



Center for Medicaid and State Operations/Survey and Certification Group

Dear Colleague:

I am pleased to send you a draft for comment of our guidance to surveyors of long term care facilities for two key requirements: Medical Director (F501) and Quality Assurance (F520 and F521). This product was developed as part of our contract with the American Institutes for Research. Our goals are to update the guidance to surveyors (popularly known as the interpretive guidelines) and to provide specific information to assist surveyors in making appropriate determinations of severity for deficiencies cited under these tags. These drafts were developed with the assistance of panels of expert clinicians and surveyors. Attachment A provides biographical information about the members of these panels.

We are providing a two-month comment period for review of the attached draft materials at Attachments B and C. We intend the guidance contained in Attachment B will replace all current text contained in the guidance to surveyors for F501 and F520-21. In addition, we have made changes to Appendix P, the Survey Protocol, to make it conform to the changes made to the guidance to surveyors for F520 and F521.

Note: In order to assist in your review of the draft severity guidance, at Attachment C we have included a copy of the current scope and severity grid from the enforcement regulation that includes the letters for each grid box and the definitions of each severity level.

Please provide comment on these materials to the contractor **by April 26, 2004**. You may reply via regular mail addressed to:

Nancy Matheson, Ph.D.
Project Director
American Institutes for Research
1000 Thomas Jefferson Street, NW
Washington, DC 20007

You may also reply via email to nmatheson@air.org. Please organize your comments by Tag and page number so that we may compare your comment to the text to which you are referring. If you have any questions about this mailout, please contact Ms. Matheson at 202-403-5050.

We look forward to your comments on this mailout as well as future mailouts of revisions to other Tags, as we proceed with this project to improve our guidance to surveyors.

Sincerely,

/s/

Thomas E. Hamilton
Director

Attachments

TIPS FOR REVIEWERS

This mail-out package includes the following materials for your review:

- Medical Director
 - Guidance to Surveyors
 - Investigative Protocol
 - Task 6: Determination of Compliance
 - V. Deficiency Categorization (i.e., Severity Guidance).

Note: V. Deficiency Categorization is considered part of Appendix P., Part V of the same title, but it will be stored in Appendix PP of the State Operations Manual (SOM) along with its tag.

- Quality Assurance and Assistance (QA&A)
 - Changes to Appendix P, the Survey Protocol, (to accompany changes to associated guidance to surveyors)
 - Guidance to Surveyors
 - Investigative Protocol
 - Task 6: Determination of Compliance
 - V. Deficiency Categorization (i.e., Severity Guidance)

Note: V. Deficiency Categorization is considered part of Appendix P., Part V of the same title, but it will be stored in Appendix PP of the State Operations Manual (SOM) along with its tag.

- Updated Severity Grid for Rating Nursing Home Deficiencies (This is a survey tool that lists the letter for each box of the grid and includes definitions of severity levels)

Tips for Commenting

When providing comments to the materials included in this mail out package, please follow the referencing guidelines below. This will aid in our ability to sort comments by section, paragraph, and sentence.

For each comment, please reference the following information, whenever possible:

- **Tag/Document** (i.e., Medical Director or F501; Quality Assurance or F520; or Updated Severity Grid)
- **Section within Document** (i.e., Guidance to Surveyors; Investigative Protocol; Task 6; Deficiency Categorization; or Appendix P—Survey Protocol)
- **Page Number**

When relevant, please also reference sub-heading within section, paragraph, and/or sentence to which the comment applies.

ATTACHMENT A

MEDICAL DIRECTOR (TAG F501) EXPERT PANEL MEMBERS

- **Juergen Bludau, MD**, is currently the Medical Director of the Joseph L. Morse Geriatric Center, Inc. in West Palm Beach, FL. Dr. Bludau is board-certified in geriatric medicine and is an American Medical Directors Association (AMDA) Certified Medical Director. He has taught at Harvard Medical School and is a member of the Harvard Division of Aging.
- **Colleen Cooper, MD, MPH**, has served as a Medical Advisor for the Facility and Provider Compliance Division of the Minnesota Department of Health (MDH) since 1994. In this capacity, Dr. Cooper consults with surveyors, investigators, case mix reviewers, and providers; provides education to MDH staff and providers; and participates in policy development on the state and national level. She is a Board Certified Internist and recently received her Masters of Public Health from the Johns Hopkins School of Public Health. She is also a physician at the Boynton Health Service of the University of Minnesota.
- **Janet Justice, ADN**, is an Executive Administrator of the Richmond Health and Rehabilitation Complex, which consists of multi-level personal care and nursing facilities. Ms. Justice also serves as a Corporate Consultant for a variety of projects including facilities' survey deficiency analysis and policy and procedure development. She is an active member of numerous professional associations including the Kentucky Association of Homes and Services for the Aging.
- **Eve Lewis, RN-C, BAH**, is Program Manager of Long Term Care Facilities with the Nebraska Health and Human Services System. Ms. Lewis is active in numerous professional organizations. She is a Chapter Formation Committee Member of the National Geriatric Nurses Association (NGNA) as well as a past president of the NGNA and the Long Term Care Resource Consortium.
- **Jonathan Musher, MD, CMD**, is currently Corporate Medical Director for Beverly Health Care. Dr. Musher is actively involved in family medicine and geriatrics, and his expertise spans the spectrum of acute care and long term care services. He has published and lectured extensively in the areas of geriatrics, long term care, and medical direction. Dr. Musher is a Past President of AMDA, Incoming Chair of the AMDA Foundation, and is also their liaison to Congress.
- **David Polakoff, MD, MSc, CMD**, is the Chief Medical Officer of Mariner Health Care. Dr. Polakoff is a certified medical director, and has held faculty appointments at Harvard Medical School and the Harvard Geriatric Education Center. Dr. Polakoff serves as Chairman of the Board of the AMDA Foundation, and is the principal investigator of the Foundation's Agency for Healthcare Research and Quality funded Partners in Quality program to assess the feasibility of implementing clinical practice guidelines in nursing facilities. In addition, he has conducted geriatric research in acute care hospitals in the Boston area.

- ***Steve Shields, BS***, is the Executive Director of Meadowlark Hills Retirement Community. He was the charter chair of the Manhattan Kansas Community Health Council, which has evolved as a federally funded national model of community collaboration and planning. Mr. Shields serves on multiple medical boards including the board of Kansas State University's Center on Aging where he is also a faculty member. He is also a Kansas Delegate to the American Association of Homes and Services for the Aging and is an early member of the Pioneer Network, an organization committed to long-term care reformation.

QUALITY ASSESSMENT AND ASSURANCE (TAG F520/521) EXPERT PANEL MEMBERS

- **Betty Andrade-Haynes, BSN, MSN**, currently serves as Nurse Consultant for CMS. She provides training, education, and guidance for surveyors on the Quality Assurance (QA) survey process in long term care. Ms. Andrade-Haynes has also held the position of Pediatric Coordinator for Carswell Air Force Base, Robert L. Thompson Regional Hospital in Fort Worth, Texas, where she served as the QA/QI Coordinator. She has over 20 years of experience in her field.
- **Jeanne Caldwell, RN**, is currently a Surveyor with the New Jersey State Department of Health and Senior Services. She previously served over 15 years as a Complaint Investigator with New Jersey State, where she was awarded the 1999 New Jersey State Surveyor of the Year. Ms. Caldwell is also an active participant in the training of new complaint investigators.
- **Tom Clark, RPh, MHS**, is the Director of Policy and Advocacy with the American Society of Consultant Pharmacists and has over 25 years of experience in the pharmacy field. Mr. Clark has made numerous presentations at state and national meetings of pharmacists, health professionals, and consumers. In addition, he is currently serving as an expert on several panels that focus on quality of care in nursing homes and long-term care facilities.
- **David Gifford, MD, MPH**, currently serves as the Chief Medical Officer for the Rhode Island Quality Partners, where he directs the hospital and nursing home-based quality improvement projects. Dr. Gifford is also the chair of the Quality Improvement Committee at Rhode Island Hospital. He serves as the medical director of a 120-bed nursing home, as well as a medical director for CareLink. Dr. Gifford is an Assistant Professor of Medicine and Community Health and a member of the Center for Gerontology and Health Services Research at Brown University.
- **Beth Irtz, RN, NHA**, is the Nursing Home Administrator of Mariner Health of Denver in Denver, Colorado. Ms. Irtz has a total of over 25 years of experience in the field of long term care. She has served as the Vice President of Patient Care Services for Horizon Healthcare Corporation. Ms. Irtz has consulted in over 250 long term care facilities in 20 states.
- **Kristin Kozelek, BS**, is a Health Services Specialist/Long Term Care Surveyor for the Wisconsin Department of Health and Family Services, where she has worked for the past five years. Ms. Kozelek has worked in long term care since 1991, including five years as the Director of Social Services and Admissions Coordinator at Mary Jude Nursing Home in West Allis, Wisconsin.

- **Janet Myder, MPA**, currently serves as the Director of Regulatory Systems for the American Health Care Association (AHCA). Ms. Myder manages AHCA's regulatory analysis and related policy development in the areas of long term care facilities' participation in Medicare and Medicaid, life safety and survey, certification, and enforcement. She began her professional career in physical therapy, and she served four years as the administrator of the physical medicine department of a 300-bed community hospital.
- **Dan Osterweil, MD, CMD**, is a Clinical Professor of Medicine and the Co-Director of the Multi-Campus Program in Geriatrics and Gerontology at University of California, Los Angeles (UCLA). In addition, Dr. Osterweil is the Director of a UCLA training program in medical management and an Associate Researcher at the Borun Center for Gerontological Research at UCLA. He has co-authored two editions of *Medical Care in the Nursing Home* and a book on *Comprehensive Geriatric Assessment*. Dr. Osterweil is also the Editor-in-Chief of the *Journal of the American Medical Directors Association* and a member of the *Caring for the Ages* editorial board.
- **Noel Petitjean, RN, BSN**, currently serves as the Director of Nursing and Quality Improvement at Providence Mount St. Vincent, a skilled nursing center and assisted living community in Seattle, Washington. Ms. Petitjean has a history of service in quality assurance/quality improvement positions within the Providence nursing system. She has over 30 years of experience in her field.

ATTACHMENT B

INTENT: (F501) 483.75(i) Medical Director

The intent of this requirement is that:

- The facility has a licensed medical director who provides clinical guidance and oversight regarding the current standards of practice for quality resident care and quality of resident life.
- The medical director collaborates with the facility leadership, staff, and other practitioners and consultants to develop, implement and periodically evaluate policies and procedures for resident care to assure that resident care and quality of life reflect current standards of practice.
- The medical director, in collaboration with the facility, monitors the provision of resident care.
- The medical director is a liaison between the facility and other practitioners to address/resolve resident care concerns and issues.

DEFINITIONS

Credentialing – Credentialing refers to the facility’s established process (collecting, reviewing, and verifying information such as training, licensure and certification) for ascertaining the professional qualifications of practitioners allowed/invited to provide care for the residents.

Note: Credentialing does not imply a formal program such as that required by various accrediting organizations.

Current standards of practice – Current standards of practice refer to approaches to care, procedures, techniques, treatments, etc., that are validated and accepted, adopted or promulgated by recognized professional organizations, State licensing authorities, national accrediting bodies, current manuals or textbooks, or publications including current clinical guidelines of recognized organizations.

Medical care – Medical care refers to services provided by a licensed physician, nurse practitioner, physician assistant, or clinical nurse specialist, to address and treat the resident’s physical and mental diseases, problems and conditions that affect the physical, psychosocial and functional well-being of residents.

Medical director - Medical director refers to the physician whom the facility retains to be responsible for the coordination and oversight of the medical care in the facility, and who is licensed under state law to practice medicine and has the skills, knowledge, and experience to fulfill the role and exercise relevant responsibilities.

Resident care policies and procedures - Resident care policies are those policies that provide direction for the delivery of care and services to residents. This means the development of policies concerning assessment, care planning, and the implementation and monitoring of care and services to residents as provided by any of the following: facility staff, licensed physicians, nurse practitioners, physician assistants, clinical nurse specialists, licensed health care professionals such as therapists, dietitians, pharmacists, social workers, and other health care workers. The resident care procedures should describe the means by which the facility provides care to residents in accord with current standards of practice and facility policies.

OVERVIEW

Each facility is required to have a medical director who is responsible for the implementation of resident care policies and the coordination of medical care. The medical director has an important leadership role in actively helping long term care facilities provide quality care consistent with current standards of practice and resident choices. In order to meet this challenge, the medical director should have knowledge, training and/or experience in the medical care of residents in the long-term care continuum and the management and oversight of care processes and practitioner performance.

The long-term care continuum has undergone fundamental changes in demographics, case mix, and care settings. Within that continuum much of the population has become increasingly frail and medically complex, requiring a greater degree and intensity of medical care. Others in the population have increasingly complex needs for psychosocial and mental health support in addition to basic medical care.

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.”¹

The text *Medical Direction in Long Term-Care*,² asserts that, the medical director is in a position to provide input to surveyors on physician issues, individual resident’s clinical issues, and facility clinical practices:

"The Medical Director has an important role in helping the facility deal with regulatory and survey issues. Before the survey, 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

¹ Institute of Medicine (2001). *Improving the quality of long-term care* (pp. 201). Washington, DC: National Academy Press.

² Levenson, S. A. (1993). *Medical direction in long-term care. A guidebook for the future* (2nd ed., pp. 135). Durham, NC: Carolina Academic Press.

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."

CMS' Sharing Innovations in Quality website (www.cms.hhs.gov/medicaid/survey-cert/siqhome.asp) contains additional information about nationally accepted standards for the provision of services of medical director. Also, see the American Medical Directors Association website (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, as medical director, a physician who is currently licensed in the state(s) in which he/she practices. 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 effectively implement resident care policies and coordinate medical care.

The facility should be able to identify how they have obtained the medical director's input, review and approval of policies and procedures; how the medical director has provided oversight for the quality of care, resident rights and quality of life, and overall implementation of the resident care policies; and how the medical director has exercised responsibility for the coordination of medical care. The facility should be able to demonstrate how they are updating and maintaining current policies and procedures to reflect accepted standards of practice.

Much of the medical director's role includes involvement in developing and approving resident care policies and procedures, monitoring the implementation of the policies in the provision of care, coordinating the medical care, and providing authoritative clinical guidance.

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 has a key role in incorporating current standards of practice into policy development.

The medical director should provide input into, and review and approve, the policies and procedures to ensure that they address the needs of the residents within the facility and are appropriate for the care being provided. Regulations do not require the medical director to sign the policies or procedures. Additionally, the regulatory intent concerning this responsibility is much broader than merely signing them.

Pertinent resident care policies include, but are not limited to:

- The delivery of medical and nursing care, including assessment, care planning, preventive care, and discharge planning;
- The facility's capacity to provide care for the types of residents who are admitted; for example, short-term stay residents, end-stage renal disease (ESRD) patients, individuals needing hospice care;
- The provision of rehabilitation therapies, dietary services, and social services;
- The provision of pharmacy services, including the ordering, acquisition, storage, and administration of medications, medication regimen review, and the assurance of clinical indications for the use of medications;
- The provision of physician services and physician coverage, including emergency care;
- The use and availability of ancillary services such as x-ray and laboratory;
- The minimum qualifications of staff (including qualifications of and orientation for temporary or registry staff);
- Resident formulation and facility implementation of advance directives (in accordance with state law);
- Provisions that enhance resident choice in the area of medical care;
- Mechanisms for ongoing communication to resolve issues related to medical care;
- The requirement that the physician reviews the resident's care and overall condition at each visit and documents findings;
- The provision of visits and orders as required;
- The provision for physician services 24 hours a day, in case of emergency;

- Systems to ensure that 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 the practitioner, including information that should be gathered prior to contacting physicians regarding a clinical issue/question or change in condition.

Facility policies for physician services should include how attending physicians are given the facility's rules and requirements regarding physician conduct and practice and how physicians are involved in the ongoing review and evaluation of the facility's clinical practices.

Monitoring the Provision of Resident Care

The responsibilities related to developing, implementing and monitoring resident care policies and overseeing the provision of medical care also include assuring that each resident receives care and services pertinent to attaining or maintaining the highest practicable physical, mental, and psychosocial well-being.

Approaches to monitoring the delivery of medical care may include identifying and acting upon issues raised during the medication regimen review; review of safety trends and the facility's response to incidents, accidents, or other safety issues (such as medical errors and medication errors); review of resident or family complaints; or other approaches.

The medical director should be involved (e.g., through direct participation in the quality assessment and assurance committee and through review and input into the facility's quality assurance activities) in coordinating and monitoring the provision of medical care including, but not limited to: the provision of pharmacy services and medication use; infection control practices and patterns of infections; and appropriate use of restraints, including restraint reduction efforts. The medical director should also be involved in developing and implementing systems to monitor practitioners' services; for example, those of physicians, nurse practitioners, physician assistants, podiatrists, and dentists.

Coordination of Medical Care/Liaison

The medical director should function as the liaison between attending physicians and facility staff to address areas of concern identified by either party. The medical director may need to review an individual resident's case, review consultant recommendations (e.g., medication regimen review, psychiatric consults, wound care consults), discuss concerns with attending physicians, and/or provide independent consultation and direction to the facility to assure that the resident care is consistent with applicable standards of practice. The medical director also helps assure that the facility meets regulatory requirements for frequency and oversight of resident care and that each resident receives care that is relevant to attaining her/his highest practical level of functioning. He/she may also need to communicate to facility

management practitioner concerns regarding the facility staff's care; for example, adequacy of assessments or consistency in following medical orders.

To help assure continuity of care, the medical director may need to help resolve issues concerning other facilities they receive residents from, or send residents to, for example, getting accurate, timely, and complete information about new admissions from referral sources.

Since using medical information effectively is important to continuity and quality of care, the medical director may need to help the facility develop approaches to communicate medical information among staff, physicians, patients, and families. The medical director may also function as a liaison between the professional and lay community and other health care organizations (e.g., Quality Improvement Organizations) with regard to clinical and patient care issues.

Medical director involvement is important for developing a process to review credentials of physicians and other health-care practitioners; for developing a framework and process for monitoring practitioner performance including physicians, nurse practitioners, physician assistants, and other health care practitioners; and for providing feedback and intervening, when necessary.

The facility may wish to designate the medical director as the key contact for discussing issues related to overall medical/practitioner provision of service or resident outcomes that arise during reviews by external agencies, such as certification surveys, accreditation surveys, and Quality Improvement Organization activities.

Clinical Guidance

As a clinician, the medical director plays a pivotal role in providing clinical leadership regarding current or revised standards of practice for resident care and new or proposed treatments, practices, and approaches to care. Medical director input, including monitoring, providing feedback and intervening when necessary, is vital to administrative decision-making about developing and incorporating care approaches and practices into facility policies and procedures.

The medical director may identify issues related to the provision of medical care and services or the implementation of resident care policies. In conjunction with facility management, the medical director should evaluate and act upon concerns regarding the adequacy of medical care, appropriate physician performance or conduct, issues related to medication use, or provision of physician services. In order to assure that corrections have been made and maintained, the medical director, through quality assessment and assurance committee meetings or other means, may:

- Identify facility or practitioner educational and informational needs;

- Provide information to the facility practitioners from sources such as nationally recognized medical care societies and organizations where current clinical information can be obtained; and
- Help educate and provide information to staff, practitioners, patients, families and others, as indicated.

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

SURVEY PROCESS

During the survey process, the surveyor should attempt to communicate with the medical director about concerns related to: admission of residents whose care needs cannot be readily met by the facility; access to or provision of physician or consultant services; identification, assessment, or provision of services to meet resident needs; effective staff deployment to provide required care; capabilities and credentials of staff or other providers/contractors; facility's success in honoring resident rights and enhancing personal dignity; implementing and maintaining current standards of practice for resident care and quality of life; and effectiveness of the various committees responsible for overseeing resident care and quality of life. When concerns are identified regarding the quality of care, quality of life, or protection and promotion of resident rights, the surveyor should evaluate the possibility of isolated or systemic failure of the provision of medical care in the facility.

If the survey process identifies the facility's lack of a functioning medical director or the lack of medical director involvement in implementing resident care policies and coordinating care, use the Medical Director Investigative protocol.

INVESTIGATIVE PROTOCOL

MEDICAL DIRECTOR

Objective:

To ascertain whether the medical director, in collaboration with the facility, coordinates medical care and the implementation of resident care policies.

Task 5 Use:

Use this protocol for all initial certification surveys and recertification surveys when the survey team has identified:

- That the facility does not employ a licensed medical director; or the medical director is not currently licensed by the State;
- Concerns with the provision of resident care or medical care; or
- Concerns with quality assurance related to the provision of medical or resident care.

Procedures:

Before gathering information about facility compliance with the medical director requirement, the survey team should first identify specific issues needing investigation. If they have any of these issues/concerns, the team will follow these procedures as applicable.

Provision of a medical director: If the survey team has identified that the facility lacks a licensed medical director, collect information from facility leadership 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: If the survey team has identified concerns related to the provision of resident care, investigate how the medical director, in coordination with the facility, provides input into the development, review, revision, and oversight of the implementation of resident care policies.

- Review any specific care policy/procedures (i.e., those related to the identified concerns) to identify how the facility determined that the policy reflects current standards of practice.
- If the facility is unable to provide such information, interview the medical director about his/her involvement in implementing resident care policies.

Note: The requirement does not imply that the medical director must carry out the policies and procedures, but rather must provide guidance, approval, and oversight of the implementation.

Coordination of medical care/physician leadership: If the survey team has discovered issues or concerns with resident care/medical care, determine how the facility obtains the medical director's input in developing policies related to these issues and her/his involvement in the coordination of medical care.

The team should evaluate how the facility and medical director collaborate in the following areas, in relation to the specific concerns identified:

- Determine how the facility has involved the medical director in establishing and maintaining policies and procedures for credentialing physicians, nurse practitioners, physician assistants and other licensed or certified health care practitioners.
- Determine how the facility has involved the medical director in monitoring the provision of physician services, including:
 - Ensuring that provisions are in place for physician services 24 hours a day and in case of emergency, if concerns are identified with regard to 42 CFR 483.40(d), F389 Availability of physicians for emergency care.
 - Ensuring that visits and orders are provided as required, if concerns are identified with regard to 42 CFR 483.40(c)(3)&(4), F388 Frequency of physician visits and 42 CFR 483.40(b), F386 Physician review of care and/or 42 CFR 483.40(c)(1)&(2), F387 Frequency of physician visits.
 - Ensuring that rules and procedures are established for ongoing coverage for physician services, if concerns are identified with regard to 42 CFR 483.40(a), F385 Physician supervision.
 - Ensuring that practitioners, who are used to perform physician delegated tasks, act within the regulatory requirements and within their scope of practice as defined by State law; and ensuring that they are under a physician's supervision, if concerns are identified with regard to 42 CFR 483.40(e), F390 Physician delegation of tasks in SNFs and 42 CFR 483.40(f), F390 Performance of physician tasks in NFs.
 - Whether the facility identified problems related to care that needed her/his consultation; for example, if concerns are identified regarding notification of a physician about resident changes at 42 CFR 483.10(b)(11), F157 Notification of changes.

- Determine how the facility involved the medical director in ensuring that physicians are kept aware of facility policies, providing guidance and feedback regarding practitioner performance as necessary, resolving issues and concerns between the facility and the attending physicians, and intervening directly in medical care decisions if a practitioner is acting contrary to established rules and procedures of the facility.
- Determine how the facility involved the medical director in identifying medically related staff education needs.
- Determine how the facility involved the medical director in quality assurance processes and activities. If the physician member of the quality assurance committee is not the medical director, determine how the facility disseminates information from the committee to the physicians regarding aspects of medical and nursing care such as infection control, restraint reduction, medication and pharmacy issues, incidents and accidents, and other emergency medical issues relating to specific care areas or to 42 CFR 483.75(o)(2), F521 Quality assessment and assurance.
 - Interview facility staff and the medical director regarding how recommendations for improvement of problems and/or concerns are identified, implemented, and monitored.

Task 6: Determination of Compliance:

Note: 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.

- Compliance with 42 CFR 483.75(i), F501: Medical Director.
 - The facility is in compliance with the provision of the requirement at 42 CFR 483.75(i)(1) to have a medical director if they have a licensed medical director. If the facility does not have a medical director or their medical director is unlicensed, cite F501.
 - The facility is in compliance with the provision of the requirement at 42 CFR 483.75(i)(2) that the medical director is responsible for the implementation of resident care policies and coordination of medical care, if the facility's medical director has assured that the facility has adopted and implemented relevant policies and procedures based on current clinical standards and if the medical director has coordinated the provision of medical care and services in the facility. If not, cite F501.

V: Deficiency Categorization

Once the survey team has determined that non-compliance exists, the team will select the appropriate level of severity for the deficiency using the guidance below.

Note: In order to cite F501 at Levels 2, 3, and 4, the surveyor must identify whether the specific non-compliance cited at other tags relates to the medical director's roles and responsibilities. In the case where a deficient practice has been identified at another tag, the surveyor must demonstrate an association between the identified deficiency and a failure of medical direction under F501, in order to cite at F501. This does not presume that non-compliance in the delivery of care necessarily reflects on the performance of the medical director.

Severity Level 4: Immediate Jeopardy to resident health or safety

In order to cite immediate jeopardy at this tag, the surveyor must be able to identify the relationship between failed practices cited at other regulatory tags and the failure of the medical director to perform his/her functions. This means that medical care and systems associated with roles and responsibilities of the medical director have failed and require immediate correction (harm has occurred or there is imminent danger to a resident or residents) as follows:

1. There is no medical director or the medical director had knowledge of an issue with care, or physician services, or lack of resident care policies that meet clinical standards of practice, and failed:
 - To intervene with the attending physician in order to facilitate and/or coordinate medical care; and/or
 - To provide guidance and/or approval for relevant resident care policies; and
2. Findings of deficient practice at another tag:
 - Must have caused or is likely to cause serious injury, harm, impairment or death and require immediate correction (Level 4). The findings of deficient practice associated with immediate jeopardy are written at care tags that show evidence of process failures with respect to the medical director's responsibilities.

Severity Level 3: Actual Harm that is not Immediate Jeopardy

In order to cite actual harm at this tag, the surveyor must be able to identify the relationship between failed practices cited at other regulatory tags and the failure of the medical director to perform his/her functions. This means that medical care and systems associated with roles and responsibilities of the medical director have failed as follows:

1. There is no medical director or the medical director had knowledge of an issue with care or physician services, and failed:
 - To intervene with the attending physicians 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 approval for resident care policies; and
2. Findings of deficient practice at another tag:
 - Must have caused actual harm (Level 3). The findings of deficient practice associated with actual harm are written at care tags that show evidence of process failures with respect to the medical director's responsibilities.

Severity Level 2: 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 that is not Immediate Jeopardy, the surveyor must be able to identify the relationship between failed practices cited at other regulatory tags and the failure of the medical director to perform his/her functions. This means that medical care and systems associated with roles and responsibilities of the medical director have failed as follows:

1. There is no medical director or the medical director had knowledge of an issue with care or physician services, and failed:
 - To intervene with attending physicians in order to facilitate and/or coordinate medical care; or
 - To provide guidance and/or approval for resident care policies; and
2. Findings of deficient practice at another tag:
 - Must have caused no actual harm with potential for more than minimal harm that is not Immediate Jeopardy. (Level 2) The findings of deficient practice associated with immediate jeopardy are written at care tags that show evidence of process failures with respect to the medical director's responsibilities.

Severity Level 1: No actual harm with potential for minimal harm

In order to cite no actual harm with potential for minimal harm, the surveyor must be able to identify that:

1. The medical director has failed:
 - To coordinate medical care in an aspect of care where there was a deficient facility practice with no negative resident outcomes as a result of that deficient practice; or
 - To implement resident care policies in an aspect of care where there was a deficient facility practice but with no negative resident outcomes that are the result of that deficient practice; and/or
2. 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.

Note: A reasonable person approach will be utilized to determine if the facility is actively seeking a medical director.

NOTE TO REVIEWER: BELOW ARE DRAFT CHANGES TO THE SURVEY PROCEDURES IN APPENDIX P THAT ARE BEING MADE TO ACCOMPANY THE CHANGES TO THE GUIDANCE TO SURVEYORS AT APPENDIX PP.

1. The following text is being added to Task 2, Entrance Conference, A.3. after bullet 6 as a separate bulleted paragraph:

- Determine through interview with the Administrator if the facility has a functioning QA&A committee. Determine:
 - Which staff participates on the committee;
 - Who leads the committee;
 - How often the committee meets; and
 - With whom should the survey team discuss QA&A concerns.

2. The following text entirely replaces current Task 5F:

TASK 5F – QUALITY ASSESSMENT AND ASSURANCE (QA&A) REVIEW

- A. General Objectives.—The quality assessment and assurance review protocol is designed to determine if:
1. A quality assessment and assurance (QA) committee exists and meets in accordance with the regulatory requirements of 42 CFR 483.75(o); and
 2. The QA committee is functional, i.e., it identifies, develops, plans, implements, monitors, and ensures correction of quality deficiencies.
- B. General Procedures.—To complete Task 5F, follow the Investigative Protocol contained in the Guidance to Surveyors at F520.

Note: The surveyor(s) completing Task 5F should not conduct a review of the minutes of the QA&A committee, as the regulation does not require the facility to disclose the records of the QA&A committee.

3. The following text is being added to part VI Post Survey Revisit in current paragraph three after the first sentence:

Always conduct Task 5F.

4. The following text is being added to part VII Abbreviated Standard Surveys as a replacement for the first sentence of the second paragraph:

Complaint investigations follow, as appropriate, the pertinent survey tasks (such as 5F and 5G) and information gathered is recorded on the appropriate survey worksheets.

NOTE TO REVIEWER: The requirements for 483.75(o) are now being considered under the single tag of F520. With the proposed release, F520 will contain a statement “use tag F520 for deficiencies concerning the function of quality assessment and assurance committees.”

INTENT: (F520 and F521) 483.75(o), Quality Assessment and Assurance

The intent of this requirement is to ensure that the facility has an ongoing and operational quality improvement (QI) process that is integrated with facility practices.

DEFINITIONS

Functional Quality Assessment and Assurance Committee (QA&A) – A functional QA&A committee identifies, develops, plans, implements, monitors, and ensures correction of quality deficiencies.

Quality Assessment – 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 – 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 Concern – Quality concerns are potential markers of quality that need investigating and which, after investigation, may or may not represent a quality deficiency.

Quality Deficiencies – Quality deficiencies are deviations from an accepted standard of quality that results in a potential or actual undesirable outcome. This may or may not be related to a determination of regulatory noncompliance found during a survey.

Quality Improvement – Quality improvement is an ongoing interdisciplinary process that is designed to improve the delivery of services and resident outcomes. The objective of quality improvement is continuous improvement through an ongoing evaluation of those administrative, managerial, clinical, and support processes that most affect resident care.

Root Cause – A root cause is the most basic cause(s) of an outcome that can reasonably be identified by the facility. The root cause may be related to a facility structure or process. Correcting a root cause is often the most definitive way to reduce the likelihood of a problem’s reoccurrence.

Root Cause Analysis – A root cause analysis is a systematic approach to identify contributing factors or root causes of an outcome for the purpose of developing effective strategies to improve performance of facility systems.

OVERVIEW

The QI process is a management tool to coordinate, integrate, and evaluate facility systems. This QI process, which is directed by an interdisciplinary committee, includes:

- Tracking facility trends and patterns relating to quality of facility operations and practices including staff performance and system of care within the facility;
- Identifying concerns or issues;
- Evaluating identified quality concerns and determining root cause(s);
- Responding to identified quality concerns by developing, implementing, and monitoring of strategies to improve quality;
- Evaluating the effects of quality improvement interventions and taking corrective actions, as needed;
- Monitoring consistency of implementation of facility care practices and protocols; and
- Proposing strategies to promote the quality of facility operations and practices.

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), Assessing Care of Vulnerable Elders (www.acponline.org), American Geriatric Society (www.americangeriatrics.org), Agency for Healthcare Research and Quality (www.ahrq.org), 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. URL addresses were current as of the date of this publication.

QUALITY ASSESSMENT AND ASSURANCE COMMITTEE

Composition

The facility QA&A Committee must include:

- The Director of Nursing Services; and
- A physician designated by the facility, which should be the facility Medical Director.

The Committee must also include at least three additional facility staff members, one of whom should be the facility administrator. Other staff members may include:

- Staff who have responsibility for direct resident care and services (e.g., nursing assistants, therapists, staff nurses, and social services);
- Staff with responsibility for the physical facility operations (e.g., maintenance and housekeeping, laundry);
- Staff with responsibility for dietary, infection control, activities, and staff development;
- The consultant pharmacist because of the importance of medications to multiple care processes and outcomes (e.g., falls, delirium, urinary incontinence, infections); and
- Individuals who provide consultative or ancillary services. These may include nurse consultants, dietitian consultants, or individuals who provide laboratory or diagnostic services.

Functions

The QA&A Committee is the facility body that monitors, evaluates, and promotes the overall quality of facility services. The Committee not only responds to quality concerns, but also proposes strategies to achieve excellence in quality of care or quality of life. The Committee encourages involvement of all staff in quality assurance by fostering a culture that emphasizes integrating quality improvement into all aspects of facility operations. The QA&A Committee oversees or performs the following functions:

- Tracking facility trends and patterns relating to quality of care and quality of life to identify quality concerns or issues;
- Identifying potential quality concerns or issues, and selecting those that need investigation;
- Analyzing selected quality concerns or issues, including identification of underlying cause(s) or contributing factor(s), i.e., root cause analysis;

- Developing action plans (with list of action items, responsible person, and date due) to address selected quality concerns or issues;
- Monitoring implementation of action plans and their effect on the quality issue;
- Modifying the action plan, as needed, to achieve the intended goals; and
- Authorizing, overseeing, and monitoring quality improvement teams.

Processes

Meetings of the QA&A Committee must be held at least quarterly, and as 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 of those attending each meeting. Persons attending individual meetings of the QA&A Committee may vary depending upon the agenda or quality issues to be addressed. The Committee utilizes internal and external sources of information to assist in identifying areas on which to focus their activities.

IDENTIFICATION OF QUALITY CONCERNS

Identification of quality concerns related to facility operations and practices are not only related to those that cause negative outcomes; it may also be directed toward enhancing quality of care and quality of life for residents. Facilities can identify and collect data about quality concerns and issues in various ways. An effective QA&A program utilizes more than one of the sources listed below:

- Facility Quality Indicator Profile And Resident Level Summary;
 - Quality indicators can provide information useful to the QA&A Committee;
 - Quality indicators will provide information on sentinel events (e.g., dehydration, fecal impaction, and low risk pressure ulcers);
 - Quality indicators identify other areas with an unusually high prevalence (greater than 75th percentile) that may require more attention from the QA&A Committee but are not necessarily identified as a problem;
 - An analysis of possible relationships among some of the quality indicators may provide additional pertinent information. Examples could include the relationship between incontinence and the development of pressure ulcers or the relationship between the use of antipsychotic medications and falls, etc.

- Publicly reported quality measures;
- CMS-2567s (Statements of Deficiencies) and plans of correction from previous surveys or complaints;
- OSCAR reports – the facility could identify repeat deficiencies, previously cited deficiencies, areas identified on complaint investigation, and scope and severity levels;
- Facility Roster/Matrix (CMS-802);
- Facility documents;
 - Adverse events (e.g., unplanned hospitalization, unexpected deaths and medication related problems);
 - Incident/accident reports to determine trends in quality issues including investigations of injuries of unknown origin, allegations of abuse and neglect, and of loss and theft;
 - Resident/family/employee satisfaction surveys;
 - Reports related to specific aspects of care and operations (e.g., falls, restraints, infections, safety committee, and environmental rounds);
 - Consultant reports (e.g., social services, activities, dietary, nursing, pharmacy);
 - Resident/family/employee complaints;
 - Minutes of meetings or recommendations from resident and family councils;
 - Information reported from the ombudsman;
 - Staff concerns and observations, which may involve numerous quality areas such as walking rounds, care plan conferences, MDS meetings, staff and departmental meetings;
 - Open and closed medical record audits; and
 - Risk management reports.

DEVELOPMENT OF ACTION PLANS

When a quality deficiency or opportunity for improvement is identified, the facility should use a systematic process to develop and implement an action plan similar to the following:

- Identify the problem and root cause(s) (e.g., What is the problem? How extensive is it? What caused it?);
- Determine the sources of information (e.g., medical record, facility departments);
- If necessary, designate a task force or ad hoc committee;
- Determine disciplines to be involved based on the nature and cause of the problem and on professional expertise and responsibilities;
- Identify a proven care process/approach;
- Develop a written plan specifying the tools, approaches, and evaluation of outcomes;
- Determine goals and timelines;
- Set timelines for completion of tasks;
- Review the existing policies and procedures, and compare to evidence-based and reliable consensus-based approaches such as may be found in references and web sites;
- Review literature and consult the medical director and other experts (e.g., nurse consultant, consultant pharmacist); and
- When an opportunity for improvement is identified, identify the extent of the problem, which may include the number of residents, units, and departments/professionals involved.

IMPLEMENTATION OF ACTION PLANS

The implementation of an action plan may include:

- A team to provide leadership;
- A statement about the team's understanding of the scope and root cause of the problem and the plan;
- Defined and planned training programs;
- Feedback mechanisms (e.g., one-to-one feedback to staff and practitioners);

- Frequency and extent of monitoring (e.g., how frequently the supervisor needs to check a process, how broad the sampling should be);
- Accountability (e.g., who is responsible to whom for their actions); and
- Appropriate review and revision, as needed, of policies and procedures to ensure consistent processes and performance.

ONGOING MONITORING AND EVALUATION

The facility's QA&A program includes methods for monitoring and evaluating the successful implementation of quality processes and practices. There must be evidence that the facility's QA&A plans, strategies, and goals are reflected in the provision of aspects of care, as identified through facility policies and procedures, staff interviews, resident interviews, resident satisfaction, and other sources of information. The facility should demonstrate that it reviews its plans or strategies and revises them as necessary when desired outcomes are not achieved.

INVESTIGATIVE PROTOCOL

QUALITY ASSESSMENT AND ASSURANCE

Objective:

To determine if the facility has an ongoing and operational quality improvement process that identifies quality problems; develops, implements, and monitors action plans; and evaluates the effectiveness of the action plans and revises them as necessary to ensure the provision of treatment and services for residents and the effort to minimize negative outcomes.

Task 5F Use:

Use this protocol during the entrance conference and in phase 2 of the survey.

Note: The survey team is to look for evidence of the QA&A committee's plans and strategies through: observations of the facility's implementation of policies, procedures, and plans of care, staff interviews; resident interviews; and other sources of information. If the desired outcomes are not achieved, look for evidence that the facility revises the plan or strategy, or reaffirms the continued appropriateness of current approaches.

Procedures:

1. During the entrance conference, determine through interview with the Administrator if the facility has a functioning QA&A committee. Determine:
 - Which staff participates on the committee;
 - Who leads the committee;
 - How often the committee meets; and
 - With whom the survey team should discuss QA&A concerns.
2. During Phase 2, the survey team will implement the QA&A process investigation. Interview staff (medical director, director of nursing, designated managers, department heads, direct care staff, activity aides, housekeepers, dietary aides, quality improvement team members, team leaders, etc.) to determine:
 - If the staff knows the facility's quality improvement and performance improvement process;
 - If the direct care staff are involved in QA&A activities and if the QA&A process enables them to relay issues or concerns to the QA&A committee;

- How the QA&A committee identifies issues to be addressed by the QA&A program (e.g., trends, patterns, positive and negative outcomes);
 - How the committee measures and monitors the results of the action plans developed by the QA&A process;
 - How the facility reviews its processes and practices, both in generally and in relation to the areas of concern found by the survey team;
 - How the facility's action plans relate to its analysis of the data and its identification of root causes, i.e., not just the content; and
 - How the facility evaluates data and draws conclusions about the nature and causes of problems and their solutions.
3. Observe care delivery for evidence that it follows defined protocols and determine if practices and processes reflect issues identified through the QA&A process. Ask facility staff how they can demonstrate that they developed, implemented, and revised appropriate corrective actions.

Note: The surveyor(s) should not conduct a review of the minutes of the QA&A committee, as the regulation does not require the facility to disclose the records of the QA&A committee.

Task 6: Determination of Compliance

- Compliance with 42 CFR 483.75(o), F520, Quality Assessment and Assurance.
 - The facility is in compliance with the provisions of the requirement at 42 CFR 483.75(o) if:
 - The facility has a functional QA&A committee consisting of the director of nursing, a physician, and at least three other members;
 - The committee meets at least quarterly;
 - The committee:
 - Identifies quality concerns;
 - Develops appropriate plans of action to correct identified quality deficiencies; and
 - Implements the plans of action.

If not, cite F520.

V: Deficiency Categorization

Once the survey team has determined that non-compliance exists, the team will select the appropriate level of severity for the deficiency using the guidance below.

Note: In order to cite F520 at Levels 2, 3, and 4, the surveyor must identify whether the specific non-compliance cited at other regulatory requirements relates to the facility's failure to have a functional QA&A committee. If deficient practices are identified at another regulation where actual or potential outcome to residents has occurred, the surveyor must demonstrate the relationship to the facility's failure to address the systems failures in order to cite F520.

Severity Level 4: Immediate Jeopardy to resident health or safety

In order to cite immediate jeopardy at this regulation, the surveyor must be able to identify the relationship between the facility's failed practices cited at other regulatory tags and the failure of the QA&A Committee to function effectively. This would mean that systems have failed, and there is an immediate and serious threat to a resident's health and safety due to the failed practices. The following components must be identified to cite at the immediate jeopardy level:

- No functional QA&A program/committee that should have identified the persistent/systemic quality concern; and
- Recurrent and persistent facility practices that have caused actual harm or have the potential for harm to residents that is likely to cause serious injury, harm, impairment, or death; and
- Deficiencies have been identified in an area other than QA&A that have been assigned the severity level of immediate jeopardy.

Severity Level 3: Actual Harm that is not Immediate Jeopardy

In order to cite actual harm to residents at this regulation, the surveyor must be able to identify the relationship between the facility's failed practices that resulted in a negative outcome (s) to residents and the failure of the QA&A Committee to function effectively. The following components must be identified to cite at the actual harm level:

- No functional QA&A program/committee that should have identified the persistent/systemic quality deficiency, and
- Recurrent or persistent facility quality issues (practices) that have caused actual harm to a resident(s); and
- Deficiencies at severity level 3 that have been identified in an area other than QA&A.

Severity Level 2: No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy

In order to cite the potential for more than minimal harm at this regulation, the surveyor must be able to identify the relationship between the facility's failed practice(s) cited at other regulatory tags and the failure of the QA&A Committee to function effectively. The following components must be identified to cite at severity level 2:

- No functional QA&A program/committee that should have identified the persistent/systemic quality deficiency, and
- Recurrent or persistent facility quality issues (practices) that have no actual harm with potential for more than minimal harm that is not immediate jeopardy; and
- Deficiencies at severity level 2 that have been identified in an area other than QA&A.

Severity Level 1: No Actual Harm with potential for minimal harm

In order to cite QA&A at severity level 1, the surveyor must be able to identify the following:

- The QA&A program/committee does not meet the composition and meeting schedule requirements, and
- There are either no deficiencies identified on the survey, or there are no deficiencies at severity levels 2, 3 or 4.

ATTACHMENT C

Severity Grid for Rating Nursing Home Deficiencies

Severity	Immediate Jeopardy to Resident Health or Safety	J	K	L
	Actual Harm That Is Not Immediate Jeopardy	G	H	I
	No Actual Harm with Potential for More than Minimal Harm That Is Not Immediate Jeopardy	D	E	F
	No Actual Harm with Potential for Minimal Harm	A	B	C
		Isolated	Pattern	Widespread

Level 4: Immediate Jeopardy to resident health or safety. (J, K, L)

Noncompliance that results in immediate jeopardy, a situation in which immediate corrective action is necessary because 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 receiving care in a facility.

Level 3: Actual Harm that is not Immediate Jeopardy. (G, H, I)

Noncompliance that results in a negative outcome that has compromised the resident's ability to maintain and/or reach his/her highest practicable physical, mental, and psychosocial well-being.

Level 2: No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy. (D, E, F)

Noncompliance that results in no more than minimal physical, mental and/or psychosocial discomfort to the resident and/or has the potential, (not yet realized) to compromise the resident's ability to maintain and/or reach his/her highest practicable physical, mental and/or psychosocial well-being.

Level 1: No Actual Harm with the potential for minimal harm.

A deficiency that has the potential for causing no more than a minor negative impact on the resident(s).