§483.75 Administration
A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

Procedures: §483.75
If there is a deficiency in §483.13, Resident behavior and facility practices; §483.15, Quality of life; or §483.25, Quality of care, which has the scope and/or severity to be defined as substandard quality of care, fully review for compliance all the tags within this section (§483.75).

§483.75(a) Licensure
A facility must be licensed under applicable State and local law.

Interpretive Guidelines: §483.75(a)
Applicable licenses, permits, and approvals must be available to you for inspection upon request.

Procedures: §483.75(a)
If there are problems with care provided or supervised by licensed personnel, verify applicable licenses, permits and approvals.

§483.75(b) Compliance With Federal, State, and Local Laws and Professional Standards
The facility must operate and provide services in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility.

Intent: §483.75(b)
The intent of this regulation is to ensure that a facility is in compliance with Federal, State, and local laws, regulations, and codes relating to health, safety, and sanitation.

Interpretive Guidelines: §483.75(b)
The State is responsible for making decisions about whether there are violations of State laws and regulations. Licenses, permits and approvals of the facility must be available to you upon request. Current reports of inspections by State and/or local health authorities are on file, and notations are made of action taken by the facility to correct deficiencies.

§483.75(c) Relationship to Other HHS Regulations
In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of handicap (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455). Although these regulations are not in themselves considered requirements under this part, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds.
Procedures: §483.75(b)
If resident/family interviews reveal possible problems with admission contracts, review these contracts for violations of requirements at §§483.10 and 483.12. As appropriate, refer problems to an ombudsman or other agencies, e.g., Office for Civil Rights.
Some State or local laws are more stringent than the Federal requirement on the same issue. Failure of the facility to meet a Federal, State or local law may be cited at this tag only when the authority having jurisdiction has both made a determination of noncompliance and has taken a final adverse action as a result.
Accepted professional standards and principles include the various practice acts and scope of practice regulations in each State, and current, commonly accepted health standards established by national organizations, boards and councils.
If interviews with residents suggest that the facility may have required deposits from Medicare residents at admission, review the facility’s admissions documents.

Procedures: §483.75(c)
If during the survey you identify problems relating to one or more of these requirements, which are under the purview of another Federal agency, forward the information to the RO, who will forward it to the appropriate Federal agency.

F493
(Rev. 70, Issued: 01-07-11, Effective: 10-01-10 Implementation: 10-01-10)

§483.75(d) Governing Body
(1) The facility must have a governing body, or designated persons functioning as a governing body, that is legally responsible for establishing and implementing policies regarding the management and operation of the facility; and
(2) The governing body appoints the administrator who is--
(i) Licensed by the State where licensing is required; and
(ii) Responsible for the management of the facility.

Interpretive Guidelines: §483.75(d)(2)(1)
The administrator must be licensed where required by the State.

§483.75(e) Required Training of Nursing Aides
(1) Definitions
“Licensed health professional” means a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker.
“Nurse aide” means any individual providing nursing or nursing-related services to residents in a facility who is not a licensed health professional, a registered dietitian, or someone who volunteers to provide such services without pay.

Interpretive Guidelines: §483.75(e)
Section 6121 of the Patient Protection and Affordable Care Act (PPACA) of 2010, amending Sections 1819(b)(5)(F) and 1919(b)(5)(F) of the Social Security Act, clarifies that nurse aides include individuals who provide such services through an agency or under contract with the facility.
Nurse aides do not include those individuals who furnish services to residents only as paid feeding assistants as defined in §488.301 of this chapter.
§483.75(e)(2) General rule
A facility must not use any individual working in the facility as a nurse aide for more than 4 months, on a full-time basis, unless:
(i) That individual is competent to provide nursing and nursing related services; and
(ii)(A) That individual has completed a training and competency evaluation program, or a competency evaluation program approved by the State as meeting the requirements of §§483.151-483.154 of this part; or
(B) That individual has been deemed or determined competent as provided in §483.150(a) and (b).
§483.75(e)(3) Non-permanent employees
A facility must not use on a temporary, per diem, leased, or any basis other than a permanent employee any individual who does not meet the requirements in paragraphs (e)(2)(i) and (ii) of this section.
(See Tag F495 for guidelines, probes, and procedures for §483.75(e)(2-4))

(Rev. 70, Issued: 01-07-11, Effective: 10-01-10 Implementation: 10-01-10)

(4) Competency
A facility must not use any individual who has worked less than 4 months as a nurse aide in that facility unless the individual--
(i) Is a full-time employee in a State-approved training and competency evaluation program;
(ii) Has demonstrated competence through satisfactory participation in a State-approved nurse aide training and competency evaluation program or competency evaluation program; or
(iii) Has been deemed or determined competent as provided in §483.150(a) and (b).

Interpretive Guidelines: §483.75(e)(2 - 4)
Facilities may use, as nurse aides, any individuals who have successfully completed either a nurse aide training and competency evaluation program or a competency evaluation program. However, if an individual has not completed a program at the time of employment, a facility may only use that individual as a nurse aide if the individual is in a nurse aide training and competency evaluation program (not a competency evaluation program alone) and that individual is a permanent employee in his or her first four months of employment in the facility. Facilities may not use non-permanent employees as nurse aides unless they have either completed a training and competency evaluation program, or a competency evaluation program. Section 6121 of the Patient Protection and Affordable Care Act (PPACA) of 2010, amending Sections 1819(f)(2)(A)(i)(I) and 1919(f)(2)(A)(i)(I) of the Social Security Act, clarifies that nurse aide training includes initial and annual dementia management and patient abuse prevention training for all nurse aides.

Probes: §483.75(e)(2 - 4)
During an extended or partial extended survey:
• Have all nurse aides completed a nurse aide training and competency evaluation program or a competency evaluation program? If not, are those nurse aides permanent employees enrolled in a training and competency evaluation program who have worked in the facility for 4 months or less?
• Ask nurse aides where they received their training, how long the training was and how long they have worked in the facility as a nurse aide.

During all surveys:
• If incorrect nurse aide work performance is observed during the survey, check to see if the nurse aide received training and licensed nurse supervision to correctly carry out the task.

A “permanent employee” is defined as any employee you expect to continue working on an ongoing basis.

Procedures: §483.75(e)(2-4)

Review competency requirements for nurse aides if you identify potential deficient care practices in quality of care, resident rights, resident behavior and facility practice or quality of life which may be related to nurse aide competency. Is there evidence that the nurse aide has successfully completed the competency evaluation program, or has the individual been grandfathered in by the State?

If you identify deficient care practices by nurse aides who do not have evidence of having successfully completed a competency evaluation program, determine:
• If the aide is currently receiving training an a State approved Nurse Aide Training Program;
• If the aide is under the supervision of a licensed nurse; and
• If the aide has been trained and determined to be proficient for the tasks to which he or she is assigned. See §483.152 for specific training that the aide is to receive. This training includes:
  • At least 16 hours of training in the following subjects before any direct contact with the resident:
    o Communication and interpersonal skills;
    o Infection control;
    o Safety and emergency procedures, including the Heimlich Maneuver;
    o Promoting resident’s independence; and
    o Respecting resident’s rights.
  • Basic nursing skills;
  • Personal care skills;
  • Mental health and social services of residents;
  • Care of cognitively impaired residents;
  • Basic restorative services; and
  • Resident’s rights.

F496

(Rev. 70, Issued: 01-07-11, Effective: 10-01-10 Implementation: 10-01-10)

§483.75(e)(5) Registry verification

Before allowing an individual to serve as a nurse aide, a facility must receive registry verification that the individual has met competency evaluation requirements unless--
(i) The individual is a full-time employee in a training and competency evaluation program approved by the State; or
(ii) The individual can prove that he or she has recently successfully completed a training and competency evaluation program or competency evaluation program approved by the State and has not yet been included in the registry. Facilities must follow up to ensure that such an individual actually becomes registered.

§483.75(e)(6) Multi-State registry verification
Before allowing an individual to serve as a nurse aide, a facility must seek information from every State registry established under sections 1819(e)(2)(A) or 1919(e)(2)(A) of the Act the facility believes will include information on the individual.

§483.75(e)(7) Required retraining
If, since an individual’s most recent completion of a training and competency evaluation program, there has been a continuous period of 24 consecutive months during none of which the individual provided nursing or nursing-related services for monetary compensation, the individual must complete a new training and competency evaluation program or a new competency evaluation program.

Interpretive Guidelines: §483.75(e)(7)
If an individual does not wish to be retrained, the individual must establish that he or she performed nursing or nursing-related services for monetary compensation for at least one documented day (i.e., 8 consecutive hours) during the previous 24 months. The State is required to remove the individual’s name from the registry if the services are not provided for monetary compensation during the 24-month period. Thus, in the absence of any evidence to the contrary, you can assume that the retraining requirement does not apply to an individual whose name appears on the registry.

Section 6121 of the Patient Protection and Affordable Care Act (PPACA) of 2010, amending Sections 1819(f)(2)(A)(i)(I) and 1919(f)(2)(A)(i)(I) of the Social Security Act, clarifies that nurse aide training includes initial and annual dementia management and patient abuse prevention training for all nurse aides.

F497
(Rev. 70, Issued: 01-07-11, Effective: 10-01-10 Implementation: 10-01-10)

§483.75(e)(8) Regular In-Service Education
The facility must complete a performance review of every nurse aide at least once every 12 months, and must provide regular in-service education based on the outcome of these reviews. The in-service training must--
(i) Be sufficient to ensure the continuing competence of nurse aides, but must be no less than 12 hours per year;
(ii) Address areas of weakness as determined in nurse aides’ performance reviews and may address the special needs of residents as determined by the facility staff; and
(iii) For nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired.

Interpretive Guidelines: §483.75(e)(8)
The adequacy of the in-service education program is measured not only by documentation of hours of completed in-service education, but also by demonstrated competencies of nurse aide staff in consistently applying the interventions necessary to meet residents’ needs.
If there has been deficient care practices identified during Phase 1 of the survey, review as appropriate training received by nurse aides in that corresponding subject area. For example, if the facility has deficiencies in infection control, review the infection control unit in the facility’s inservice nurse aide training program.
Each nurse aide must have no less than twelve hours of in-service education per year. Calculate the date by which a nurse aide must receive annual in-service education by the employment date rather than the calendar year. Section 6121 of the Patient Protection and Affordable Care Act (PPACA) of 2010, amending Sections 1819(f)(2)(A)(i)(I) and 1919(f)(2)(A)(i)(I) of the Social Security Act, clarifies that nurse aide training includes initial and annual dementia management and patient abuse prevention training for all nurse aides.
Security Act, clarifies that nurse aide training includes initial and annual dementia management and patient abuse prevention training for all nurse aides.

Probes: §483.75(e)(8)
During an extended or partial extended survey, or during any survey in which nurse aide performance is questioned. (See §483.75(f).)
- Does the facility review the performance of its nurse aides?
- How has in-service education addressed areas of weakness identified in performance reviews, special resident needs, and needs of residents with cognitive impairments?
- How has in-service education addressed quality of care problems including those of special care needs and resident rights?

F498
§483.75(f) Proficiency of Nurse Aides
The facility must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents’ needs, as identified through resident assessments, and described in the plan of care.

Interpretive Guidelines: §483.75(f)
“Competency in skills and techniques necessary to care for residents’ needs” includes competencies in areas such as communication and personal skills, basic nursing skills, personal care skills, mental health and social service needs, basic restorative services and resident rights.

Procedures: §483.75(f)
During the Resident Review, observe nurse aides.

Probes: §483.75(f)
Do nurse aides show competency in skills necessary to:
- Maintain or improve the resident’s independent functioning, e.g.:
  - Performing range of motion exercises,
  - Assisting the resident to transfer from the bed to a wheelchair,
  - Reinforcing appropriate developmental behavior for persons with MR, or
  - Psychotherapeutic behavior for persons with MI;
- Observe and describe resident behavior and status and report to charge nurse;
- Follow instructions; and
- Carry out appropriate infection control precautions and safety procedures.

F499
§483.75(g) Staff Qualifications
(1) The facility must employ on a full-time, part-time or consultant basis those professionals necessary to carry out the provisions of these requirements.
(2) Professional staff must be licensed, certified, or registered in accordance with applicable State laws.

Procedures: §483.75(g)
If there is reason to doubt the qualifications of temporary agency personnel working in the facility, check with the appropriate registry or professional licensing board.

F500
§483.75(h) Use of Outside Resources
(1) If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility must have that service furnished to residents by a person or agency outside the facility under an arrangement described in section 1861(w) of the Act or an agreement described in paragraph (h)(2) of this section. 
(2) Arrangements as described in section 1861(w) of the Act or agreements pertaining to services furnished by outside resources must specify in writing that the facility assumes responsibility for--
(i) Obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility; and
(ii) The timeliness of the services.

F501
§483.75(i) Medical Director
(1) The facility must designate a physician to serve as medical director.
(2) The medical director is responsible for –
(i) Implementation of resident care policies; and
(ii) The coordination of medical care in the facility.

INTENT:
The intent of this requirement is that:
• The facility has a licensed physician who serves as the medical director to coordinate medical care in the facility and provide clinical guidance and oversight regarding the implementation of resident care policies;
• The medical director collaborates with the facility leadership, staff, and other practitioners and consultants to help develop, implement and evaluate resident care policies and procedures that reflect current standards of practice; and
• The medical director helps the facility identify, evaluate, and address/resolve medical and clinical concerns and issues that:
  o Affect resident care, medical care or quality of life; or
  o Are related to the provision of services by physicians and other licensed health care practitioners.

NOTE: While many medical directors also serve as attending physicians, the roles and functions of a medical director are separate from those of an attending physician. The medical director’s role involves the coordination of facility-wide medical care while the attending physician’s role involves primary responsibility for the medical care of individual residents.1

DEFINITIONS
Definitions are provided to clarify terms related to the provision of medical director services.
• “Attending Physician” refers to the physician who has the primary responsibility for the medical care of a resident.
• “Current standards of practice” refers to approaches to care, procedures, techniques, treatments, etc., that are based on research and/or expert consensus and that are contained in current manuals, textbooks, or publications, or that are accepted, adopted or promulgated by recognized professional organizations or national accrediting bodies.
• “Medical care” refers to the practice of medicine as consistent with State laws and regulations.
• “Medical director” refers to a physician who oversees the medical care and other designated care and services in a health care organization or facility. Under these regulations, the medical
director is responsible for coordinating medical care and helping to develop, implement and evaluate resident care policies and procedures that reflect current standards of practice.

• “Resident care policies and procedures” – Resident care policies are the facility’s overall goals, directives, and governing Statements that direct the delivery of care and services to residents. Resident care procedures describe the processes by which the facility provides care to residents that is consistent with current standards of practice and facility policies.

OVERVIEW
The medical director has an important leadership role in actively helping long term care facilities provide quality care. The regulation requires each facility to have a medical director who is responsible for the implementation of resident care policies and the coordination of medical care. These two roles provide the basis for the functions and tasks discussed in this guidance. The medical director’s roles and functions require the physician serving in that capacity to be knowledgeable about current standards of practice in caring for long term care residents, and about how to coordinate and oversee related practitioners. As a clinician, the medical director plays a pivotal role in providing clinical leadership regarding application of current standards of practice for resident care and new or proposed treatments, practices, and approaches to care. The medical director’s input promotes the attainment of optimal resident outcomes which may also be influenced by many other factors, such as resident characteristics and preferences, individual attending physician actions, and facility support. The 2001 Institute of Medicine report, “Improving the Quality of Long Term Care,” urged facilities to give medical directors greater authority for medical services and care. The report states, “nursing homes should develop structures and processes that enable and require a more focused and dedicated medical staff responsible for patient care.”

The medical director is in a position, because of his/her roles and functions, to provide input to surveyors on physician issues, individual resident’s clinical issues, and the facility’s clinical practices. The text “Medical Direction in Long Term Care” asserts that: “The Medical Director has an important role in helping the facility deal with regulatory and survey issues…the medical director can help ensure that appropriate systems exist to facilitate good medical care, establish and apply good monitoring systems and effective documentation and follow up of findings, and help improve physician compliance with regulations, including required visits.

During and after the survey process, the medical director can clarify for the surveyors clinical questions or information about the care of specific residents, request surveyor clarification of citations on clinical care, attend the exit conference to demonstrate physician interest and help in understanding the nature and scope of the facility's deficiencies, and help the facility draft corrective actions.”

Nationally accepted statements concerning the roles, responsibilities and functions of a medical director can be found at the American Medical Directors Association Web site at www.amda.com.

NOTE: References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

MEDICAL DIRECTION
The facility is responsible for designating a medical director, who is currently licensed as a physician in the State(s) in which the facility(ies) he/she serves is (are) located. The facility may
provide for this service through any of several methods, such as direct employment, contractual arrangements, or another type of agreement. Whatever the arrangement or method employed, the facility and the medical director should identify the expectations for how the medical director will work with the facility to effectively implement resident care policies and coordinate medical care.

**NOTE:** While the roles of medical directors who work for multi-facility organizations with corporate or regional offices may vary for policy development, the medical directors, nonetheless, should be involved in facility level issues such as application of those policies to the care of the facility’s residents.

**Implementation of Resident Care Policies and Procedures**
The facility is responsible for obtaining the medical director’s ongoing guidance in the development and implementation of resident care policies, including review and revision of existing policies. The medical director’s role involves collaborating with the facility regarding the policies and protocols that guide clinical decision making (for example, interpretation of clinical information, treatment selection, and monitoring of risks and benefits of interventions) by any of the following: facility staff; licensed physicians; nurse practitioners; physician assistants; clinical nurse specialists; licensed, certified, or registered health care professionals such as nurses, therapists, dieticians, pharmacists, social workers, and other health care workers. The medical director has a key role in helping the facility to incorporate current standards of practice into resident care policies and procedures/guidelines to help assure that they address the needs of the residents. Although regulations do not require the medical director to sign the policies or procedures, the facility should be able to show that its development, review, and approval of resident care policies included the medical director’s input.

This requirement does not imply that the medical director must carry out the policies and procedures or supervise staff performance directly, but rather must guide, approve, and help oversee the implementation of the policies and procedures. Examples of resident care policies include, but are not limited to:

- Admission policies and care practices that address the types of residents that may be admitted and retained based upon the ability of the facility to provide the services and care to meet their needs;
- The integrated delivery of care and services, such as medical, nursing, pharmacy, social, rehabilitative and dietary services, which includes clinical assessments, analysis of assessment findings, care planning including preventive care, care plan monitoring and modification, infection control (including isolation or special care), transfers to other settings, and discharge planning;
- The use and availability of ancillary services such as x-ray and laboratory;
- The availability, qualifications, and clinical functions of staff necessary to meet resident care needs;
- Resident formulation and facility implementation of advance directives (in accordance with State law) and end-of-life care;
- Provisions that enhance resident decision making, including choice regarding medical care options;
- Mechanisms for communicating and resolving issues related to medical care;
- Conduct of research, if allowed, within the facility;
- Provision of physician services, including (but not limited to):
  - Availability of physician services 24 hours a day in case of emergency;
Review of the resident’s overall condition and program of care at each visit, including medications and treatments;

- Documentation of progress notes with signatures;
- Frequency of visits, as required;
- Signing and dating all orders, such as medications, admission orders, and re-admission orders; and
- Review of and response to consultant recommendations.

- Systems to ensure that other licensed practitioners (e.g., nurse practitioners) who may perform physician-delegated tasks act within the regulatory requirements and within the scope of practice as defined by State law; and
- Procedures and general clinical guidance for facility staff regarding when to contact a practitioner, including information that should be gathered prior to contacting the practitioner regarding a clinical issue/question or change in condition.

**Coordination of Medical Care**

The medical director is responsible for the coordination of medical care in the facility. The coordination of medical care means that the medical director helps the facility obtain and maintain timely and appropriate medical care that supports the healthcare needs of the residents, is consistent with current standards of practice, and helps the facility meet its regulatory requirements. In light of the extensive medical needs of the long term care population, physicians have an important role both in providing direct care and in influencing care quality. The medical director helps coordinate and evaluate the medical care within the facility by reviewing and evaluating aspects of physician care and practitioner services, and helping the facility identify, evaluate, and address health care issues related to the quality of care and quality of life of residents. “A medical director should establish a framework for physician participation, and physicians should believe that they are accountable for their actions and their care.”

The medical director addresses issues related to the coordination of medical care identified through the facility’s quality assessment and assurance committee and quality assurance program, and other activities related to the coordination of care. This includes, but is not limited to, helping the facility:

- Ensure that residents have primary attending and backup physician coverage;
- Ensure that physician and health care practitioner services are available to help residents attain and maintain their highest practicable level of functioning, consistent with regulatory requirements;
- Develop a process to review basic physician and health care practitioner credentials (e.g., licensure and pertinent background);
- Address and resolve concerns and issues between the physicians, health care practitioners and facility staff; and
- Resolve issues related to continuity of care and transfer of medical information between the facility and other care settings.

Throughout this guidance, a response from a physician implies appropriate communication, review, and resident management, but does not imply that the physician must necessarily order tests or treatments recommended or requested by the staff, unless the physician agrees that those are medically valid and indicated.

In addition, other areas for medical director input to the facility may include:

- Facilitating feedback to physicians and other health care practitioners about their performance and practices;
• Reviewing individual resident cases as requested or as indicated;
• Reviewing consultant recommendations;
• Discussing and intervening (as appropriate) with a health care practitioner about medical care that is inconsistent with applicable current standards of care;
• Assuring that a system exists to monitor the performance of the health care practitioners;
• Guiding physicians regarding specific performance expectations;
• Identifying facility or practitioner educational and informational needs;
• Providing information to the facility practitioners from sources such as nationally recognized medical care societies and organizations where current clinical information can be obtained; and
• Helping educate and provide information to staff, practitioners, residents, families and others.

NOTE: This does not imply that the medical director must personally present educational programs.

REFERENCES

INVESTIGATIVE PROTOCOL
MEDICAL DIRECTOR
Objective
• To determine whether the facility has designated a licensed physician to serve as medical director; and
• To determine whether the medical director, in collaboration with the facility, coordinates medical care and the implementation of resident care policies.

Use
Use this protocol for all initial and extended surveys or, as indicated, during any other type of survey. Use this protocol if the survey team has identified:
• That the facility does not have a licensed physician serving as medical director; and/or
• That the facility has designated a licensed physician to serve as medical director; however, concerns or noncompliance identified indicate that:
  o The facility has failed to involve the medical director in his/her roles and functions related to coordination of medical care and/or the implementation of resident care policies; and/or
  o The medical director may not have performed his/her roles and functions related to coordination of medical care and/or the implementation of resident care policies.

Procedures
The investigation involves interviews, review of pertinent policies and procedures, and may involve additional review of resident care.

Provision of a Medical Director
Determine whether the medical director is available during the survey to respond to surveyor questions about resident care policies, medical care, and physician issues.
Interview the facility leadership (e.g., Administrator, Director of Nursing [DON], others as appropriate) about how it has identified and reviewed with the medical director his/her roles and
functions as a medical director, including those related to coordination of medical care and the facility’s clinical practices and care. Interview the medical director about his/her understanding and performance of the medical director roles and functions, and about the extent of facility support for performing his/her roles and functions.

If the survey team has identified that the facility lacks a medical director, collect information from the facility administrator to:

- Determine the duration and possible reasons for this problem; and
- Identify what the facility has been doing to try to retain a medical director.

**Facility/Medical Director Responsibility for Resident Care Policies**

After identifying actual or potential noncompliance with the provision of resident care or medical care:
- Review related policies/procedures;
- Interview facility leadership (e.g., Administrator, DON) to determine how or if they involved the medical director in developing, reviewing, and implementing policies and procedures regarding clinical care of residents (especially where these involve medical and clinical issues; for example, management of causes of delirium, falling, and weight loss) to ensure that they are clinically valid and consistent with current standards of care;
- Interview the medical director regarding his/her input into:
  - Scope of services the facility has chosen to provide;
  - The facility’s capacity to care for its residents with complex or special care needs, such as dialysis, hospice or end-of-life care, respiratory support with ventilators, intravenous medications/fluids, dementia and/or related conditions, or problematic behaviors or complex mood disorders;
  - The following areas of concern:
    - Appropriateness of care as it relates to clinical services (for example, following orders correctly, communicating important information to physicians in a timely fashion, etc.);
    - Processes for accurate assessment, care planning, treatment implementation, and monitoring of care and services to meet resident needs; and
    - The review and update of policies and procedures to reflect current standards of practice for resident care (e.g., pressure ulcer prevention and treatment and management of incontinence, pain, fall risk, restraint reduction, and hydration risks) and quality of life.

**Coordination of Medical Care/Physician Leadership**

If the survey team has identified issues or concerns related to the provision of medical care:
- Interview appropriate facility staff and management as well as the medical director to determine what happens when a physician (or other healthcare practitioner) has a pattern of inadequate or inappropriate performance or acts contrary to established rules and procedures of the facility; for example, repeatedly late in making visits, fails to take time to discuss resident problems with staff, does not adequately address or document key medical issues when making resident visits, etc;
- If concerns are identified for any of the following physician services, determine how the facility obtained the medical director’s input in evaluating and coordinating the provision of medical care:
  - Assuring that provisions are in place for physician services 24 hours a day and in case of emergency (§483.40(b));
○ Assuring that physicians visit residents, provide medical orders, and review a resident’s medical condition as required (§483.40(b)&(c));
○ Assuring that other practitioners who may perform physician delegated tasks, act within the regulatory requirements and within their scope of practice as defined by State law (§483.40(e)&(f));
○ Clarifying that staff know when to contact the medical director; for example, if an attending or covering physician fails to respond to a facility’s request to evaluate or discuss a resident with an acute change of condition;
○ Clarifying how the medical director is expected to respond when informed that the staff is having difficulty obtaining needed consultations or other medical services; or
○ Addressing other concerns between the attending physician and the facility, such as issues identified on medication regimen review, or the problematic use of restraints.

In addition, determine how the facility and medical director assure that physicians are informed of expectations and facility policies, and how the medical director reviews the medical care and provides guidance and feedback regarding practitioner performance, as necessary. Regardless of whether the medical director is the physician member of the quality assurance committee, determine how the facility and medical director exchange information regarding the quality of resident care, medical care, and how the facility disseminates information from the committee to the medical director and attending physicians regarding clinical aspects of care and quality such as infection control, medication and pharmacy issues, incidents and accidents, and other emergency medical issues (§483.75(o)).

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)
Synopsis of Regulation (F501)
This requirement has 3 aspects: Having a physician to serve as medical director, implementing resident care policies, and coordinating medical care. As with all other long term care requirements, the citation of a deficiency at F501, Medical Director, is a deficiency regarding the facility’s failure to comply with this regulation. The facility is responsible for designating a physician to serve as medical director and is responsible for oversight of, and collaboration with, the medical director to implement resident care policies and to coordinate medical care.

Criteria for Compliance
The facility is in compliance if:
• They have designated a medical director who is a licensed physician;
• The physician is performing the functions of the position;
• The medical director provides input and helps the facility develop, review and implement resident care policies, based on current clinical standards; and
• The medical director assists the facility in the coordination of medical care and services in the facility.

If not, cite F501.

Noncompliance for F501
After completing the Investigative Protocol, analyze the data in order to determine whether or not noncompliance with the regulation exists. The survey team must identify whether the noncompliance cited at other tags relates to the medical director’s roles and responsibilities. In order to cite at F501 when noncompliance has been identified at another tag, the team must demonstrate an association between the identified deficiency and a failure of medical direction. Noncompliance for F501 may include (but is not limited to) the facility’s failure to:
• Designate a licensed physician to serve as medical director; or
• Obtain the medical director’s input for timely and ongoing development, review and approval of resident care policies;  
Noncompliance for F501 may also include (but is not limited to) the facility and medical director failure to:
• Coordinate and evaluate the medical care within the facility, including the review and evaluation of aspects of physician care and practitioner services;
• Identify, evaluate, and address health care issues related to the quality of care and quality of life of residents;
• Assure that residents have primary attending and backup physician coverage;
• Assure that physician and health care practitioner services reflect current standards of care and are consistent with regulatory requirements;
• Address and resolve concerns and issues between the physicians, health care practitioners and facility staff;
• Resolve issues related to continuity of care and transfer of medical information between the facility and other care settings;
• Review individual resident cases, as warranted, to evaluate quality of care or quality of life concerns or other problematic situations and take appropriate steps to resolve the situation as necessary and as requested;
• Review, consider and/or act upon consultant recommendations that affect the facility’s resident care policies and procedures or the care of an individual resident, when appropriate;
• Discuss and intervene (as appropriate) with the health care practitioner about medical care that is inconsistent with applicable current standards of care; or
• Assure that a system exists to monitor the performance and practices of the health care practitioners.
This does not presume that a facility’s noncompliance with the requirements for the delivery of care necessarily reflects on the performance of the medical director.

V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)
Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.
The key elements for severity determination for F501 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of resident care policies and/or medical care.
Deficient practices related to actual or potential harm/negative outcome for F501 may include but are not limited to:
• Lack of medical director involvement in the development, review and/or implementation of resident care policies that address the types of residents receiving care and services, such as a resident with end-stage renal disease, pressure ulcers, dementia, or that address practices such as restraint use;
• Lack of medical director involvement in coordinating medical care regarding problems with physician coverage or availability; or
• Lack of medical director response when the facility requests intervention with an attending physician regarding medical care of a resident.

2. Degree of harm (actual or potential) related to the noncompliance.
Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:
• If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and
• If harm has not yet occurred, determine the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.

3. The immediacy of correction required.
Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.
The survey team must evaluate the harm or potential for harm based upon the following levels of severity for F501. First, the team must rule out whether Severity Level 4, Immediate Jeopardy, to a resident’s health or safety exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety
Immediate Jeopardy is a situation in which the facility’s noncompliance with one or more requirements of participation:
• Has allowed/caused/resulted in, or is likely to allow/cause/result in serious injury, harm, impairment, or death to a resident; and
• Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the noncompliance which allowed or caused the immediate jeopardy.
In order to cite immediate jeopardy at this tag, the surveyor must be able to identify the relationship between noncompliance cited as immediate jeopardy at other regulatory tags, and the failure of the medical care and systems associated with the roles and responsibilities of the medical director. In order to select severity level 4 at F501, both of the following must be present:
1. Findings of noncompliance at Severity Level 4 at another tag:
   • Must have allowed, caused or resulted in, or is likely to allow, cause or result in serious injury, harm, impairment or death and require immediate correction. The findings of noncompliance associated with immediate jeopardy are written at tags that also show evidence of process failures with respect to the medical director’s responsibilities; and
2. There is no medical director or the facility failed to involve the medical director in resident care policies or resident care or medical care as appropriate, or the medical director had knowledge of a problem with care, or physician services, or lack of resident care policies and practices that meet current standards of practice and failed:
   • To get involved or to intercede with the attending physician in order to facilitate and/or coordinate medical care; and/or
   • To provide guidance and/or oversight for relevant resident care policies.

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy
Level 3 indicates noncompliance that results in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident’s inability to maintain and/or reach his/her highest practicable well-being.
In order to cite actual harm at this tag, the surveyor must be able to identify a relationship between noncompliance cited at other regulatory tags and failure of medical care or processes and practices associated with roles and responsibilities of the medical director, such as:

1. Findings of noncompliance at Severity Level 3 at another tag must have caused actual harm:
   • The findings of noncompliance associated with actual harm are written at tags that show evidence of process failures with respect to the medical director’s responsibilities; and
2. There is no medical director or the facility failed to involve the medical director in resident care policies or resident care as appropriate or the medical director had knowledge of a problem with care, or physician services, or lack of resident care policies and practices that meet current standards of practice and failed:
   • To get involved or intercede with the attending physician in order to facilitate and/or coordinate medical care (medical care and systems associated with roles and responsibilities of the medical director show evidence of breakdown); or
   • To provide guidance and/or oversight for resident care policies.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with Potential for More than Minimal Harm that is not Immediate Jeopardy
In order to cite no actual harm with potential for more than minimal harm at this tag, the surveyor must be able to identify a relationship between noncompliance cited at other regulatory tags and the failure of medical care, processes and practices associated with roles and responsibilities of the medical director, such as:

1. Findings of noncompliance at Severity Level 2 at another tag:
   • Must have caused no actual harm with potential for more than minimal harm (Level 2). Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided; and
2. There is no medical director or the facility failed to involve the medical director in resident care policies or resident care as appropriate or the medical director had knowledge of an issue with care or physician services, and failed:
   • To get involved with or intercede with attending physicians in order to facilitate and/or coordinate medical care; or
   • To provide guidance and/or oversight for resident care policies.

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm
In order to cite no actual harm with potential for minimal harm at this tag, the survey team must have identified that:

• There is no medical director; and
  o There are no negative resident outcomes that are the result of deficient practice; and
  o Medical care and systems associated with roles and responsibilities of the medical director are in place; and
  o There has been a relatively short duration of time without a medical director; and
  o The facility is actively seeking a new medical director.
§483.75 Administration

§483.75(j) Laboratory services

(1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

Intent: §483.75(j)(1)

The intent of this regulation is to assure that laboratory services are accurate and timely so that the utility of laboratory testing for diagnosis, treatment, prevention or assessment is maximized. The facility is responsible for quality and timely laboratory services whether or not services are provided by the facility or an outside agency.

Interpretive Guidelines: §483.75(j)(1)

A “laboratory service or test” is defined as any examination or analysis of materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings. Services provided must be both accurate and timely. Timely means that laboratory tests are completed and results are provided to the facility (or resident’s physician) within timeframes normal for appropriate intervention. All laboratories providing services for facility residents must meet applicable requirements of 42 CFR Part 493. The purpose of this requirement is to assist in assuring quality of laboratory services.

Procedures: §483.75(j)(1)

Verify that laboratory services are provided to meet the needs of the residents. If a problem in quality of care leads you to suspect a problem in laboratory services, timeliness or quality, refer to the interpretive guidelines for laboratory testing found in Appendix C.

Probes: §483.75(j)(1)

Are problems attributable to:

• An inability to order laboratory tests in a timely manner, including delays in transporting the resident to and from the source of service, if needed?
• A delay of treatment due to untimely receipt of lab results?
• A large lag time between an order for a test and the recording of the results that may have resulted in poor care?

F503

§483.75(j)(1)(i) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

§483.75(j)(1)(ii) If the facility provides blood bank and transfusion services, it must meet the applicable requirements for laboratories specified in Part 493 of this chapter.

§483.75(j)(1)(iii) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

§483.75(j)(1)(iv) If the facility does not provide laboratory services on site, it must have an agreement to obtain these services from a laboratory that meets the applicable requirements of part 493 of this chapter.

Intent: §483.75(j)(1)(i) - (iv)

The intent of this regulation is to assure that laboratory services, blood bank and transfusion services are obtained from an entity that meets the requirements of 42 CFR Part 493 in order to provide a standard of quality for laboratory and transfusion services. If the long term care facility
does not provide laboratory services on site, there must be an agreement to obtain these services from a laboratory that meets the same requirements.

**Interpretive Guidelines: §483.75(j)(1)(i) - (iv)**

If a facility provides its own laboratory services, the provisions of 42 CFR Part 493 apply. The facility must have a Clinical Laboratory Improvement Amendments (CLIA) certificate appropriate for the level of testing performed. An application for a certificate of waiver may be made if the facility performs only those tests categorized as waived under CLIA. Direct questions concerning the application of these requirements to your State laboratory consultant or the CMS RO.

**Procedures: §483.75(j)(1)(i) - (iv)**

Determine if all laboratory services provided for the facility are provided by a laboratory that meets the requirements of 42 CFR Part 493. The surveyor should determine if the facility has an arrangement in writing to assume responsibility for (a) obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility; and (b) the timeliness of the services.

**Probes: §483.75(j)(1)(i) - (iv)**

Are problems attributable to:
- Lack of an arrangement to provide or obtain clinical laboratory services from a source that meets the applicable conditions for coverage of the services?
- Delays in interpreting the results of laboratory tests?

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**F504**

§483.75(j)(2) The facility must—

§483.75(j)(2)(i) Provide or obtain laboratory services only when ordered by the attending physician;

**Intent §483.75(j)(2)(i)**

The intent of this regulation is to assure that only medically necessary laboratory services are ordered.

**Procedures §483.75(j)(2)(i)**

Verify that all laboratory services received were ordered by the attending physician.

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**F505**

§483.75(j)(2)(ii) Promptly notify the attending physician of the findings;

**Intent §483.75(j)(2)(ii)**

The intent of this regulation is to assure that the physician is notified of all lab results so that prompt, appropriate action may be taken if indicated for the resident’s care.

**Procedures §483.75(j)(2)(ii)**

If you have reason to believe that a physician(s) may not have been notified of laboratory results in a timely manner, determine if the facility has a policy/procedure for routine notification of physician and if the procedure is implemented.

**Probes: §483.75(j)(2)(ii)**

• Are any problems identified as relating to lack of prompt notification of the attending physician, contributing to delays in changing the course of treatment or care plan?
§483.75(j)(2)(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance; and

**Intent §483.75(j)(2)(iii)**
The intent of this regulation is to assure that residents are able to get to and receive necessary laboratory testing when the testing is conducted outside of the facility.

**Probes: §483.75(j)(2)(iii)**
- Does the resident ever have to cancel lab service appointments due to difficulties with transportation?

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F507

§483.75(j)(2)(iv) File in the resident’s clinical record laboratory reports that are dated and contain the name and address of the testing laboratory.

**Intent §483.75(j)(2)(iv)**
The intent of this regulation is to assure that the laboratory performing the tests is Medicare approved, and that test results are accurate and are available for clinical management.

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F508

§483.75(k) Radiology and Other Diagnostic Services
(1) The facility must provide or obtain radiology and other diagnostic services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

**Intent §483.75(k)(1)**
The intent of this regulation is to assure that the resident receives quality radiologic and diagnostic services in a timely manner to meet his/her needs for diagnosis, treatment, and prevention.

**Probes: §483.75(k)(1)**
If problems are identified in radiology or other diagnostic services, are problems attributable to:
- An inability to order radiological and diagnostic services in a timely manner, including delays in transporting the resident for these services?
- Delays in interpreting the results of x-rays and other tests?
- Lack of prompt notification, in writing, of test results to the attending physician, contributing to delays in changing care plans or the course of treatment?

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F509

§483.75(k)(1)(i) If the facility provides its own diagnostic services, the services must meet the applicable conditions of participation for hospitals contained in §482.26 of this subchapter.

§483.75(k)(1)(ii) If the facility does not provide its own diagnostic services, it must have an agreement to obtain these services from a provider or supplier that is approved to provide these services under Medicare.

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F510

§483.75(k)(2) The Facility must---
(i) Provide or obtain radiology and other diagnostic services only when ordered by the attending physician;
§483.75(k)(2)(ii) Promptly notify the attending physician of the findings;

§483.75(k)(2)(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance; and

§483.75(k)(2)(iv) File in the resident’s clinical record signed and dated reports of x-ray and other diagnostic services.

§483.75(l) Clinical Records
(1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are--
   (i) Complete;
   (ii) Accurately documented;
   (iii) Readily accessible; and
   (iv) Systematically organized.

Intent §483.75(l)(1)
To assure that the facility maintains accurate, complete and organized clinical information about each resident that is readily accessible for resident care.

Interpretive Guidelines §483.75(l)(1)
A complete clinical record contains an accurate and functional representation of the actual experience of the individual in the facility. It must contain enough information to show that the facility knows the status of the individual, has adequate plans of care, and provides sufficient evidence of the effects of the care provided. Documentation should provide a picture of the resident’s progress, including response to treatment, change in condition, and changes in treatment.

The facility determines how frequently documentation of an individual’s progress takes place apart from the annual comprehensive assessment, periodic reassessments when a significant change in status occurs, and quarterly monitoring assessments. Good practice indicates that for functional and behavioral objectives, the clinical record should document change toward achieving care plan goals. Thus, while there is no “right” frequency or format for “reporting” progress, there is a unique reporting schedule to chart each resident’s progress in maintaining or improving functional abilities and mental and psychosocial status. Be more concerned with whether the staff has sufficient progress information to work with the resident and less with how often that information is gathered.

In cases in which facilities have created the option for an individual’s record to be maintained by computer, rather than hard copy, electronic signatures are acceptable. In cases when such attestation is done on computer records, safeguards to prevent unauthorized access, and reconstruction of information must be in place. The following guideline is an example of how such a system may be set up:
• There is a written policy, at the health care facility, describing the attestation policy(ies) in force at the facility.
• The computer has built-in safeguards to minimize the possibility of fraud.
• Each person responsible for an attestation has an individualized identifier.
• The date and time is recorded from the computer’s internal clock at the time of entry
• An entry is not to be changed after it has been recorded.
• The computer program controls what sections/areas any individual can access or enter data, based on the individual’s personal identifier (and, therefore his/her level of professional qualifications).

Procedures §483.75(l)(1)

In reviewing sampled residents’ clinical records:
• Is there enough record documentation for staff to conduct care programs and to revise the program, as necessary, to respond to the changing status of the resident as a result of interventions?
• How is the clinical record used in managing the resident’s progress in maintaining or improving functional abilities and mental and psychosocial status?

§483.75(l)(5) the clinical record must contain--
(i) Sufficient information to identify the resident;
(ii) A record of the resident’s assessments;
(iii) the plan of care and services provided;
(iv) The results of any preadmission screening conducted by the State; and
(v) progress notes.

F515

§483.75(l)(2) Clinical records must be retained for--
(i) The period of time required by State law; or
(ii) Five years from the date of discharge when there is no requirement in State law; or,
(iii) For a minor, three years after a resident reaches legal age under State law.

F516

§483.20(f)(5)
(5) Resident-identifiable information.
(i) A facility may not release information that is resident-identifiable to the public.
(ii) The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.

Interpretive Guidelines §483.20(f)(5):
Automated RAI data are part of a resident’s clinical record and as such are protected from improper disclosure by facilities under current law. Facilities are required by §§1819(c)(1)(A)(iv) and 1919(c)(1)(A)(iv) of the Act and 42 CFR Part 483.75(l)(3) and (l)(4), to keep confidential all information contained in the resident’s record and to maintain safeguards against the unauthorized use of a resident’s clinical record information, regardless of the storage method of the records.

§483.75(l) (3) The facility must safeguard clinical record information against loss, destruction, or unauthorized use;

Intent §483.75(l)(3)
To maintain the safety and confidentiality of the resident’s record.

Procedures §483.75(l)(3)
Determine through observations and interviews with staff, the policy and implementation of that policy, for maintaining confidentiality of residents’ records.

**Probes: §483.75(1)(3)**
- How does the facility ensure confidentiality of resident records?
- If there is a problem with confidentiality, is it systematic, that is, does the problem lie in the recordkeeping system, or with a staff person’s use of records, e.g., leaving records in a place easily accessible to residents, visitors, or other unauthorized persons?

**Intent: §483.75(l)(3)**
To maintain the safety and confidentiality of the resident’s record.

**Procedures: §483.75(l)(3)**
Determine through observations and interviews with staff, the policy and implementation of that policy, for maintaining confidentiality of residents’ records.

**Probes: §483.75(1)(3)**
- How does the facility ensure confidentiality of resident records?
- If there is a problem with confidentiality, is it systematic, that is, does the problem lie in the recordkeeping system, or with a staff person’s use of records, e.g., leaving records in a place easily accessible to residents, visitors, or other unauthorized persons?

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**§483.75(m) Disaster and Emergency Preparedness**

**F517**
§483.75(m)(1) The facility must have detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing residents.

**F518**
§483.75(m)(2) The facilities must train all employees in emergency procedures when they begin to work in the facility, periodically review the procedures with existing staff, and carry out unannounced staff drills using those procedures.

**Interpretive Guidelines §483.75(m)**
The facility should tailor its disaster plan to its geographic location and the types of residents it serves. “Periodic review” is a judgment made by the facility based on its unique circumstances, changes in physical plant or changes external to the facility can cause a review of the disaster review plan. The purpose of a “staff drill” is to test the efficiency, knowledge, and response of institutional personnel in the event of an emergency. Unannounced staff drills are directed at the responsiveness of staff, and care should be taken not to disturb or excite residents.

**Procedures: §483.75(m)**
Review and disaster and emergency preparedness plan, including plans for natural or man made disasters

**Probes: §483.75(m)**
Ask two staff persons separately (e.g., nurse aide, housekeeper, maintenance person) and the charge nurse:
- If the fire alarm goes off, what do you do?
- If you discover that a resident missing, what do you do?
- What would you do if you discovered a fire in a resident’s room?
• Where are fire alarms and fire extinguisher(s) located on this unit?
• How do you use the fire extinguisher?

**NOTE:** Also, construct probes relevant to a geographically specific natural emergencies (e.g., for areas prone to hurricanes, tornadoes, earthquakes, or floods, each of which may require a different response).

Are the answers to these questions correct (staff answers predict competency in assuring resident safety)?

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**F519**

§483.75(n) Transfer Agreement

(1) In accordance with section 1861(1) of the Act, the facility (other than a nursing facility which is located in a State on an Indian reservation) must have in effect a written transfer agreement with one or more hospitals approved for participation under the Medicare and Medicaid programs that reasonably assures that—

(i) Residents will be transferred from the facility to the hospital, and ensured of timely admission to the hospital when transfer is medically appropriate, as determined by the attending physician; and

(ii) Medical and other information needed for care and treatment of residents, and, when the transferring facility deems it appropriate, for determining whether such residents can be adequately cared for in a less expensive setting than either the facility or the hospital, will be exchanged between the institutions.

(2) The facility is considered to have a transfer agreement in effect if the facility has attempted in good faith to enter into an agreement with a hospital sufficiently close to the facility to make transfer feasible.

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**F520**

483.75(o) Quality Assessment and Assurance

(1) A facility must maintain a quality assessment and assurance committee consisting of—

(i) The director of nursing services;

(ii) A physician designated by the facility; and

(iii) At least 3 other members of the facility’s staff.

(2) The quality assessment and assurance committee—

(i) Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and

(ii) Develops and implements appropriate plans of action to correct identified quality deficiencies.

(3) State or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this section.

(4) Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

**Intent: 483.75(o) Quality Assurance and Assessment**

The intent of this requirement is that:

• The facility has an ongoing quality assessment and assurance (QAA) committee that includes designated key members and that meets at least quarterly; and
• The committee identifies quality deficiencies and develops and implements plans of action to correct these quality deficiencies, including monitoring the effect of implemented changes and making needed revisions to the action plans.

Definitions
Definitions are provided to clarify terms related to the requirement for a quality assessment and assurance committee.

• “Quality Assessment” is an evaluation of a process and/or outcomes of a process to determine if a defined standard of quality is being achieved.
• “Quality Assurance” is the organizational structure, processes, and procedures designed to ensure that care practices are consistently applied and the facility meets or exceeds an expected standard of quality. Quality assurance includes the implementation of principles of continuous quality improvement.
• “Quality Deficiencies” are potential markers of quality that the facility considers to be in need of investigating and which, after investigation, may or may not represent a deviation from quality that results in a potential or actual undesirable outcome. The term “quality deficiency” in this regulation is meant to describe a deficit or an area for improvement. This term is not synonymous with a deficiency cited by surveyors.
• “Quality Improvement (QI)” is an ongoing interdisciplinary process that is designed to improve the delivery of services and resident outcomes.

NOTE: Many facilities have changed their terminology for the QAA processes to “quality improvement (QI).” However, in these guidelines, we will continue to use the designation of QAA, as specified in the requirement. The elements are comparable regardless of the terminology.

Overview
QAA is a management process that is ongoing, multi-level, and facility-wide. It encompasses all managerial, administrative, clinical, and environmental services, as well as the performance of outside (contracted or arranged) providers and suppliers of care and services. Its purpose is continuous evaluation of facility systems with the objectives of:
• Keeping systems functioning satisfactorily and consistently including maintaining current practice standards;
• Preventing deviation from care processes from arising, to the extent possible;
• Discerning issues and concerns, if any, with facility systems and determining if issues/concerns are identified; and
• Correcting inappropriate care processes.

Several studies conducted under the auspices of the U.S. Department of Health and Human Services have examined quality of care and quality of life in nursing homes. These studies have concluded that QAA committees provide an important point of accountability for ensuring both quality of care and quality of life in nursing homes. The QAA committees represent key internal mechanisms that allow nursing homes opportunities to deal with quality deficiencies in a confidential manner.

Resources are available that recommend processes and standards to develop and enhance quality improvement programs. Some Web site resources include:
• American Medical Directors Association (www.amda.com);
• American Health Care Association (www.ahca.org);
• American College of Physicians Quality Indicators for Assessing Care of Vulnerable Elders (www.acponline.org/sci-policy/acove/);
• American Geriatric Society (www.americangeriatrics.org);
• Agency for Healthcare Research and Quality (www.ahrq.gov);
• Medicare Quality Improvement Community (www.Medqic.org);
• American Association of Homes and Services for the Aging (www.aahsa.org); and
• The American Health Quality Association (www.ahqa.org).

NOTE: References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. The URL addresses were current as of the date of this publication.

The guidance below includes sections that describe facility responsibilities to meet the various aspects of the QAA requirement, including:
• The composition of the QAA committee and the minimum frequency of committee meetings;
• The committee’s monitoring of systems and identification of concerns with the quality of facility systems; and
• Modification and correction of facility systems, when needed, including monitoring the effect of action plans.

QAA COMMITTEE FUNCTIONS

Key aspects of the QAA requirements include the specifications that the facility must have a QAA committee, that this committee must include certain staff members, and that the committee must meet at least quarterly. The QAA committee is responsible for identifying whether quality deficiencies are present (potential or actual deviations from appropriate care processes or facility procedures) that require action. If there are quality deficiencies, the committee is responsible for developing plans of action to correct them and for monitoring the effect of these corrections. These functions of the QAA committee are described below.

Committee Composition and Frequency of Meetings

The regulation states that the QAA committee must include the director of nursing, a physician, and three other staff. These additional members may include:
• The administrator (facilities with effective QAA committees include members who have knowledge of facility systems and the authority to change those systems, including the administrator or assistant administrator due to their responsibility to manage the facility, and make changes to facility systems);
• The medical director (part of the medical director’s responsibility (see F501)) is to guide the facility’s development and implementation of resident care policies and coordination of medical care. If the medical director is not a committee member, exchange of information with the medical director enhances the functioning of the QAA committee);
• Staff with responsibility for direct resident care and services, such as nursing aides, therapists, staff nurses, social workers, activities staff members; and
• Staff with responsibility for the physical plant, such as maintenance, housekeeping, and laundry staff.

NOTE: Facilities may have a larger committee than required by the regulation. Consideration should be given as to how committee information is provided to consultants who may not be members of the committee, but whose responsibilities include oversight of departments or services.

Meetings of the QAA committee must be held at least quarterly or more often as the facility deems necessary to fulfill committee functions and operate effectively. The Committee should
maintain a record of the dates of all meetings and the names/titles of those attending each meeting.

Identification of Quality Deficiencies

Facilities can collect and analyze data about their performance from various sources that may help them to identify quality deficiencies. These may include information from reports such as open and closed record audits, facility logs and tracking forms, incident reports, consultants’ reports, and other reports as part of the QAA function. Quality deficiencies related to facility operations and practices are not only related to those that cause negative outcomes, but also may be directed toward enhancing quality of care and quality of life for residents. The committee responds to quality deficiencies and serves a preventative function by reviewing and improving systems.

Records of the committee meetings identifying quality deficiencies, by statute, may not be reviewed by surveyors unless the facility chooses to provide them. However, the documents the committee used to determine quality deficiencies are subject to review by the surveyors.

NOTE: A State or the Secretary may not require disclosure of the records of the QAA committee except insofar as such disclosure is related to the compliance of the QAA committee with the regulations.

If concerns, especially repeat survey deficiencies, have not been identified by the facility’s QAA committee, this may be an indication that the committee is not performing the functions required by this regulation.

Development of Action Plans

In order to fulfill the regulatory mandate, the facility’s QAA committee, having identified the root causes which led to their confirmed quality deficiencies, must develop appropriate corrective plans of action. Action plans may include, but are not limited to, the development or revision of clinical protocols based on current standards of practice, revision of policies and procedures, training for staff concerning changes, plans to purchase or repair equipment and/or improve the physical plant, and standards for evaluating staff performance.

Implementation of Action Plans and Correction of Identified Quality Deficiencies

The facility’s action plans to address quality deficiencies may be implemented in a variety of ways, including: staff training and deployment of changes to procedures; monitoring and feedback mechanisms; and processes to revise plans that are not achieving or sustaining desired outcomes. The committee may delegate the implementation of action plans to various facility staff and/or outside consultants.

ENDNOTES


INVESTIGATIVE PROTOCOL

QUALITY ASSESSMENT AND ASSURANCE

Objectives

• To determine if the facility has a QAA committee consisting of the director of nursing, a physician designated by the facility, and at least three other staff members; and

• To determine if the QAA committee:
  o Meets at least quarterly (or more often, as necessary);
  o Identifies quality deficiencies; and
Develops and implements appropriate plans of action to address identified quality deficiencies.

**Use**

Use this protocol for all initial and standard surveys. Also, use it as necessary on revisits and abbreviated standard surveys (complaint investigations).

**Procedures**

During Offsite Survey Preparation (see Appendix P, Task 1), the survey team must review information about the facility prior to the survey. Sources include, at a minimum:

- Quality Measure/Quality Indicator Reports;
- The OSCAR 3 Report (includes a 4-year history of the facility’s deficiencies from standard surveys, revisits, and complaint surveys). The survey team should determine if the facility has had repeat deficiencies as well as recent serious deficiencies (Levels F and H and above); and
- Information from the State ombudsman.

The regulation states that good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions. The facility is not required to release the records of the QAA committee to the surveyors to review, and the facility is not required to disclose records of the QAA committee beyond those that demonstrate compliance with the regulation (F520). However the facility may choose such disclosure if it is the facility’s only means of showing the composition and functioning of the QAA committee. If the facility has provided the records for surveyor review, this information may not be used to cite deficiencies unrelated to the QAA committee requirement. It is recommended that surveyors not review QAA records (if provided) until after they complete their investigations of other tags.

If the survey team’s review of the QAA committee records reveals that the committee is making good faith efforts to identify quality deficiencies and to develop action plans to correct quality deficiencies, this requirement (F520) should not be cited. However, if the survey team had already independently (not through use of the records) identified noncompliance in the same areas as those that have been selected by the QAA committee, the team is expected to cite the noncompliance for the other requirements.

Throughout the survey, the survey team may become aware of other concerns regarding the delivery of care and services that may reflect that the QAA committee is not functioning in identifying ongoing and current quality deficiencies.

During the daily meetings, the team discusses concerns about facility compliance that they are identifying through observations, interviews, and record reviews. The information from the entrance conference about the composition and meetings of the QAA committee is reviewed and relayed to the team.

The team coordinator assigns a surveyor to obtain information from the person the facility has designated as responsible for the QAA committee. The surveyor should interview this designated person to determine:

- How the committee identifies current and ongoing issues for committee action. This could include how they monitor the provision of care and services on an ongoing basis, and how they ascertain from residents and/or their families information regarding the facility’s provision of care and services, in addition to facility staff throughout the various departments, and outside consultants and/or suppliers and providers of care;
- The methods the committee uses to develop action plans; and
- How current action plans are being implemented, including: staff training; deployment of changes to procedures; monitoring and feedback mechanisms that have been established; and, for
any plans that are not achieving or sustaining desired outcomes to correct the deficiencies, the process underway for revision to these plans.
The assigned surveyor should interview staff in various departments to determine if they know how to bring an issue to the attention of the QAA committee.
If, during the course of the survey, the survey team identifies noncompliance at a particular requirement, the assigned surveyor should interview the designated person responsible for the QAA committee to determine whether the committee knew of or should have known of the issues related to the noncompliance. The assigned surveyor should determine if the committee had considered the quality deficiency and if it was determined that an action plan was needed. If so, the surveyor determines whether the committee developed and implemented any action plans to address these concerns. The survey team should verify that the action plans that are described are actually implemented, and that staff are providing care and services according to the directives of these action plans.

**DETERMINATION OF COMPLIANCE (Task 6, Appendix P)**

**NOTE:** Although the literature of QAA and QI provides various definitions of the facility’s achievement of quality, surveyors will need to determine the facility’s compliance based on the language of this regulation.

**Synopsis of Regulation (F520)**

This requirement has two aspects: the facility must have a committee composed of certain key members that meets at least quarterly (or more often, as necessary); and the committee functions to develop and implement appropriate plans of actions to correct identified quality deficiencies.

**Criteria for Compliance**
The facility is in compliance if:
- It has a functioning QAA committee, consisting of the director of nursing, a physician, and at least three other staff members, that meets at least quarterly; and
- The committee:
  - Identifies quality deficiencies; and
  - **Develops and implements appropriate plans of actions.**

If not, cite F520.

**Noncompliance for F520**
After completing the investigative protocol, the survey team determines whether or not compliance with the regulation exists. Examples of noncompliance may include, but are not limited to, the following:
- Lack of a physician member of the committee;
- The committee met only twice during the previous year;
- The action plan to correct a quality deficiency regarding food temperatures was not being followed by staff in the dietary department, and food was not being served at proper temperatures; or
- An action plan was developed to correct a problem with inadequate assessment of root causes of falls. Staff did not implement the plan, and residents continued to experience serious falls.
- An action plan that was developed to correct the issue of resident falls did not take account of the root cause of the falls being overuse of sedative type medications. The plan was to increase the use of restraints which was an inappropriate action plan.

**DEFICIENCY CATEGORIZATION (Part V, Appendix P)**
Once the survey team has determined that noncompliance exists, the team will select the appropriate level of severity for the deficiency using the guidance below.
The survey team must identify a relationship between noncompliance at other regulatory requirements and the facility’s failure to have a functional QAA committee. The key elements for severity determination for F520 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of a failure of the QAA committee structure or function

   Actual or potential harm/negative outcome for F520 may include, but is not limited to:
   • Failure of the QAA committee to identify and implement an action plan to reduce the number of medication errors committed by agency staff, resulting in the noncompliance for medication errors based on the resident receiving the wrong medication, which resulted in the resident experiencing insulin shock; or
   • Failure of the QAA committee to develop an action plan to address assessment of the cause of a pattern of recent falls of several residents, resulting in noncompliance at the accident requirement based on several residents sustaining avoidable falls with bruises but no fractures.

2. Degree of harm (actual or potential) related to the noncompliance

Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:
• If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and
• If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.

3. The immediacy of correction required

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for Tag F520. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident’s health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility’s noncompliance with one or more requirements of participation:
• Has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident; and
• Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventive or corrective measures.

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the noncompliance which allowed or caused the immediate jeopardy.

In order to select Severity Level 4 for this regulation, the surveyor must be able to identify the relationship between the facility’s noncompliance cited at Severity Level 4 at other regulatory tags, and the failure of the QAA Committee to function effectively. In order to select Severity Level 4 at F520, both of the following must be present:
• Deficiency(ies) has been cited at Severity Level 4 in other tags that are related to QAA committee failure; and
• The facility does not have a QAA committee, or the facility’s QAA committee failed to develop and implement appropriate plans of action to correct identified quality deficiencies.

Severity Level 3: Actual Harm that is Not Immediate Jeopardy
In order to select Severity Level 3 for this regulation, the surveyor must be able to identify the relationship between the facility’s noncompliance cited at Severity Level 3 at other regulatory tags, and the failure of the QAA Committee to function effectively. In order to select Severity Level 3 at F520, both of the following must be present:

• Deficiency(ies) has been cited at Severity Level 3 in other tags that are related to QAA committee failure; and

• The facility does not have a QAA committee, or the facility’s QAA committee failed to develop and implement appropriate plans of action to correct identified quality deficiencies.

Severity Level 2: No Actual Harm with Potential for More than Minimal Harm that is Not Immediate Jeopardy

In order to select Severity Level 2 for this regulation, the surveyor must be able to identify the relationship between the facility’s noncompliance cited at Severity Level 2 at other regulatory tags, and the failure of the QAA Committee to function effectively. In order to select Severity Level 2 at F520, both of the following must be present:

• Deficiency(ies) has been cited at Severity Level 2 in other tags that are related to QAA committee failure; and

• The facility does not have a QAA committee, or the facility’s QAA committee failed to develop and implement appropriate plans of action to correct identified quality deficiencies.

Severity Level 1: No Actual Harm with Potential for Minimal Harm

Severity Level 1 should be selected if any of the following circumstances are present:

• The facility does not have a QAA committee, and there have been no other deficiencies cited above Severity Level 1; or

• The facility’s QAA committee meets regulatory specifications for the composition of the committee and/or the frequency of committee meetings, and there have been no deficiencies cited above Severity Level 1; or

• The facility’s QAA committee meets regulatory specifications for committee membership and frequency of meetings, and deficiencies have been cited at Severity Level 1 in other tags. In order to select Severity Level 1 in this case, the surveyor must be able to identify the relationship between the facility’s noncompliance cited at Severity Level 1 at other tags, and the failure of the QAA committee to function effectively.

F522

§483.75(p) Disclosure of Ownership

(1) The facility must comply with the disclosure requirements of §§420.206 and 455.104 of this chapter.

(2) The facility must provide written notice to the State agency responsible for licensing the facility at the time of change, if a change occurs in--

(i) Persons with an ownership or control interest, as defined in §§420.201 and 455.101 of this chapter;

(ii) The officers, directors, agents, or managing employees;

(iii) The corporation, association, or other company responsible for the management of the facility; or

(iv) The facility’s administrator or director of nursing.

(3) The notice specified in the paragraph (p)(2) of this section must include the identity of each new individual or company.

§483.75(q) Required Training of Feeding Assistants
A facility must not use any individual working in the facility as a paid feeding assistant unless that individual has successfully completed a State-approved training program for feeding assistants, as specified in §483.160 of this part.

Guidelines: §483.75(q)

Note: Refer to F373

**Transmittals Issued for this Appendix**

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04/10/2009
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Revisions to Appendix PP - Interpretive Guidelines for Long-Term Care Facilities, Tags F325 and F371
09/01/2008
N/A R26SOM
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Revised Appendix P and Appendix PP-New Tag F373
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N/A R19SOM
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N/A R07SOM
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Revision of Appendix PP-Section 483.25(d)-Urinary Incontinence, Tags F315 and F316 – Replaced by Transmittal 8
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N/A R05SOM

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Revisions to Appendix P and Appendix PP
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Guidance to Surveyors for Long Term Care Facilities
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