).

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

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

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

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

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

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

5. Reserved Bed Payments

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

D. Other Risk Areas

1. Physician Self-Referrals

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

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

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

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

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

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

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

[109] 42 CFR 1001.952(d).

[110] The Provider Reimbursement Manual provides as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

2. Anti-Supplementation

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

3. Medicare Part D

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

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

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

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

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

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

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

[120] *Id.*

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

[122] *Id.*

[123] *Id.*

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

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

E. HIPAA Privacy and Security Rules

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

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

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

IV. Other Compliance Considerations

A. An Ethical Culture

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

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

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

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

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[124] *Id.*

[125] 42 U.S.C. 1395w–101.

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

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

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

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

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

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

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

B. Regular Review of Compliance Program Effectiveness

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

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

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

V. Self-Reporting

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

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

VI. Conclusion

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

Dated: September 24, 2008.

Daniel R. Levinson,

Inspector General.

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BILLING CODE 4152–01–P

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

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

[135] Appropriate Federal and State authorities include OIG, CMS, the Criminal and Civil Divisions of the Department of Justice, the U.S. Attorney in relevant districts, the Food and Drug Administration, the Department's Office for Civil Rights, the Federal Trade Commission, the Drug Enforcement Administration, the Federal Bureau of Investigation, and the other investigative arms for the agencies administering the affected Federal or State health care programs, such as the State Medicaid Fraud Control Unit, the Defense Criminal Investigative Service, the Department of Veterans Affairs, the Health Resources and Services Administration, and the Office of Personnel Management (which administers the Federal Employee Health Benefits Program).

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

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

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

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

AMDA'S PRIMARY SOURCE VERIFICATION RESOURCES

This resource list is not all-inclusive and is intended only to provide additional resources to the attending physician involved in the care of post-acute and long-term care residents.

AMDA — The Society for Post-Acute and Long-Term Care Medicine in connection with any organization included on this list gives no guarantee or endorsement of any kind.

American Board of Medical Specialties (ABMS)
1007 Church Street, Suite 404
Evanston, Illinois 60201-5913
(847) 491-9091
Fax (847) 328-3596
Phone Verification (866) ASK-ABMS
www.abms.org

American Medical Association (AMA)
515 North State Street
Chicago, IL 60610
(312) 464-5000
www.ama-assn.org

Federation of State Medical Boards (FSMB)
P.O. Box 619850
Dallas, TX 75261-9850
817-868-4000
www.fsmb.org

National Board of Medical Examiners (NBME)
3750 Market Street
Philadelphia, PA 19104
215-590-9500
webmail@mail.nbme.org
www.nbme.org

National Practitioner Data Bank (NPDB)
Healthcare Integrity and Protection Data Bank
P.O. Box 10832
Chantilly, VA 20153-0832
1-800-767-6732
npdb@sra.comwww.npdb-hipdb.com

Office of the Inspector General List of Excluded Individuals (OIG)
Office of Investigations
Health Care Administrative Sanctions
Room N2-01-26
7500 Security Boulevard
Baltimore, MD 21244-1850
410-786-9603
sanction@oig.hhs.gov
http://oig.hhs.gov/fraud/exclusions/listofexcluded.html

Medical Licensing Boards

(Licensure information by state)

Alabama State Medical Board
848 Washington St.
Montgomery, AL 36104
334-242-4116
www.albme.org

Alaska State Medical Board
333 Willoughby Ave., 9th Flr.
Juneau, AK 99801
P.O. Box 110806
Juneau, AK 99811
907-465-2541 or 907-465-2756
www.dced.state.ak.us/occ/pmed.htm

Arizona Medical Board
9545 E. Doubletree Ranch Rd.
Scottsdale, AZ 85258
480-551-2700
877-255-2212
www.bomex.org
questions@azmd.gov

Arkansas State Medical Board
2100 Riverfront Drive, Suite 200
Little Rock, AR 72202
501-296-1802
www.armedicalboard.org/info/sub-Contact.asp

California Medical Board
1426 Howe Ave., Suite 54
Sacramento, CA 95825
916-263-2382
www.medbd.ca.gov

Colorado Board of Medical Examiners
1560 Broadway, Suite 1300
Denver, CO 80202-5140
303-894-7690
www.dora.state.co.us/medical

Connecticut Dept. of Public Health
Physician Licensure
410 Capitol Ave.
MS#12APP
Hartford, CT 06134-0308
860-509-7563
www.dph.state.ct.us/MD_Profile/hlthprof.htm

Delaware Board of Medical Practice
Cannon Bldg., Suite 203
Suite 203
861 Silver Lake Blvd
Dover, DE 19904
302-744-4507
http://professionallicensing.state.de.us/boards/medicalpractice/index.shtml

District of Columbia Board of Medicine
Health Licensing Specialist
717 14th Street, NW
Suite 600
Washington, DC 20005
202-724-4900
888-204-6193
http://doh.dc.gov/doh/cwp/view,a,1371,q,575606,dohNav_
GID,1881,dohNav,|34373|34382|,.asp

Florida Board of Medicine
4052 Bald Cypress Way, Bin # C00
Tallahassee, FL 32399-3250
850-488-0595
www.doh.state.fl.us/RW_webmaster/professionals/

Georgia Composite State Board of Medical Examiners
2 Peachtree Street, N.W., 36th Floor
Atlanta, Georgia 30303-3465
404-656-3913
E-Mail: medbd@dch.state.ga.us
www.sos.state.ga.us/plb/medical/_olddefault.htm

Hawaii Board of Medical Examiners
Professional & Vocational Licensing Division
1010 Richard Street
Honolulu, HI 96801
P.O. Box 3469
Honolulu, HI 96801
808-586-3000
www.practicesight.com/Directories/State%20License%20BD/hawaii_state_license_boards.htm

Idaho Board of Medicine
Westgate Office Plaza
1755 Westgate Dr., Suite 140
Boise, ID 83704
info@bom.state.id.us
208-327-7000
www.bom.state.id.us/contact.html

Illinois Dept. of Professional Regulation
320 W. Washington St., 3rd Flr.
Springfield, IL 62786
217-785-0800
www.idfpr.com/dpr/WHO/med.asp

Indiana Health Professions Board
402 W. Washington St., Room 41
Indianapolis, IN 46204
317-234-2060
hpb3@hpb.IN.gov
www.in.gov/pla/

Iowa State Board of Medical Examiners
400 SW 8th Street, Suite C
Des Moines, IA 50309-4686
515-281-5171
www.docboard.org/ia/ia_home.htm

Kansas State Board of Healing Arts
235 SW Topeka Blvd.
Topeka, KS 66603-3068
785-296-7413
www.ksbha.org

Kentucky Board of Medical Licensure
310 Whittington Pkwy., Suite 1-B
Louisville, KY 40222
502-429-7150
KBML@ky.gov
www.state.ky.us/agencies/kbml/

Louisiana State Board of Medical Examiners
630 Camp St.
New Orleans, LA 70130
P.O. Box 30250
New Orleans, LA 70190-0250
504-568-6820 ext. 221
www.lsbme.org/

Maine Board of Licensure in Medicine
Board of Licensure in Medicine
137 State House Station
Augusta, Maine 04333-0137
207-287-3601
207-287-6590
www.docboard.org/me/me_home.htm

Maryland Board of Physician
4210 Patterson Ave.
Baltimore, MD 21215
410-764-4777
www.mbp.state.md.us/pages/phys.html

Massachusetts Board of Registration in Medicine
Commonwealth of Massachusetts
Board of Registration in Medicine
560 Harrison Avenue, Suite G-4
Boston, MA 02118
617-654-9800
www.massmedboard.org

Michigan Board of Medicine
611 W. Ottawa, First Flr.
Lansing, MI 48933
P.O. Box 30670
Lansing, MI 48909
517-373-6873
www.michigan.gov/cis/0,1607,7-154-10568_17671_17681-58914--,00.html

Minnesota Board of Medical Practice
2829 University Ave., S.E., Suite 400
Minneapolis, MN 55414-3246
612-617-2130
www.bmp.state.mn.us

Mississippi State Board of Medical Licensure
1867 Crane Ridge Drive, Suite 200-B
Jackson, Mississippi 39216
601-987-3079
www.msbml.state.ms.us

Missouri Division of Professional Registration
3605 Missouri Boulevard
P.O. Box 1335
Jefferson City, MO 65102-1335
573-751-0293
profreg@pr.mo.gov
http://pr.mo.gov/

Montana Board of Medical Examiners
HEALTH CARE LICENSING BUREAU
Board of Medical Examiners
301 South Park, Room 430
PO Box 200513
Helena, MT 59620-0513
406-844-2300
www.discoveringmontana.com/dli/bsd/license/bsd_boards/med_board/board_page.asp

Nebraska Department of
HHS Regulation and Licensure
P.O. Box 95007
Lincoln, NE 68509-5007
402-471-2133
www.hhs.state.ne.us/lis/lisindex.htm

Nevada State Board of Medical Examiners
1105 Terminal Way, Suite 301
Reno, NV 89502
P.O. Box 7238
Reno, NV 89510
775-688- 2559
nsbme@govmail.state.nv.us or nsbme@medboard.nv.gov
http://medboard.nv.gov/

New Hampshire Board of Medicine
2 Industrial Park Drive, Suite 8
Concord, NH 03301-8520
603-271-1203
www.state.nh.us/medicine/pi.html

New Jersey State Board of Medical Examiners
140 E. Front St., 2nd Flr.
Trenton, NJ 08608
609-826-7100
bme@dca.lps.state.nj.us
www.state.nj.us/lps/ca/bme/bme.htm

New Mexico Medical Board
2055 S. Pacheco
Building 400
Santa Fe, NM 87505
505-476-7220
nmbme@state.nm.us
http://www.state.nm.us/nmbme/

New York State Education Department
Office of the Professions
Division of Professional Licensing Services
Medicine Unit
89 Washington Avenue
Albany, NY 12234-1000
518-474-3817, ext. 260
opunit2@mail.nysed.gov
http://www.op.nysed.gov/medcontact.htm

North Carolina Medical Board
1201 Front St., Suite 100
Raleigh, NC 27609
919-326-1100 or 919-326-1109
info@ncmedboard.org
www.ncmedboard.org/Clients/NCBOM/Public/Index.htm

North Dakota State Board of Medical Examiners
418 E. Broadway Ave. Suite 12,
Bismarck, ND 58501
701-328-6500
www.ndbomex.com/Default.htm

Ohio State Medical Board
77 S. High St., 17th Flr.
Columbus, OH 43215-6108
614-466-3934
http://med.ohio.gov/

Oklahoma Board of Medical Licensure and Supervision
5104 N. Francis Ave., Suite C
Oklahoma City, OK 73118-6020
P.O. Box 18256
Oklahoma City, OK 73154-0256
405-848-6841
www.okmedicalboard.org/

Oregon Board of Medical Examiners
1500 S. W. First Ave., Suite 620
Portland, OR 97201
503-229-5770
bme.info@state.or.us
www.bme.state.or.us/search.html

Pennsylvania State Board of Medicine
P.O. Box 2649
Harrisburg, PA 17105-2649
717-783-1400
ST-MEDICINE@state.pa.us

Rhode Island Dept. of Health
Board of Medical Licensure and Discipline
3 Capitol Hill Room 205
Providence, RI 02908
401-222-2828
www.health.state.ri.us/hsr/professions/license.php

South Carolina Board of Medical Examiners
Synergy Business Park
Kingstree Building
110 Centerview Dr.,Suite 202
Columbia, SC 29210
803-896-4500
www.llr.state.sc.us/pol/medical/index.asp?file=main.htm

South Dakota State Board of Medicine and Osteopathic Examiners
1323 S. Minnesota Ave,
Sioux Falls, SD 57105
605-336-1965
www.state.sd.us/doh/medical/

Tennessee Department of Health Medical Board
425 Fifth Avenue, North
Cordell Hull Building, 3rd Floor
Nashville, TN 37247
615-532-4384
TN.health@state.tn.us
http://www2.state.tn.us/health/Boards/index.htm

Texas State Board of Medical Examiners
Physician Licensure Mailing Address:
P.O. Box 2029
Austin, TX 78768-2029
800-248-4062
512-305-7030
verifcic@tsbme.state.tx.us
www.tsbme.state.tx.us

Utah Department of Commerce
Division of Occupational & Professional Licensure
P.O. Box 146741
Salt Lake City, Utah · 84114-6741
801-530-6628
Toll-Free in Utah 866-275-3675
801-530-6511 (fax)
www.commerce.utah.gov/opl/index.htm

Vermont Board of Medical Practice
P.O. Box 70
Burlington, VT 05402-0070
802-657-4220
Toll-free: 800-745-7371 (from within Vermont)
medicalboard@vdh.state.vt.us
www.healthyvermonters.info/bmp/bmp.shtml

Virginia Department of Health Professions
P.O. Box 70
Burlington, VT 05402-0070
804-662-9900
Automated Licensure Verification
For All Boards: 804-662-7636
www.dhp.state.va.us/about/phone.htm

Washington Department of Health
Health Professionals Quality Assurance
310 Israel Rd
Tumwater WA 98501
360-236-4700
hpqa.csc@doh.wa.gov
www.dhp.state.va.us/about/phone.htm

West Virginia Board of Medicine
Wisconsin Department of Regulation and Licensing
1400 East Washington Avenue, Room 173
Madison, WI 53703
608-266-2811
web@drl.state.wi.us
http://drl.wi.gov/prof/burhealth.htm

Wisconsin Department of Regulation and Licensing
Wisconsin Medical Examining Board
1400 E Washington Avenue
Madison WI 53703
608-266-2112
http://drl.wi.gov/prof/doct/def.htm

Wyoming Board of Medicine
Colony Building 2nd Floor
211 West 19th Street
Cheyenne, Wyoming 82002
307-778-7053 or 800-438-5784
wyomedboard@state.wy.us
http://wyomedboard.state.wy.us/roster.asp

This resource list is not all-inclusive and is intended only to provide additional resources to the attending physician involved in the care of post-acute and long-term care residents.

AMDA — The Society for Post-Acute and Long-Term Care Medicine in connection with any organization included on this list gives no guarantee or endorsement of any kind.

SELECTED REFERENCES AND RESOURCES IN GERIATRICS AND POST-ACUTE AND LONG-TERM CARE

AMDA Clinical Practice Guidelines

- Acute Change of Condition in the Long Term Care Setting
- Altered Nutritional Status
- Anemia in the Long-Term Care Setting
- COPD Management in the Long Term Care Setting
- Common Infections in the Long Term Care Setting
- Dehydration and Fluid Maintenance
- Delirium and Acute Problematic Behavior in the Long Term Care Setting
- Dementia in the Long Term Care Setting
- Depression
- Diabetes Management in the Long Term Care Setting
- Falls and Fall Risk
- Gastrointestinal Disorders in the Long Term Care Setting
- Health Maintenance in the Long-Term Care Setting
- Heart Failure
- Osteoporosis and Fracture Prevention in the Long Term Care Setting
- Pain Management in the Long Term Care Setting
- Parkinson's Disease
- Pressure Ulcers in the Long Term Care Setting
- Sleep Disorders in the Long Term Care Setting
- Stroke Management and Prevention in the Long Term Care Setting
- Transitions of Care
- Urinary Incontinence

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SOCIETIES AND ORGANIZATIONS

Administration on Aging	**AoA** One Massachusetts Ave, NW Washington, DC 20001 202-619-0724 www.aoa.gov/
Agency for Healthcare Research and Quality	**AHRQ** 540 Gaither Road, Ste 2000 Rockville, MD 20852 301-427-1104 www.ahrq.gov
Alzheimer's Association National Office	**ALZ** 225 N. Michigan Ave., Fl. 17 Chicago, IL 60601 24/7 Nationwide Contact Center: 1.800.272.3900 www.alz.org
American Academy of Family Physicians	**AAFP** 11400 Tomahawk Creek Parkway Leawood, KS 66211-2672 800-274-2237 www.aafp.org/
American Academy of Home Care Medicine Constance Row, Executive Director	**AAHCM** PO Box 1037 Edgewood, MD 21040 410-676-7966 www.aahcp.org
American Academy of Hospice and Palliative Medicine	**AAHPM** 4700 W Lake Avenue Glenview, IL 60025 847-375-4712 Fax: 877-375-6475 E-mail: info@aahpm.org www.aahpm.org/
American Academy of Physical Medicine & Rehabilitation	**AAPMR** 9700 West Bryn Mawr Ave, Ste 200 Rosemont, IL 60018-5701 info@aapmr.org www.aapmr.org

American Association for Geriatric Psychiatry	**AAGP** 7910 Woodmont Ave Suite 1050 Bethesda, MD 20814-3004 301-654-7850 fax: 301-654-4137 main@aagponline.org www.aagpgpa.org
American Association of Retired Persons	**AARP** 601 E Street NW Washington, DC 20049 1-888-687-2277 www.aarp.org
American College of Health Care Administrators	**American College of Health Care Administrators** 1321 Duke Street, Ste 400 Alexandria, VA 22314 Phone: 202-536-5120 Fax: 866-874-1585 www.achca.org
American Federation of Aging Research	**AFAR** 70 West 40th Street, 11th Floor New York, NY 10018 Phone: 212-703-9977 Toll-free: 888-582-2327 grants@afar.org, or info@afar.org www.afar.org
American Geriatrics Society	**AGS** 55 West 39th St, 16th Fl New York, NY 10018 Phone 212-703-9977 info@americangeriatrics.org www.americangeriatrics.org/
American Health Care Association	**AHCA** 1201 L Street NW Washington, DC 20005 Phone: 202- 842-4444 Fax: 202-842-3860 www.ahca.org
AMDA — The Society for Post-Acute and Long-Term Care Medicine	**AMDA** 11000 Broken Land Parkway, Suite 400 Columbia, MD 21044 410-740-9743 www.amda.com

American Society of Consultant Pharmacists	**ASCP** 1321 Duke Street Alexandria, VA 22314 703-739-1300 info@ascp.com www.ascp.com/
American Speech-Language-Hearing Association	**ASHA** 2200 Research Blvd Rockville, MD 20852 1-800-498-2071 www.asha.org/default.htm
Assisted Living Federation of America	**ALFA** 1650 King St, Ste 602 Alexandria, VA 22314 703-894-1805 info@alfa.org
Centers for Disease Control and Prevention	**CDC** 1600 Clifton Road Atlanta, GA 30333 404-639-0385 www.cdc.gov/page.do/ id/0900f3ec80112422
Gerontological Advanced Practice Nurses Association *(formerly National Conference of Gerontological Nurse Practitioners)*	**GAPNA** *(formerly NCGNP)* East Holly Ave Box 56 Pitman, NJ 08071 866-355-1392 www.ncgnp.org
LeadingAge	**LeadingAge** 2519 Connecticut Ave., NW Washington, D.C. 20008 phone 202.783.2242; fax 202.783.2255 info@leadingage.org www.leadingage.org/
National Association of Directors of Nursing Administration in Long Term Care	**NADONA** 11353 Reed Hartman Hgwy, Ste 210 Cincinnati OH 45241 800-222-0539 info@nadona.org www.nadona.org

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INTERNET RESOURCES

AMDA—The Society for Post-Acute and Long-Term Care Medicine
www.amda.com

Administration on Aging
www.aoa.gov

Age Pages
www.nih.gov/nia/health/pubpub/pubpub.htm

Agency for Healthcare Research and Quality
www.ahrq.gov

Alzheimer's Association
www.alz.org

American Academy of Allergy, Asthma and Immunology
www.aaaai.org

American Academy of Physician Assistants
www.aapa.org

American Association of Clinical Endocrinologists
www.aace.com

American Association of Retired Persons
www.aarp.org

American Board of Quality Assurance and Utilization Review Physicians
www.abqaurp.org

American College of Health Care Administrators
www.achca.org

American College of Physicians
www.acponline.org

American Geriatrics Society
www.americangeriatrics.org

American Health Care Association
www.ahca.org

American Health Quality Association
www.ahqa.org

American Heart Association
www.amhrt.org

American Hospital Association
www.aha.org

American Medical Association
www.ama-assn.org

American Medical Directors Association
www.amda.com

American Psychiatric Association
www.psych.org

American Society on Aging
www.asaging.org

American Speech-Language-Hearing Association
www.asha.org

Arthritis Foundation
www.arthritis.org

British Geriatrics Society
www.bgs.org.uk/

Catholic Health Association
www.chausa.org

Centers for Disease Control and Prevention
www.cdc.gov

Centers for Medicare & Medicaid Services (CMS)
www.cms.hhs.gov

Department of Health and Human Services
www.os.dhhs.gov

Food and Drug Administration
www.fda.gov

Federal Register
www.gpoaccess.gov/fr/

Gerontological Society of America
www.geron.org

Immunization Action Coalition
www.immunize.org

Joint Commission on Accreditation of Healthcare Organizations
www.jcaho.org

LeadingAge
www.leadingage.com

National Association of Directors of Nursing Administration in Long Term Care
www.nadona.org

National Committee for Quality Assurance
www.ncqa.org

National Guideline Clearinghouse
www.guideline.gov

National Hospice Organization
www.nho.org

National Institute of Diabetes and Digestive and Kidney Diseases
www.niddk.nih.gov

National Institutes of Health
National Library of Medicine
www.nlm.nih.gov

National Pressure Ulcer Advisory Board
www.npuap.org

New England Journal of Medicine
www.nejm.org

Physician Assistant (Journal)
www.pajournal.com

Physicians' Desk Reference®
www.pdr.net

Social Security Administration
www.ssa.gov

The Nurse Practitioner (Journal)
www.tnpj.com

U.S. Dept. of Health and Human Resources
www.hhs.gov

World Health Organization
www.who.int

World Organization of Family Doctors
www.wonca.org

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