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SUBJECT: Medical Director Guidance

NOTE: *Transmittal 14, dated November 25, 2005 is rescinded and replaced with Transmittal 15, dated November 28, 2005. An error was made in the numbering of the 42 CFR 483.75(i) citation. All other information remains the same.*

I. SUMMARY OF CHANGES: Appendix PP, Tag F501, Medical Director – Guidance to Surveyors is entirely replaced with this revision

NEW/REVISED MATERIAL - EFFECTIVE DATE*: November 25, 2005

IMPLEMENTATION DATE: November 25, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

**II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)**

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix PP/F501/Medical Director

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

	Business Requirements
x	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

(Rev. 15, Issued: 11-28-05; Effective/Implementation: 11-25-05)

§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:
 - Affect resident care, medical care or quality of life; or
 - 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.”²

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"³ 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, dietitians, 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.”⁴

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

- ¹ Pattee JJ, Otteson OJ. (1991). Medical direction in the nursing home (p.5). Minneapolis, MN: Northridge Press.
- ² Institute of Medicine (2001). Improving The Quality Of Long-Term Care (pp. 201). Washington, DC: National Academy Press.
- ³ Levenson, S. A. (1993). Medical Direction In Long-Term Care. A Guidebook For The Future (2nd ed., pp. 135). Durham, NC: Carolina Academic Press.
- ⁴ Levenson, SA. Medical Director and Attending Physicians Policy and Procedure Manual for Long-term Care. Dayton, Ohio: MedPass. 2005.

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