This Handbook will serve as a ready reference to assist with the many challenges facing Long-Term Care Medical Directors and/or Attending Physicians serving Kindred Healthcare-affiliated nursing centers. It is not meant to be a comprehensive reference work, nor the definitive source for medical information relating to long-term care. Rather, this Handbook will provide some handy pointers for both the novice and seasoned Long-Term Care Medical Director and Attending Physician, particularly as it relates to the management issues and regulatory aspects of the practice (all the stuff we never learned in medical school).

Having an historical perspective for the manner in which long-term care has evolved is helpful. Long-term care has its roots in the “welfare state” — places for impoverished older persons to rest (rest home) until they passed. Up until the last couple of decades, LTC was primarily a custodial service for those without the financial means or family support to exist on their own. The Nursing Home Reform Act (OBRA 87) provided a federal mandate to change the industry from primarily a custodial environment to a healthcare service.

Even before OBRA 87 was enacted, however, changes in hospital reimbursement [away from fee-for-service and toward prospective payment for certain diagnosis-related groups (DRGs)] caused a fundamental change in the post-acute care landscape. Hospitalized patients were discharged quicker and sicker than ever before, and the most frail were discharged to nursing homes. By the mid 1990s, many nursing centers had morphed into providing a range of medical services including IV therapy, total parenteral nutrition, post-operative care, tracheotomy and respiratory care, complex wound care, neurobehavioral management, physical, occupational and speech therapies, and dementia care, to name just a few.

In the 1960s and 70s, prospective nursing home residents generally arrived at the “home” to spend the rest of their lives there (usually many years). Today, we have several distinct sub-populations moving through nursing centers. There is a short-stay population consisting primarily of patients who spend a few days to several weeks and a long-stay population consisting primarily of residents requiring ADL care and/or dementia management who may stay for several months up to a year or two.

The short-stay population is further subdivided into patients who are recovering or rehabilitating from an acute event or exacerbation of a chronic condition and a second group who are either terminally ill or have multi-system failure with a grim prognosis. The former group arrives with plans for discharge back to home (or independent senior living or assisted living). The latter group may hope to return home, but most often will require ongoing nursing center care until death.

Regardless of the circumstances precipitating nursing center care, all residents/patients must receive care that:

• promotes dignity and respect,
• honors residents’ (or their proxies’) right to direct their own care and make informed decisions about treatment options
• maintains residents’ highest practicable level of function, and
• seeks to achieve the least restrictive environment.
There are a multitude of state and federal regulations and oversight agencies involved in LTC. (The Appendix of this Handbook contains excerpts from the LTC Federal Regulations and Guidance to Surveyors germane to physician services.) Difficult bioethical issues are everyday occurrences. Funding issues and nursing shortages are perennial challenges. Yet, the demand for long-term care and chronic care services will continue to grow with each passing year. Modern medicine is helping people to live longer, but often at a price. Maladies that used to take lives acutely are now treated successfully — reducing mortality but increasing the numbers of those who live on with a multitude of chronic conditions.

Enjoy this Handbook. Hopefully, there are a few insights to be gleaned from its use. You have selected a challenging area of healthcare, and we sincerely appreciate you for it.
ABOUT KINDRED HEALTHCARE

The word “kindred” has many meanings, including allied, similar and family. We believe the name reflects our business, as well as our values. We are dedicated to providing quality long-term care, as well as to the principles of service, compassion, integrity and sound fiscal stewardship.

Kindred Healthcare is a healthcare services company that, through its subsidiaries, operates hospitals, nursing centers, institutional pharmacies and a contract rehabilitation services business across the United States.

At December 31, 2006, the company’s Hospital Division operated 81 LTAC hospitals (6,419 licensed beds) in 24 states. The company’s Health Services Division operated 242 nursing centers (30,664 licensed beds) in 28 states. Additionally, the company operated a contract rehabilitation services business, which provides rehabilitative services primarily in long-term care settings. The company’s pharmacy division operated an institutional pharmacy business with 46 pharmacies in 26 states and a pharmacy management business servicing substantially all of the company’s hospitals.
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Every nursing center must have a qualified physician serving as Medical Director.

This section contains a brief overview of key points and is not intended to be a comprehensive analysis of the document nor substitute for the Medical Director candidate’s personal review of the Agreement.

Generally speaking, this Agreement compares favorably to the American Medical Directors Association’s (AMDA) “Model Agreement” published as a guide for their members.

**Key Provisions of the Agreement:**

The agreement will be for a one-year term and automatically renew for successive one-year terms unless either party gives written notice. This notice may occur with or without cause. The contract may be terminated immediately for a variety of situations, such as loss of license or a material breach of the contract, etc.

The contract is for medical administrative services only. Nursing centers do not pay Medical Directors for their doctor/patient visits (attending physician services). The Medical Director shall be considered an independent contractor (not an employee) and shall possess certain minimum qualifications, including being a duly licensed physician in the state in which the facility is located and having a current DEA registration number. The compensation will be negotiated by the Executive Director and Medical Director candidate and shall be recorded as an hourly fee for a minimum number of administrative service hours per month.

The Medical Director stipend must comply with “Fair Market Value” standards, meaning that the Medical Director must be paid a fee appropriate for the services rendered and in line with local market factors.

These facts are important to note because the federal government has created legislation, generally known as the “Stark Regulations,” which deal with physician contracts. In summary, this series of legislation deals with anti-kickback issues for patient referrals and “safe harbor” provisions that characterize appropriate and inappropriate referral patterns between a healthcare entity and the physicians who practice there.

The Executive Director of your center will keep a copy of your executed Agreement (signed and dated) on file in his or her office. Medical Directors should also keep a copy of their executed agreement in their personal files for reference.
STATEMENT OF LIABILITY INSURANCE COVERAGE

Kindred nursing centers will maintain professional liability insurance for Medical Director administrative duties (as described within the Medical Director Agreement) and clinical services performed by the Medical Director in emergency situations for patients of other physicians.

Medical Directors must maintain their own professional liability insurance (generally known as Medical Malpractice Insurance) for the treatment of their own patients in their doctor/patient relationship.
ROLES AND RESPONSIBILITIES OF THE MEDICAL DIRECTOR IN THE NURSING HOME

Physician Leadership:

1. Provides guidance for appropriate physician coverage and the provision of physician and healthcare practitioner services
2. Reviews the process for reviewing physician and healthcare practitioner credentials
3. Provides guidance for Attending Physician performance expectations
4. Provides guidance on systems to monitor the performance of healthcare practitioners
5. Provides ongoing feedback to physicians and other healthcare practitioners on performance and practices

Patient Care – Clinical Leadership:

1. Participates in administrative decision-making
2. Reviews current resident-centered Standards of Practice
3. Assists in the development of specific clinical practices for the facility to incorporate into its care-related Standards of Practice, including areas required by laws and regulations
4. Reviews, responds to, and participates in federal, state, local, and other external surveys and inspections
5. Reviews Standards of Practice regarding the adequate protection of patients’ rights, advance care planning and other ethical issues

Quality of Care:

1. Assists the facility in establishing systems and methods for reviewing the quality and appropriate clinical care and other health-related services and provides appropriate feedback (e.g., Standards of Care)
2. Actively participates in the facility’s performance improvement process
3. Advises on infection control issues and approves specific infection control Standards of Practice
4. Assists the facility in providing a safe and caring environment
5. Assists the facility administration in promoting employee health and safety
6. Assists in the implementation of employee health Standards of Practice

Education, Information and Communication:

1. Promotes a learning culture within the facility by educating, informing, and communicating with all levels of staff, families, and community
2. Assists the facility in developing medical information and communications systems with staff, patients, families, and others
3. Represents the facility to professional and lay community on medical and patient care
4. Maintains knowledge of the changing social, regulatory, political, and economic factors in the medical and health services of long-term patients
5. Assists in the establishment of appropriate relationships with other healthcare organizations

1AMDA Position Statement A03, March 20, 2002, Roles and Responsibilities of the Medical Director
**Key Points:**

AMDA is the professional association for LTC Medical Directors. All Kindred Medical Directors are enrolled in AMDA. AMDA conducts annual symposiums and seminars with excellent CME opportunities. AMDA distributes journals and newsletters with valuable info for LTC physicians.

Fortunately, LTC Medical Directors and Attendings have an extraordinary resource in the American Medical Directors Association (AMDA).

AMDA is the professional association of medical directors and physicians practicing in the long-term care continuum. AMDA is dedicated to excellence in patient care by providing education, advocacy, information and professional development.

Kindred Healthcare will sponsor and pay your annual membership dues as long as you serve as Medical Director for a Kindred nursing center (unless paid by another corporate entity). We strongly encourage your participation and certifications with the American Medical Directors Association.

Every Medical Director is encouraged to go to the AMDA Website, [www.amda.com](http://www.amda.com), as it provides a wealth of information specific to this very important position.

As an AMDA member, you will receive a multitude of resources germane to your LTC practice, including:

- *Journal of the American Medical Directors Association* (JAMDA), an indexed medical journal of LTC management, applied research and clinical issues
- *Caring for the Ages* – a monthly newsletter for Long-Term Care practitioners
- *AMDA Reports* – a quarterly newsletter offering a recap of AMDA activities and initiatives, the latest information and analysis of legislative and regulatory issues, highlights of the AMDA CMD program, updates on state chapters, news about products and publications, conferences, and services of interest to AMDA members

In addition, we highly recommend your attendance and participation at the annual AMDA Symposium usually offered in March of each year. AMDA is the premier source of education in both clinical and leadership/management topics for the long-term care continuum. You will also discover great networking opportunities to discuss and share experiences with like-minded colleagues from around the country.

Additionally, AMDA has created a series of Clinical Practice Guidelines on the important and difficult clinical issues facing the long-term care practitioner along with a variety of tool kits and other resources for the inquisitive physician. Following is a list of offerings for 2006:

- Acute Change of Condition in the Long Term Care Setting
- Altered Mental States
- Altered Nutritional Status
- COPD Management in the Long Term Care Setting
- Common Infections in the Long Term Care Setting
- Dehydration and Fluid Maintenance
- Dementia
• Depression
• Falls and Fall Risk
• New! Gastrointestinal Disorders in the Long Term Care Setting
• Guideline Implementation
• Heart Failure
• Managing Diabetes in the Long Term Care Setting
• Osteoporosis
• Pain Management in the Long Term Care Setting
• Parkinson's Disease
• Pharmacotherapy Companion to Depression
• Pressure Ulcer Therapy Companion
• Pressure Ulcers
• New! Sleep Disorders in the Long Term Care Setting
• Stroke Management and Prevention in the Long Term Care Setting
• Urinary Incontinence

Implementation Tool Kits

• Tool Kit for Implementation of the Clinical Practice Guideline for Dementia (NEW)
• Tool Kit for Implementation of the Clinical Practice Guideline for Depression (NEW)
• Tool Kit for Implementation of the Clinical Practice Guideline for Osteoporosis/Falls (NEW)
• Tool Kit for Implementation of the Clinical Practice Guideline for Pain Management
• Tool Kit for Implementation of the Clinical Practice Guideline for Pressure Ulcers
• We Care: Implementing Clinical Practice Guidelines Tool Kit

Again, all can be ordered at a reasonable cost at www.amda.com or by calling 800.876.AMDA.

You will note several references to AMDA in this Handbook as the physician members of this outstanding association, in their dedication to improving LTC, have created multiple resources and tools to assist the busy LTC Medical Director and Attending Physician.
THE LONG-TERM CARE SURVEY PROCESS

Key Points:

Nursing centers are heavily regulated at the federal and state levels. State regulation may not be less stringent than federal regulation. Medical Director and Attending Physician requirements are driven by regulation. State surveyors make annual and ad hoc visits to assess compliance with regulation. Medical Director and Attending Physician non-compliance may result in deficiencies and sanctions against the nursing center.

Annual regulatory surveys (also known as Standard Surveys) are usually conducted once per year. Federal LTC regulations are developed and updated by the Centers for Medicare and Medicaid Services (CMS). Individual states have the option to create their own state regulations; however, state regulations must be more stringent (not less) than the federal regulations. In other words, CMS has created minimum standards by which states must abide; however, states may require more specifics or detail (but not less) than the federal regulations. This usually explains why, at national or regional symposiums, physicians note inconsistencies in cases or regulatory requirements from physicians from other states.

You will also hear the words “survey cycle” used by your center’s administration. By rule, the standard survey must occur between nine and 15 months after the previous standard survey. That six-month period is generally referred to as the “survey window” because surveyors can be expected to arrive for the annual survey during that window of time. LTC surveyors may arrive at any time of the day or night, weekday or weekend to begin the survey process.

In addition to the annual standard survey, there is also a type of survey called a complaint survey. The general public has the right to call their state LTC regulatory agency and file a complaint against a nursing facility. In addition, there are requirements for facility administration to self-report certain situations or outcomes to their state LTC regulatory agency. Both may result in LTC surveyors arriving at the nursing facility to conduct a survey of the complaint or self-reported concern. On occasion and depending on the nature of the complaint, state surveyors may batch several complaints together into one complaint survey.

In addition to the actual regulations, there is another document entitled Guidance to Surveyors – Long Term Care Facilities outlining specific instructions (procedures and probes) for the surveyors to use in assessing the facility during the survey process. It is here that one can find the detail and rationale for the surveyor’s focus and the writing of deficiencies against the nursing facility. If you have questions about survey requirements, this document will answer them. The Appendix of this Handbook contains many LTC federal regulations and interpretive guidelines to surveyors in topic areas most germane to Medical Director and Attending Physician services. The Appendix table of contents is on page 50.

Deficiencies are written by numerical designation called F Tags, which relate directly back to the actual regulation that was allegedly violated. Deficiencies also are labeled with an alphabetical Scope and Severity designation. “Scope” meaning, was the violation isolated or widespread; “severity” meaning, was there potential for harm or did actual harm occur.

There are a variety of sanctions that can be levied against the nursing center based on the survey findings to include: monetary fines, denial of payment for services,
bans on admission, or even decertification from the Medicare program. Additionally, Medical Directors may be able to offer clarification, specifically regarding issues of medical diagnosis and the selection of treatment options.

At the conclusion of the survey, the surveyors will hold an exit conference with the nursing facility administration to generally review their findings. We encourage Medical Directors to participate in this exit conference to hear first hand the concerns of the surveyors. Additionally, Medical Directors may be able to offer clarification, specifically regarding issues of medical diagnosis and the selection of treatment options.

However, the official survey findings usually arrive a few weeks later in a document known as the 2567 (government assigned form number). Based on these official findings, the nursing facility must develop and file a Plan of Correction (PoC) to address each deficiency, both on a case-by-case basis and systemically, to assure that the infractions will not occur in the future. Surveyors will then return at a future date to determine if the Plan of Correction has been satisfactorily instituted to rectify the cited deficiencies. Occasionally, if the infractions are of a minor nature, the LTC survey agency may conduct a “desk review” of the Plan of Correction rather than returning to the facility to conduct an onsite follow-up.

Needless to say, all of the above is an oversimplification of the survey process as the interpretation and application of regulations in each particular case may be extremely complex with multiple shades of gray. Additionally, there are procedures for the resolution of disputes by which nursing facilities may contest the deficiencies and sanctions levied against them. There is a not-too-small army of attorneys in this country making a living by involvement in this process.

It is important to note that while several LTC regulations directly concern Medical Director and Attending Physician’s responsibilities, deficiencies and sanctions for breaches of these regulations are levied against the nursing facility and not the Medical Director or Attending Physician. LTC surveyors have no jurisdiction over the medical community, but they will hold the nursing center accountable for rectifying Medical Director or Attending Physician issues. Unfortunately, this scenario often places the nursing facility administration and staff at odds with the physician community and has been a source of considerable consternation and irritation among the medical staff. However, the nursing facility has no recourse but to adhere to the letter of the regulations, and surveyors will expect nursing facility administration to address the physician practices or behaviors that led to the deficiencies cited.

Lastly, it is important to appreciate the significance that has come to surround LTC survey outcomes. CMS captures all the nursing facility survey data in a public domain database called Online Survey, Certification And Reporting (OSCAR) and has created a website called Nursing Home Compare, which lists every nursing facility in the country and their survey history for multiple years. Go to www.medicare.gov/NHCompare/home.asp to look up your nursing facility.

Consumers are becoming increasingly sophisticated in using resources like this to select a nursing facility for their loved ones. The Consumer Reports organization uses this data to report on nursing home quality. Legislators and congressman at the state and federal level are reviewing the data. Plaintiffs’ attorneys are carefully scrutinizing the data for their legal cases.

In this Handbook, you will find relevant excerpts from the LTC regulations and the Guidance to Surveyors for your review.
FEDERAL GUIDELINES SPECIFIC TO MEDICAL DIRECTORS

Key Points:

Regulatory compliance requirements for Medical Directors were strengthened in November 2005. Medical Directors are to be viewed as key members of the nursing facility leadership team. Medical Directors have a key role in implementation of resident care policies, coordination of clinical care and oversight of the medical staff.

F 501 Medical Director, required duties

The facility must designate a physician to serve as Medical Director. The Medical Director is responsible for implementation of resident care policies and the coordination of medical care in the facility.

INTENT: (F 501) CFR 483.75(i) Medical Director

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.
- 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
  - Are related to the provision of services by physicians and other licensed healthcare 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.

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 healthcare 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” refers to 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 are consistent with current standards of practice and facility policies.

**Overview**

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

The Medical Director is in a position, because of his or her roles and functions, to provide input to surveyors on physician issues, individual resident’s clinical issues, and the facility’s clinical practices. The text “Medical Direction in Long-Term Care” asserts that:

“The Medical Director has an important role in helping the facility deal with regulatory and survey issues...the Medical Director can help ensure that appropriate systems exist to facilitate good medical care, establish and apply good monitoring systems and effective documentation and follow up of findings, and help improve physician compliance with regulations, including required visits. During and after the survey process, the Medical Director can clarify for the surveyors clinical questions or information about the care of specific residents, request surveyor clarification of citations on clinical care, attend the exit conference to demonstrate physician interest and help in understanding the nature and scope of the facility’s deficiencies, and help the facility draft corrective actions.”

Nationally accepted statements concerning the roles, responsibilities and functions of a medical director can be found at the American Medical Directors Association website at [www.amda.com](http://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 or 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 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 healthcare professionals, such as nurses, therapists, dietitians, pharmacists, and social workers; and other healthcare 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 include 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
  - 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
• 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 healthcare issues related to the quality of care and quality of life of residents. “A medical director should establish a framework for physician participation, and physicians should believe that they are accountable for their actions and their care.”

The Medical Director addresses issues related to the coordination of medical care identified through the facility's Quality Assessment and Assurance Committee, 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 healthcare 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 healthcare practitioner credentials (e.g., licensure and pertinent background)
• Address and resolve concerns and issues between the physicians, healthcare practitioners, and facility staff
• 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 healthcare 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 healthcare practitioner about medical care that is inconsistent with applicable current standards of care
• Assuring that a system exists to monitor the performance of the healthcare 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
• 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

FEDERAL GUIDELINES SPECIFIC TO QUALITY ASSURANCE

Key Points:

Nursing facilities must maintain a Quality Assessment and Assurance Committee. Federal guidelines require physician involvement in a Quality Assurance process. Kindred Medical Directors are members of our Performance Improvement Committee.

F Tag 520

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

   (i) The director of nursing services

   (ii) A physician designated by the facility

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

(2) The quality assessment and assurance committee

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

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

F Tag 521

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

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

Key Points:

Kindred Medical Directors serve on the Performance Improvement Committee (PIC). The PIC holds monthly meetings to address a wide range of quality issues. The CMS Quality Indicators/Quality Measures are reviewed at the PIC.

Kindred nursing centers meet the regulatory requirement for Quality Assessment and Assurance (QAA) through the activities of the Performance Improvement Committee (PIC). Each nursing center will hold PIC meetings at least once per month. Kindred Medical Directors are to be actively involved in the deliberations of the PIC.

Physicians can offer valuable contributions to the committee, not the least of which is their familiarity with rigors of the scientific method when examining details and interpreting data. In addition, physicians have unique insights into the overall assessment of general medical care principles (such as assessing the overall prognostic trend of patient groups with multiple co-morbidities, or recent literature dispelling a traditionally held medical belief). However, physicians tend to be classical scientists, not social scientists, and often have much to learn about basic committee meeting skills.

In referring to basic meeting skills, I mean strategies that produce successful meetings. For example, creating an agenda appropriate for the time allotment, utilizing work groups to prepare materials in advance of the meeting, establishing ground rules and adhering to them, engaging all participants in the discussion, and assigning specific roles to ensure the success of the meeting – chairperson, timekeeper and recorder. Also, designating a participant adept at facilitating group interaction to formally facilitate the meeting can be extremely helpful. For example, skilled facilitators will diplomatically discourage only the most vocal or most senior person from dominating the meeting. A good facilitator will assess when the group is hung up on a topic and move them on to more productive territory and encourage all participants to become engaged in the process through the use of techniques such as brainstorming, nominal group technique, and multi-voting. Good facilitation also involves reminding the group to look for the “root cause” of an issue, usually by repeatedly asking the question why (why does this happen; well then, why does that happen, etc.).

It has been estimated that CEOs of large companies spend 75% of their time in meetings. In fact, they will tell you that conducting effective, successful meetings is critical to the success of the organization. Physicians on the other hand tend to loathe meetings, often because most of their historical experience has been predicated on participation in dismally ineffective and poorly run meetings. Until very recently there were no classes on conducting effective meetings in medical schools. Also, physicians tend to view meetings as non-revenue-producing time – one can easily see how this may be construed as ineffective use of our time. However, LTC Medical Directors are, indeed, provided recompense for their medical administrative duties, including participation on the PIC.

There are a variety of activities and reports that should be addressed within the auspices of the Performance Improvement Committee including:

• CMS Quality Indicator/Quality Measure Reports (see page 58)
• Special attention to weight loss and dehydration, pressure sores, falls, restraint use, and pain management
• Pharmacy reports and med errors
• Infection control logs
• Clinical process reviews
• Recent survey findings and the Plan of Correction
• Incidents, accidents and significant risk events
• Mortality data
• Special Kindred programs such as Angel Care, Falling Stars, P&P implementation

And those are just the more concrete clinical issues. The Performance Improvement Committee should also discuss:

• Staff morale issues
• Staff turnover and retention
• Employee and customer satisfaction
• The overall caring culture of the organization

These social science topics are critically important to improving the culture of and the care delivered in a nursing facility. The successful Medical Director will take note and endeavor to become conversant in these topic areas. AMDA symposiums and management meetings are a great source of information on these and a variety of other relevant topics.

Kindred addresses the function of the Performance Improvement Committee in its “Great Eight” (eight policies and procedures manuals). Each center also has a Resource Guide on Performance Improvement, which is a great reference work on everything you ever wanted to know about improving quality, conducting a successful PIC meeting, nominal group technique and data review.
MEDICAL DIRECTOR CHECKLIST

Medical Director Action Items

Check the box beside those items completed during this visit.

Weekly:

☐ Walking Rounds through the Nursing Center stopping by each nursing station to respond to questions and communicating with DNS if issues arise

Monthly:

☐ Formally meet with Executive Director (ED) and Director of Nursing Services (DNS) regarding overall clinical care and attending physician issues
☐ Meet with Staff Development / Infection Control Coordinator if requested
☐ Review Licensed Independent Practitioner (LIP) Credentialing files as appropriate
☐ Review 5 charts (or 5% of admissions, whichever is greater) from different physicians, randomly selected by medical records (see chart review form)
☐ Meet with Sub-acute Medical Director (if exists)
☐ Attend Kindred Performance Improvement Committee Meeting:
  ☐ To include Infection Control issues and Consultant Pharmacist recommendations
  ☐ Review the five residents that flagged the largest number of QIs (is attending physician aware and addressing issues, family aware, etc.)
  ☐ Review Event Reporting System trends

Quarterly:

☐ Conduct or assist with in-service education as requested
☐ Conduct walking rounds with Department Heads and/or Interdisciplinary representatives to discuss patient issues. For example: Nursing, Therapy, Unit Managers, Nutrition, Social Services, Activities, Wound Care, MDS Coordinator

Annually:

☐ Participate in State and Federal Surveys as requested
☐ Review Policy and Procedure updates and ongoing implementation

Signature: __________________________

Date: __________________________
This chart review is conducted to ascertain compliance with Federal LTC Regulations

1. History and Physical completed according to regulation  YES ☐  NO ☐  NOT APPLICABLE ☐

2. Progress Note completed according to regulation  YES ☐  NO ☐  NOT APPLICABLE ☐

3. Orders signed according to regulation  YES ☐  NO ☐  NOT APPLICABLE ☐

4. Laboratory ordered to monitor medication use  YES ☐  NO ☐  NOT APPLICABLE ☐

5. Required signatures and co-signatures present (e.g., Medicare and Therapy Certs, verbal/phone orders)  YES ☐  NO ☐  NOT APPLICABLE ☐

6. Discharge note/summary completed  YES ☐  NO ☐  NOT APPLICABLE ☐

7. Advanced Directives addressed  YES ☐  NO ☐  NOT APPLICABLE ☐

8. Mantoux/PPD testing ordered  YES ☐  NO ☐  NOT APPLICABLE ☐

9. Annual influenza vaccine received  YES ☐  NO ☐  NOT APPLICABLE ☐

10. Pneumococcal vaccine received  YES ☐  NO ☐  NOT APPLICABLE ☐

11. Triggered QIs addressed adequately  YES ☐  NO ☐  NOT APPLICABLE ☐

Comments: 

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Signature: ____________________________

Date: ____________________________
KINDRED HEALTH SERVICES DIVISION MEDICAL ADVISORY BOARD (MAB)

The Kindred Health Services Division Medical Advisory Board (MAB) was created to foster an improved appreciation and understanding of the concerns and issues of the center-based medical staff. The MAB will meet formally, at least twice per year, and conduct ongoing reviews of programs and policies throughout the year.

The MAB consists of physician Medical Directors with backgrounds in family practice, internal medicine, and/or geriatrics and a keen professional interest and commitment to long-term care. They also have an interest in the leadership and management attributes that are inherent in the Medical Director’s role.

MAB members come from a diverse background of nursing center demographics—geographically dispersed; urban and rural; large and small bed size; traditional routine long-stay geriatric; and the growing short-stay rehabilitation, transitional care, and sub-acute populations.

Collectively, the MAB will serve as the liaison between the nursing center Medical Directors and the Company leadership in much the same manner as Kindred’s Executive Director Council and Director of Nursing Services Council.

MAB Members will serve rotating terms, and there will be opportunities for new members to become involved as existing members transition from the Board when their terms expire.

Your center Executive Director will be able to obtain contact information for MAB members should you wish to communicate. All three operating regions of the Health Services Division have at least two MAB members.
RESPONSIBILITIES OF THE ATTENDING PHYSICIAN

1. Provide competent, safe medical care to patients under their care with relevant age-appropriate medical and/or geriatric principles.
2. Orders are related to medically necessary items and services.
3. Conduct physician rounds and timely physician visits for all of your patients and complete appropriate documentation in each resident’s medical record in accordance with their problems, needs, responses to therapies, and applicable regulatory requirements.
4. Coordinate oral and/or written communication, medical plans of care, and treatment between the facility staff, consulting physicians, and other healthcare providers and consultants.
5. Ensure 24-hour availability of physician services by providing on-call and telephone access or designating an alternative, qualified Attending Physician staff member of the facility to do so. The Attending Physician is responsible for finding an appropriate licensed physician to cover, who is also credentialed within the facility.
6. Maintain current professional license and certifications to practice medicine and to prescribe controlled substances in the state in which the facility resides.
7. Obtain and maintain levels of professional liability insurance acceptable to facility administration, including sufficient continuity of coverage for “claims made” policies.
8. Participate as needed in matters of peer review, compliance and quality assurance for the facility.
9. Participate as needed in level-of-care conferences, certifications of medical necessity and placement recommendations for their patients who reside in the facility.
10. Maintain the relevant clinical competencies in the provision of medical care to residents of nursing homes.
11. Maintain confidentiality of resident-specific and facility information.
12. Provide all services in compliance with federal and state laws and regulations governing the provision of physician services and reimbursement for services to residents in nursing facilities.
13. Advise the Medical Director and facility administrator of relevant medical issues affecting the residents of this facility.
14. Maintain good standing to participate in all federal and state healthcare programs.
15. Provide complete financial disclosure to the facility administration regarding relevant financial interests in designated health services to which residents of this facility may be referred.
16. Assume complete responsibility to continuously update their credential files with the most recent information available and to immediately provide written notice to the administrator and Medical Director of any changes or standing to practice medicine under state or federal law.
PHYSICIAN REIMBURSEMENT FOR PATIENT VISITS

Key Points:

*Physicians use specific CPT codes for SNF and NF patient visits.*
*New nursing facility CPT codes were implemented in January 2006.*
*AMDA journals, newsletters and website are great resources for questions about billing issues.*

Medicare Carrier Manual, Chapter 15509.1

Payment for Physician Visits to Residents of Skilled Nursing Facilities and Nursing Facilities

Visits to Comply with Federal Regulations (42 CFR 483.40)

Pay for visits required to monitor and evaluate residents at least once every 50 days for the first 90 days after admission and at least once every 60 days thereafter (some states may require visits every 50 days throughout the resident’s stay).

These visits and all other medically necessary visits for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member are covered under Medicare Part B.

Nursing Home CPT Codes (codes are new as of January 1, 2006)

General guidelines for use of nursing home CPT codes:
• All E & M codes require face-to-face contact (? NF discharges)
• Place of Service (POS) Differential (51 or 52)
  - SNF = POS 31
  - NF = POS 32
  - Note: Medicare payment requires that each billed service be provided with a place of service code. The payment source for the resident is the determining factor for which POS code you are to report in facilities that are dually licensed. If, at the time of your visit, the patient is receiving skilled care (Medicare A, HMO or managed care), the POS is 31. If the patient is receiving intermediate (non-skilled) care (long-term Medicaid, private pay, LTC insurance), the POS is 52.
• Use of templates for visits is acceptable (obviously, must perform all items checked or marked in the document)
  - The AMDA website, www.amda.com, is an excellent reference for reviewing updated information on nursing home CPT codes.

Below are the new descriptors for the redefined nursing facility code family. CPT Codes 99501-99503 and 99511-99513 have been deleted and have been replaced by 99504-99506 and 99507-99510, respectively.

Visits to Provide Initial Nursing Facility Care

99504 Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these three key components:
• a detailed or comprehensive history;
• a detailed or comprehensive examination; and
• medical decision-making that is straightforward or of low complexity.
Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs.

Usually, the problem(s) requiring admission is/are of low severity.

**Sample Vignette:** Initial nursing facility admission visit for an 80-year-old Alzheimer’s patient with associated bowel and bladder incontinence, plus controlled glaucoma, hypertension and moderate osteoarthritis who is no longer able to be maintained at an Assisted Living Facility and is requiring nursing facility placement. He is presently on a topical eye medication, a mild analgesic and a cholinesterase inhibitor but no psychotropics.

99305 Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these three key components:
- a comprehensive history;
- a comprehensive examination; and
- medical decision-making of moderate complexity.

Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs.

Usually, the problem(s) requiring admission is/are of moderate severity.

**Sample Vignette:** Initial nursing facility admission visit for an 88-year-old, cognitively intact patient who suffered a hip fracture from a mechanical fall while living at home. While in the hospital for treatment of the fracture, he developed a UTI and a Stage II heel pressure ulcer. Prior to the fracture he was known to have multiple health problems including controlled CHF and HTN, chronic constipation, BPH, osteoarthritis, old CVA and depression. He was also known to have peripheral perfusion compromise.

99306 Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these three key components:
- a comprehensive history;
- a comprehensive examination; and
- medical decision-making of high complexity.

Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs.

Usually, the problem(s) requiring admission is/are of high severity.

**Sample Vignette:** Initial nursing facility admission visit of a 72-year-old diabetic patient who previously lived at the same nursing facility and is now being admitted post hospitalization for aspiration pneumonitis, blood sugars running in the 500+ range, CHF and delirium associated with on-going history of dementia. She also suffers from chronic atrial fibrillation, constipation, and stress incontinence, and a recent vertebral compression fracture associated with osteoporosis. She returns on IV hydration, antibiotics, O2 and new psychotropics and she requires continued titration of her diabetes and diuretic regimen, control of her pain which is reducing her inspiratory effort, rehabilitation of swallowing and respiratory function and a stabilizing of cardiovascular and mental status.
Visits for Subsequent Nursing Facility Care (there are now four codes in this category):

99307 Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least two of these three key components:
- a problem-focused interval history;
- a problem-focused examination;
- straightforward medical decision-making.

Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs.

Usually, the patient is stable, recovering or improving.

**Sample Vignette:** Subsequent nursing facility visit for evaluation and management of an 88-year-old demented, non-diabetic patient with a previously evaluated Stage IV sacral pressure sore with peripheral, localized inflammation is seen in follow-up to evaluate the wound’s response to present plan of care.

99308 Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least two of these three key components:
- an expanded problem-focused interval history;
- an expanded problem-focused examination;
- medical decision-making of low complexity.

Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs.

Usually, the patient is responding inadequately to therapy or has developed a minor complication.

**Sample Vignette:** Subsequent nursing facility visit for evaluation and management of an acute urinary tract infection in a 55-year-old male with multiple sclerosis with indwelling catheter presenting with new intermittent hematuria and fever.

99309 Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least two of these three key components:
- a detailed interval history;
- a detailed examination;
- medical decision-making of moderate complexity.

Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs.

Usually, the patient has developed a significant complication or a significant new problem.

**Sample Vignette:** Subsequent nursing facility visit for evaluation and management of a 72-year-old patient with COPD, HTN, PVD, GERD, chronic constipation, bladder stress incontinence, osteoarthritis, osteoporosis, dementia and hypothyroidism on 9+ medications is seen for interval disease management of her chronic health issues and also to evaluate the status of a recent URI, increased constipation, new behavioral changes and a skin tear that have occurred since the last medical visit.
Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least two of these three key components:

- a comprehensive interval history;
- a comprehensive examination;
- medical decision-making of high complexity.

Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs.

The patient may be unstable or may have developed a significant new problem requiring immediate physician attention.

Sample Vignette: Subsequent nursing facility visit for evaluation and management of a 69-year-old, long-time resident of a nursing facility with a long history of multi-infarct dementia, non-insulin dependent diabetes mellitus, hypertension, and chronic renal insufficiency develops an acute decline in mental status with decreased intake and vague right-side weakness. The family requests that she not be transferred to the hospital but receive treatment at the facility. Her blood pressure is 188/102, pulse 92/regular and respirations are 20/min off O2. Physical examination reveals a dry mucosa and decreased skin turgor, no cyanosis, reduced lung sounds, no pedal or sacral edema, a soft, non-distended abdomen and a slight right hemiparesis leg>arm. Lab values drawn just prior to visit reveal blood glucose 552, Na 152, BUN 78, creatinine 2.8, Hct 32, Hb10.1, a WBC of 18.0, O2 sat of 87% on room air and a portable CXR that “cannot rule out” an LLL pneumonia.

The discharge codes:

99315 Nursing facility discharge day management; 30 minutes or less
99316 Nursing facility discharge day management; more than 30 minutes

NEW - Annual assessment code:

99318 Evaluation and management of a patient involving an annual nursing facility assessment, which requires these three key components:

- a detailed interval history;
- a comprehensive examination; and
- medical decision-making that is of low to moderate complexity.

Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs.

Usually, the patient is stable, recovering or improving.

Sample Vignette: Annual nursing facility history and physical assessment and MDS/RAI evaluation for a two-year nursing facility resident who is an 84-year-old female with multiple chronic health problems, including: stable controlled hypertension, chronic constipation, osteoarthritis, and moderated stable dementia.

Medicare does not pay separately for the following services:

- Interdisciplinary team (IDT) meetings
- Telephone calls
- Care plan oversight
- Physician standby service
Such services are considered to be “bundled” into the NH visits. You may add time spent in these activities and complexity of the service into the documentation of the next face-to-face visit, which may (or may not) result in choosing a higher subsequent care code.

**Hospital/Nursing Home Transfers and Subsequent Payment Issues**

The following are examples of issues surrounding billing for hospital and nursing home services occurring on the same date and by the same physician.

Nursing facility admission and office/outpatient or emergency department visit on same date by same physician:
- Medicare does not pay for the office or ED visit.
- Medicare will pay only initial nursing facility care code.

Nursing facility visit and hospital visit or admission on same date by same physician:
- Medicare does not pay for the NH visit.
- Medicare will pay only initial hospital care code.

Nursing facility admission and hospital discharge management on same date by same physician:
- Medicare does pay for the hospital discharge visit.
- Medicare will also pay initial nursing facility care code.

Nursing facility admission and hospital observation on same date by same physician:
- Medicare does pay for the hospital observation discharge visit.
- Medicare will also pay initial nursing facility care code.
Key Points:

Federal regulation guides requirements for nursing facility patient visits. Patient visits must be performed timely according to a minimal regulatory visit schedule. Patients may also be seen as often as medically necessary. The medical necessity of a physician visit must be carefully documented in the medical record.

The following guidelines have been developed in accordance with LTC federal regulations at:

F Tag 385, 386, 387, 388, 389 and 390

Attending Physician Responsibilities

A physician oversees the healthcare of each resident, including admission, discharge and transfers as appropriate.

The physician (or midlevel practitioner, where states allow their use) personally visits the resident at least once every 30 days for the first 90 days after admission, and at least once every 60 days thereafter.

- The physician (or midlevel practitioner) is not required to visit the resident at the time of admission.
- A physician visit is considered timely if it occurs not later than 10 days after the date the visit was required. This however, does not affect the next due date.
- In a Medicare-certified center, where states allow their use, a midlevel practitioner may make every other required visit after the initial physician visit.
- In a Medicaid-certified center, in accordance with state law, a midlevel practitioner may satisfy the physician visit requirement.
- Allowance of visits by a midlevel practitioner does not relieve the physician of the obligation to visit a resident when the resident’s medical condition makes that visit necessary.
- It is expected that visits will occur at the center rather than the physician’s office unless office equipment is needed or a resident specifically requests an office visit.

Physician services are available 24 hours a day in case of emergency.

- If the resident’s own physician is unavailable, the center should attempt to contact that physician’s designated referral (on call) physician before assuming the responsibility of assigning a physician.
- Arrangement for physician services may include assuring resident transportation to a hospital emergency department or other medical center if the center is unable to provide emergency medical care at the center.

During a physician’s visit, the physician must:

- Review the resident’s total program of care at each required visit that includes:
  - Medical services,
  - Medication management,
- Physical, occupational, and speech/language therapy,
- Nursing care,
- Nutritional interventions, and
- Social work and activity services that maintain or improve psychosocial functioning.

- Write, sign and date progress notes at each visit that include the resident’s progress and problems in maintaining or improving his/her mental and physical functional status; and

- Sign and date all orders

**Physician Orders**

- Admission order for the resident's immediate care is acceptable as “personal approval” of the admission.

NOTE: There is no requirement for face-to-face contact with the physician at the time of admission, since the decision to admit an individual to a nursing center (whether from a hospital or from the individual's own residence) generally involves physician contact during the period immediately preceding the admission.

- Physician orders may be transmitted by facsimile machine if the following conditions are met:
  - The physician should have signed and retained the original copy of the order from which the facsimile was transmitted and be able to provide it upon request. Alternatively, the original may be sent to the center at a later time and substituted for the facsimile.
  - The center should photocopy the faxed order if the order is received on a machine that uses thermal paper that fades over time. The facsimile copy can be destroyed after the center photocopies it.
  - A center using such a system should establish adequate safeguards to assure that it is not subject to abuse.
  - It is not necessary for a physician to re-sign the facsimile order when he or she visits.

- When the center's management authorizes rubber stamp signatures, the individual whose signature the stamp represents places in the administrative offices of the center a signed statement to the effect that he/she is the only one who has the stamp and uses it. A list of computer codes and written signatures are readily available and maintained under adequate safeguards.

- **Standing Orders**
  - “Standing orders” are orders created by facility policies and procedures, approved by the Medical Director for application to all residents. CMS currently recommends the use of standing orders only for Influenza vaccination and Pneumovax.

- **Routine Orders**
  - “Routine orders” are orders generally created by a physician or group of physicians, signed and dated, designed for only those patients admitted to their service. These are generally PRN orders for OTC medications and other minor treatments for minor conditions.
  - Physicians are encouraged to work with one another and the center
nursing staff to develop appropriate and consistent routine orders. One set of routine orders that were agreeable to all physicians would be optimal.

– Routine orders will still need to be entered into the initial admission orders by the nursing staff and entered into the order system of the electronic record (RCS) for each resident admission.

The center supports regulations regarding Attending Physician services:

• Assist the resident, when necessary, in his or her efforts to obtain Attending Physician services.
• Support the physicians’ efforts to meet their responsibilities.
• Share the MDS and other assessment data with the physician.

Consultative services are made available from community-based consultants or from a local hospital or medical center.

Residents are provided with treatment and care for specialized professional services. Services may include, but are not limited to:

• Podiatry
• Audiology
• Optometry
• Dentistry

Hospital inpatient service or procedures are provided at one or more local hospitals.

At the discretion of the Medical Director and Executive Director, a center may require that each Attending Physician review and sign a practice agreement for Attending Physicians and place in their credential file.

• [FRM 00007-15] Performance Requirements and Practice Agreement for Attending Physicians
• Each Attending Physician is expected to fulfill basic responsibilities as outlined in the Attending Physician practice agreement.

Licensed Independent Practitioner (LIP) Qualifications and Credentials

Each LIP practicing in the center has a current license to practice in the state where the center is located, training and experience that is relevant to the center population, and agrees to abide by the center’s policies and procedures.

Each LIP has submitted the following to the Executive Director:

• A copy of current license
• A copy of current malpractice insurance coverage
• Any other credentials or documentation required by the center for purposes of its licensure, accreditation, or legal or regulatory compliance.

NOTE: Some of these credentials may be obtained from a local hospital at which the Licensed Independent Practitioner has privileges. Such credentials do not automatically imply eligibility to practice at the center, but will be taken into account when reviewing qualifications.

The Executive Director/designee keeps the files up to date and informs the Medical Director if a LIP fails to provide updates as requested.
The Medical Director reviews the information submitted by the LIP.

The Medical Director exercises his or her authority, as necessary, to promote compliance with this policy.

NOTE: Centers applying for Joint Commission Accreditation (JCAHO) must follow the specific standards and requirements mandated by JCAHO.
THE RESIDENT ASSESSMENT INSTRUMENT (RAI) AND MINIMUM DATA SET (MDS)

Key Points:

The Resident Assessment Instrument (RAI) and Minimum Data Set (MDS) are federally required patient assessment tools that must be completed and submitted to the state. Key elements of the MDS Assessments populate the Quality Indicator/Quality Measure Reports. The MDS Assessments also drive reimbursement via the Resource Utilization Groups (RUGS).

Overview of the Resident Assessment Instrument

Providing care to residents with post-acute and long-term care needs is complex and challenging work. It utilizes clinical competence, observational skills and assessment expertise from all disciplines to develop individualized care plans. The Resident Assessment Instrument (RAI) helps facility staff to gather definitive information on a resident’s strengths and needs, which must be addressed in an individualized care plan. It also assists staff to evaluate goal achievement and revise care plans accordingly by enabling the facility to track changes in the resident’s status. As the process of problem identification is integrated with sound clinical interventions, the care plan becomes each resident’s unique path toward achieving or maintaining his or her highest practicable level of well-being.

The RAI helps facility staff to look at residents holistically — as individuals for whom quality of life and quality of care are mutually significant and necessary. Interdisciplinary use of the RAI promises this very emphasis on quality of care and quality of life. Facilities have found that involving disciplines such as dietary, social work, physical therapy, occupational therapy, speech-language pathology, pharmacy, and activities in the RAI process has fostered a more holistic approach to resident care and strengthened team communication.

Persons generally enter a nursing facility due to functional status problems caused by physical deterioration, cognitive decline, the onset or exacerbation of an acute illness or condition, or other related factors. The individual’s ability to manage independently has been limited to the extent that skilled nursing, medical treatment, and/or rehabilitation is needed for residents to maintain and/or restore function or to live safely from day to day. While we recognize that there are often unavoidable declines, particularly in the last stages of life, all necessary resources and disciplines must be used to ensure that residents achieve the highest level of functioning possible (quality of care) and maintain their sense of individuality (quality of life). This is true for long-term residents, as well as the resident in a rehabilitative program anticipating return to a less restrictive environment.

Clinicians are generally taught a problem identification process as part of their professional education. For example, the nursing profession’s problem identification model is called the nursing process, which consists of assessment, planning, implementation and evaluation. The RAI simply provides a structured, standardized approach for applying a problem identification process in long-term care facilities.
Content of the RAI for Nursing Facilities

The RAI consists of three basic components:

1. **Minimum Data Set (MDS) Version 2.0**

2. **Resident Assessment Protocols (RAPs), and**


Utilization of the three components of the RAI yields information about a resident's functional status, strengths, weaknesses, and preferences and offers guidance on further assessment once problems have been identified. Each component flows naturally into the next as follows:

- **Minimum Data Set (MDS).** A core set of screening, clinical, and functional status elements (over 200 elements), including common definitions and coding categories, that forms the foundation of the comprehensive assessment for all residents of long-term care facilities certified to participate in Medicare or Medicaid. The items in the MDS standardized communication about resident problems and conditions within facilities, between facilities, and between facilities and outside agencies.

- **Resident Assessment Protocols (RAPs).** The RAPs are structured, problem-oriented frameworks for organizing MDS information and examining additional clinically relevant information about an individual. RAPs help identify social, medical, and psychological problems and form the basis for individualized care planning. There are 18 RAPs.

- **Utilization Guidelines.** Instructions concerning when and how to use the RAI.

Additional Uses of the Minimum Data Set

Over the course of time, the role of the MDS has expanded beyond its primary purpose as an assessment tool used to identify resident care problems that are addressed in an individualized care plan. Data collected from MDS assessments is used for the Medicare reimbursement system and many state Medicaid reimbursement systems and to monitor the quality of care provided to nursing facility residents. The MDS instrument has also been adapted for the hospital swing bed program. Swing bed providers are required to complete a unique two-page MDS for the Medicare Prospective Payment System (PPS).

Medicare and Medicaid Payment Systems

The MDS contains items that reflect the acuity level of the resident, including diagnoses, treatments and an evaluation of the resident's functional status. The MDS is used as a data collection tool to classify Medicare and Medicaid residents into the Resource Utilization Groups (RUG-III). The RUG-III Classification system is used in the Prospective Payment System for nursing facilities, hospital swing bed programs, and in many state Medicaid case mix payment systems to group residents into similar resource usage categories for the purposes of reimbursement. Beginning in 2006, CMS increased the number of RUGs groups from 44 to 53, adding nine new RUG categories to essentially define a higher acuity patient population requiring more extensive nursing care as well as rehabilitation.
Monitoring the Quality of Care

MDS assessment data is also used to monitor the quality of care in the nation’s nursing facilities. In the early 1990s, an original set of 24 quality indicators (QIs) was developed by researchers to assist state surveyors to identify potential care problems in a nursing facility. CMS has made additions and modifications to further enhance the effectiveness of the QI system. Beginning in 2005, a set of 30 QI/QM indicators became available to providers to assist them in their ongoing quality improvement activities, to surveyors to assist in identifying potential problem areas that should be addressed during the survey process, and to CMS for long-term quality monitoring and program planning.

Consumers are also able to access information about every Medicare and Medicaid certified nursing facility in the country. The Nursing Home Compare tool available at www.medicare.gov provides the following sections of detailed information:

- About the Nursing Facility: Including the number of beds and type of ownership.
- About the Nursing Facility Inspection: Including health deficiencies found during the most recent state nursing facility survey and from recent substantiated complaint investigations.
- About the Nursing Facility Staff: Including the average number of hours worked by registered nurses, licensed practical nurses and certified nursing assistants per resident per day.
- About the Quality of Care Received at the Facility: In 2002, CMS began a new program called the Nursing Home Quality Initiative (NHQI). The purpose of this program is to provide consumers with information on the quality of care delivered in nursing facilities to help them make informed decisions. CMS expanded the original quality indicators to a set of 32 quality measures/quality indicators (QM/QI). These quality measure domains include pain and measures for the short-stay and post-acute population. The quality measures are posted on the Nursing Home Compare website, a CMS developed internet search tool to allow comparisons between nursing facilities.

The Nursing Home Compare website is: www.medicare.gov/nhcompare/home.asp.

Statutory and Regulatory Basis for the RAI in Nursing Facilities

Minimum Data Set (MDS): The statutory authority for the MDS Version 2.0 and the RAI is found in Section 1819(f)(6)(A-B) for Medicare and 1919 (f)(6)(AB) for Medicaid in the Social Security Act, as amended by the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987).

Federal requirements at 42 CFR 485.20(b)(1)(i)—(F272) require that facilities use an RAI that has been specified by the state. This assessment system provides a comprehensive, accurate, standardized, reproducible assessment of each long-term care facility resident's functional capabilities and helps staff to identify health problems. The federal requirement also mandates facilities to encode and electronically transmit the MDS data from the facility to the state MDS database.
CMS QUALITY INDICATORS AND QUALITY MEASURES

Background of Quality Indicators (QI)

In 1989, the Health Care Financing Administration (HCFA) [now known as the Centers for Medicare and Medicaid Services (CMS)] and the Office of Research and Demonstrations (ORD) funded a multi-state Nursing Home Case Mix and Quality Demonstration (NIHCMQ). The purpose of the demonstration was to develop a system that would classify residents into groups for equitable prospective payment and monitor quality of both processes and outcomes of care.

As a result of this demonstration, a reporting system called the Quality Monitoring System was developed by the Center for Health Systems Research and Analysis (CHSRA). Data reported by facilities on the Minimum Data Set (MDS) are used to create Quality Indicators (QIs) that relate to common conditions and aspects of resident care and quality of life. These QI scores and reports help nursing homes (NHs) plan their internal quality improvement initiatives. State surveyors in the NH survey process also use QI scores and reports to help plan decisions before surveying a facility.

Consolidated MDS QI/QM Reports

In 2005, a second set of publicly reported nursing home quality measures (QMs) found on the Nursing Home Compare website were combined with the original quality indicators (QIs) for both surveyors and facilities in the form of a revised and consolidated QI/QM report. This consolidated report will allow nursing facilities to have more up-to-date information on the QMs to help guide their quality improvement efforts. It will also allow surveyors to have and use the information provided by the QMs, as well as the QIs to help guide them as they plan surveys of facilities. It is important to remember that the QM values being reported on Nursing Home Compare will not match the values on the facilities’ consolidated QI/QM reports because they are based on different timeframes.

The new Consolidated QI/QM Facility Reports:

- A new user interface was created due to the reports being generated from the central CASPER system, as opposed to the state system.
- The addition of a QI/QM trend report so facilities can track how they’re doing over a period of time.
- QI/QM measure calculation every weekend, with refreshed scores available every Monday.
- QMs reported in CASPER are not risk-adjusted. This is due to the fact that they are being supplied for use by the facility and not as a comparison across nursing homes where a risk adjustment would make sense.
- Availability of resident level reports that map directly to the publicly reported NH QMs.
- QIOs (Quality Improvement Organizations) are to refer NHs to their state survey agency when they have questions or problems with these reports.
- The survey process will not change as a result of surveyors having the additional QM information.
Complete Listing of the QI/QMs

12 Domain Groups Plus Post-Acute Care (PAC) Measures and 50 Total QI/QMs

1. Accidents
   • 1.1 Incidence of new fractures
   • 1.2 Prevalence of falls

2. Behavior/Emotional Patterns
   • 2.1 Residents who have become more depressed or anxious
   • 2.2 Prevalence of behavioral symptoms affecting others (HIGH risk and LOW risk)
   • 2.3 Prevalence of depression without antidepressant therapy

3. Clinical Management
   • 3.1 Use of nine or more different medications

4. Cognitive Patterns
   • 4.1 Incidence of cognitive impairment

5. Elimination/Incontinence
   • 5.1 Low-risk residents who lost control of their bowels or bladder
   • 5.2 Residents who have/had a catheter inserted and left in their bladder
   • 5.3 Prevalence of occasional or frequent bladder or bowel incontinence without a toileting plan
   • 5.4 Prevalence of fecal impaction

6. Infection Control
   • 6.1 Residents with a UTI

7. Nutrition/Eating
   • 7.1 Residents who lose too much weight
   • 7.2 Prevalence of tube feeding
   • 7.3 Prevalence of dehydration

8. Pain Management
   • 8.1 Residents who have moderate to severe pain

9. Physical Functioning
   • 9.1 Residents whose need for help with daily activities has increased
   • 9.2 Residents who spend most of their time in bed or in a chair
   • 9.3 Residents whose ability to move in and around in their room got worse
   • 9.4 Incidence of decline in ROM

10. Psychotropic Drug Use
    • 10.1 Prevalence of antipsychotic use in the absence of psychotic and related conditions (HIGH risk and LOW risk)
    • 10.2 Prevalence of any anti-anxiety/hypnotic use
    • 10.3 Prevalence of hypnotic use more than two times in the past week

11. Quality of Life
    • 11.1 Residents who were physically restrained
    • 11.2 Prevalence of little or no activity
12. Skin Care  
   • 12.1 High-risk residents with pressure ulcers  
   • 12.2 Low-risk residents with pressure ulcers  

15. Post Acute Care (PAC) Measures  
   • 15.1 Short-stay residents with delirium  
   • 15.2 Short-stay residents who had moderate to severe pain  
   • 15.3 Short-stay residents with pressure ulcers  

The facility-specific QI/QM results are listed in the report along with comparison percentages for the state in which the nursing facility is located as well as the nation at large. Determining how an individual facility compares to the state and national averages can be helpful in assessing quality of care and services. However, it is important to note that variations in patient acuity and admissions practices can also impact these comparisons.  

The QI/QMs help to identify areas for potential concern. However, only a careful review of the patients involved in a particular QI/QM plus a review of the “care systems” in the nursing facility can help determine whether a facility’s negative variation from the state or national averages is due to care issues or patient acuity/admission practices.  

Medical Directors need to be familiar with the new QI/QMs as they will be reviewed in Kindred’s monthly Performance Improvement Committee meetings.
FAMILY EDUCATION

Key Points:

Today’s vertically integrated healthcare system with multiple sites of care can be confusing to both the patient and their families, and cause unnecessary conflict. Medical Directors and LTC Attending Physicians can be instrumental in helping families develop realistic expectations for care and services in the nursing facility setting. The first steps in clarifying expectations are education and communication. Angel Care is an important program to enhance patient and family satisfaction.

Due to societal changes that have occurred during the past century, we now have a generation or two of individuals with little or no direct experience with death and dying. Many families approach the decline of an aging loved one as though it was the first time it ever happened in the history of mankind. Guilt, denial, frustration, and unrealistic expectations may cloud the better judgment of otherwise very level-headed and even-tempered individuals.

It is imperative that an experienced and caring medical community communicate clearly with family members so they may better understand their loved one’s medical condition and prognosis. Helping family members to form realistic expectations for nursing center care is an important part of the admission process. Below are excerpts from Family Education materials available to families on admission to a Kindred center. There are brochures and a video also available to families for their review.

A Door Opens

Phases of life often begin with change.

At Kindred Healthcare, we know that life changes – one door opening as another door closes – can occur at the most unexpected times, in the most unexpected ways. And our doors are open to help you deal with the changes that you and your loved one are experiencing.

Kindred’s Family Education Program: Partners in Caring focuses on answering questions, offering information and insight, and helping you or your loved one through the admission process into one of our nursing homes, whether for a short-term stay or for long-term recovery. Our aim is to convey facts about what to expect, listen to your concerns, and, above all, open the door to reveal what life is like in a Kindred nursing home.

Creating a Partnership

Partners in Caring is designed to educate, inform and assist in the formation of realistic expectations about nursing homes. The first step is to outline what must occur in order for the resident and his or her family to make realistic decisions about long-term healthcare. Entering a nursing home requires adaptation on the part of the resident and his or her support network. We can help by informing you about what to expect as this new life phase begins.

Our objective is to teach you and your loved ones by listening to your questions and concerns and by giving you as much information as possible about aging, as well as about choosing a nursing home and the quality of life it offers.
**Short-Term Rehabilitation**

A nursing home generally includes two types of residents – those who are receiving short-term rehabilitation to recover from an injury or illness and those with multiple medical, cognitive, or emotional problems or illnesses who are receiving long-term care.

Whenever possible, the short-term resident is sent home. In some cases, they resume their lives and continue their recovery; in other cases, they may experience a relapse or another health issue and be readmitted.

**Realities about Aging**

**Challenges**
There is no fountain of youth, no magic potion to diminish the effects of the aging process. Aging inevitably brings on physical, mental and emotional challenges for the people who are aging, as well as the loved ones caring for them. Hearing and vision are almost always affected to some degree, and even a mild infection can have a serious impact on a resident’s fragile state of health. Many mental changes are a normal part of the aging process, including decreased memory and slower thinking. Pain from a joint or muscle problem also becomes more frequent.

Fear and apprehension about these changes can be reduced by open, honest conversation. And the support of family or friends is very important in several ways:

- to keep the resident engaged in what is going on around the nursing home as well as engaged with his or her family
- to provide valuable information to caregivers and staff about the person’s unique characteristics, including family and work history, food preferences, and activities they find enjoyable
- to assist caregivers in keeping the resident comfortable
- to alert the staff to any history of falls or wandering
- to help the resident maintain a balance between independence and appropriate risk

**Stress**
Upon admission to a nursing home, a resident might feel disoriented and stressed over the new environment. Moving at any age is difficult, and sometimes a move to a nursing home may have overtones of finality or, at least, semi-permanence.

Very few family members admit their loved ones to a nursing home without experiencing feelings of guilt – even if caring for that loved one at home has become an overwhelming task. This stage of life is filled with conflicting emotions, and guilt is a natural part of that. One way to deal with any guilt feelings is to stay involved through regular visits, by getting to know the staff, and by acting as an advocate for your loved one.

**Working Together through Angel Care**
To help keep communication open between family members and caregivers, Kindred’s Angel Care program offers yet another dimension of care. This one-on-one program pairs an Angel Care representative with a resident in order to focus extra attention on the needs of the people we care for.

As the Angel Care representative and resident form a special friendship, our commitment to our residents and family members is emphasized. For more information on the Angel Care program, contact the Executive Director of your nursing home.
As We Age...

Through the efforts of researchers, physicians and other caregivers, we know and understand more about how we age than ever before. Because many of the elderly have multiple health, psychological, and emotional issues, it’s more difficult to diagnose and treat illnesses. In addition, a longer recovery time makes it difficult to determine if treatments are working. Although this list certainly is not all-inclusive, here are a few effects and risk factors involved in aging:

- Bone density decreases. This is a fact in virtually all women and men from about age 50.
- Risk of falling increases. Each year, over 30% of senior citizens experience falls at home.
- Appetite may decrease. The change in the sense of taste and smell that most people experience as they age may lead to a diminished appetite.
- Risk of dehydration increases. As people age, their ability to sense thirst can lessen, making dehydration more difficult to detect or diagnose.
- Skin becomes more fragile. As we age, our skin becomes less elastic and the layer of fat under our skin decreases.
- Mental status/ability may change. Even senior citizens with no history of Alzheimer’s or other dementia experience some normal mental changes as they age, including decreased memory, confusion, or a decline in intellectual function.
- Incontinence problems may develop. Whether through decreased awareness of bodily function or muscle weakness, incontinence occurs often in the elderly.
In the year 2000, Medicare paid for approximately 67% of hospital care, 61% of physician costs for care of the elderly, and 8% of nursing facility care. Much public debate has centered on the rising cost of care in the last six months of life and policy makers, worried about the aging population, are carefully scrutinizing these costs.

Although Medicare payment for hospital care dwarfs payments to nursing facilities, Medicare payment to nursing facilities is increasing as patients are discharged from hospitals to nursing facilities quicker and sicker than ever before. In fact, policy trends in both the public and private sector may be driving this increase in Medicare payments to nursing facilities, as payors seek to move patients out of higher-cost centers and into lower-cost environments.

The following paragraphs briefly outline Medicare benefits in regard to payment for services in the healthcare continuum.

**Medicare Part A**

Medicare Part A covers:

- Inpatient hospital stays
- Skilled care at a nursing center
- Hospice

To qualify for Medicare Part A benefits in a nursing center, a qualifying three-day stay in a hospital must occur within 30 days of the admission to the nursing center. Medicare benefits include up to 100 days of care within a calendar year:

- Days 1 – 20: no deductible or co-pay
- Days 20 – 100: co-pay
- >100 days: no coverage

**Medicare Part B**

Medicare Part B covers:

- Physician services
- Outpatient
  - Diagnostics
  - PT, OT, speech therapy
  - Audiology
  - Some ambulance services
  - Some home health

**Medicare Carriers**

Medicare carriers are local insurance companies that contract with CMS to do Part B billing (some also do Part A). Medicare carriers follow broad national guidelines found in the Medicare Carrier Manual. Chapter 15 deals with fee schedules for physician services. Section 15509 deals with nursing home codes.

However, these guidelines may be modified by Local Medical Review Policy (LMRP). LMRPs are individualized guidelines specific to each carrier. They generally follow the AMDA CPT descriptions and CMS guidelines.
1. Your mailbox is located ____________________________________________________.
   (insert location)

2. The primary fax number is ________________________________________________.
   (insert number)

5. Meeting Schedule: (Attach a calendar)
   a. Meeting with Executive Director (ED) and Director of Nursing Services (DNS) occurs on
      ____________________________________________.
      (This meeting should occur at least monthly at a time convenient to the Medical Director.)
   b. Monthly Performance Improvement Meeting occurs
      ____________________________________________.
      (insert time and location)
   c. Infection Control meeting occurs
      ____________________________________________.
      (if separate from PI)
   d. The Rehab Team Meeting is held
      ____________________________________________.
      (insert time frame)
   e. The Ethics Committee is held
      ____________________________________________.
      (insert time frame)
   f. Others
      ____________________________________________.
      (list)?

4. The lab company we utilize is
   ____________________________________________.
   Phone number and representative’s name are
   ____________________________________________.
   The standard lab draw occurs at
   ____________________________________________.
   (time)
The expected lab turnaround is

(time in hours)

The expected stat lab turnaround is

(time in hours)

5. The mobile X-ray company is

The expected turn around time for stat X-ray is

(time in hours)

6. Our pharmacy provider is Kindred Pharmacy Services (KPS); a copy of the Kindred formulary can be received from

This is to be utilized with our Medicare Part A residents.

7. Our medical supplies distributor is

We follow the Kindred wound care formulary.

8. Our facility follows all applicable state laws and guidelines for CPR. The identification process for residents with “No Code” or “DNR” orders is


# IMPORTANT NAMES AND PHONE NUMBERS

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<th>Role</th>
<th>Name</th>
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<td>Executive Director</td>
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<td>Staff Development Coordinator</td>
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<td>Consultant Pharmacist</td>
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<td>Admissions Director</td>
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<td>Case Manager</td>
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<td>Social Services Director</td>
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<td>Director of Respiratory</td>
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<td>Business Office Manager</td>
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<td>District Director of Operations</td>
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<td>District Director of Clinical Operations</td>
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<td>Attending Physician 1</td>
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<td>Mid-Level Practitioners (NP/PA)</td>
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<td>Podiatrist</td>
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<td>Ophthalmologist</td>
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<td>Psychiatrist</td>
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Excerpts from the LTC Federal Regulations

This Appendix includes excerpts from the LTC federal regulations most germane to Medical Director and Attending Physician services. In some cases, only the F tag number and regulation are included. In other instances, where physicians may have an interest in the level of detail with which the surveyors are judging compliance, the F tag, regulation and Guidance to Surveyors language are included.

Many physicians may be surprised at the substantive nature of the information included in the Guidance to Surveyors in F tags related to, for example: unnecessary drugs, pressure sores, urinary incontinence and restraints. Generally speaking, LTC regulations are based on sound clinical practice standards and, occasionally, on expert opinion where the literature is scant. Reviewing the Guidance to Surveyors may allow for an enhanced dialogue with the nursing center staff (particularly, nurses, pharmacists, therapists and social workers) as they endeavor to comply with the LTC regulations.
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RESIDENT RIGHTS

§483.10 Resident Rights

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following rights:

Interpretive Guidelines §483.10

All residents in long-term care facilities have rights guaranteed to them under federal and state law. Requirements concerning resident rights are specified in §§483.10, 483.12, 483.13 and 483.15. Section 483.10 is intended to lay the foundation for the remaining resident’s rights requirements which cover more specific areas. These rights include the resident’s right to:

- Exercise his or her rights;
- Be informed about what rights and responsibilities he or she has;
- If he or she wishes, have the facility manage his personal funds;
- Choose a physician and treatment and participate in decisions and care planning;
- Privacy and confidentiality;
- Voice grievances and have the facility respond to those grievances;
- Examine survey results;
- Work or not work;
- Privacy in sending and receiving mail;
- Visit and be visited by others from outside the facility;
- Use a telephone in privacy;
- Retain and use personal possessions to the maximum extent that space and safety permit;
- Share a room with a spouse, if that is mutually agreeable;
- Self-administer medication, if the interdisciplinary care planning team determines it is safe; and
- Refuse a transfer from a distinct part, within the institution.

A facility must promote the exercise of rights for each resident, including any who face barriers (such as communication problems, hearing problems and cognition limits) in the exercise of these rights. A resident, even though determined to be incompetent, should be able to assert these rights based on his or her degree of capability.
§483.10(a) Exercise of Rights

§483.10(a)(1) The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

§483.10(a)(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights.

§483.10(a)(3) In the case of a resident adjudged incompetent under the laws of a state by a court of competent jurisdiction, the rights of the resident are exercised by the person appointed under state law to act on the resident’s behalf.

§483.10(a)(4) In the case of a resident who has not been adjudged incompetent by the state court, any legal-surrogate designated in accordance with state law may exercise the resident’s rights to the extent provided by state law.

§483.10(b)(2) The resident or his or her legal representative has the right —

(i) Upon an oral or written request, to access all records pertaining to himself or herself including current clinical records within 24 hours (excluding weekends and holidays); and

(ii) After receipt of his or her records for inspection, to purchase at a cost not to exceed the community standard photocopies of the records or any portions of them upon request and two working days advance notice to the facility.

§483.10(b)(4) The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section; and

Interpretive Guidelines §483.10(b)(4)

“Treatment” is defined as care provided for purposes of maintaining/restoring health, improving functional level or relieving symptoms.
“Experimental research” is defined as development and testing of clinical treatments, such as an investigational drug or therapy, that involve treatment and/or control groups. For example, a clinical trial of an investigational drug would be experimental research.

“Advance directive” means a written instruction, such as a living will or durable power of attorney for healthcare, recognized under state law relating to the provision of healthcare when the individual is incapacitated.

As provided under state law, a resident who has the capacity to make a healthcare decision and who withholds consent to treatment or makes an explicit refusal of treatment either directly or through an advance directive, may not be treated against his/her wishes.

A facility may not transfer or discharge a resident for refusing treatment unless the criteria for transfer or discharge are met. (See §483.12(a)(1) and (2).)

If the resident is unable to make a healthcare decision, a decision by the resident's surrogate or representative to forego treatment may, subject to state law, be equally binding on the facility. The facility should determine exactly what the resident is refusing and why. To the extent the facility is able, it should address the resident’s concern. For example, a resident requires physical therapy to learn to walk again after sustaining a fractured hip. The resident refuses therapy. The facility is expected to assess the reasons for this resident’s refusal, clarify and educate the resident as to the consequences of refusal, offer alternative treatments, and continue to provide all other services.

If a resident’s refusal of treatment brings about a significant change, the facility should reassess the resident and institute care planning changes. A resident’s refusal of treatment does not absolve a facility from providing a resident with care that allows him or her to attain or maintain his or her highest practicable physical, mental and psychosocial well-being in the context of making that refusal.

The resident has the right to refuse to participate in experimental research. A resident being considered for participation in experimental research must be fully informed of the nature of the experiment (e.g., medication, treatment) and understand the possible consequences of participating. The opportunity to refuse to participate in experimental research must occur prior to the start of the research. Aggregated resident statistics that do not identify individual residents may be used for studies without obtaining residents’ permission.

§483.10(b)(1) The facility must inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility. The facility must also provide the resident with the notice (if any) of the state developed under §1919(e)(6) of the act. Such notification must be made prior to or upon admission and during the resident's stay. Receipt of such information, and any amendments to it, must be acknowledged in writing.
SELF-ADMINISTRATION OF DRUGS

§483.10(n) Self-Administration of Drugs

An individual resident may self-administer drugs if the interdisciplinary team, as defined by §483.20(d)(2)(ii), has determined that this practice is safe.

Interpretive Guidelines §483.10(n)

If a resident requests to self-administer drugs, it is the responsibility of the interdisciplinary team to determine that it is safe for the resident to self-administer drugs before the resident may exercise that right. The interdisciplinary team must also determine who will be responsible (the resident or the nursing staff) for storage and documentation of the administration of drugs, as well as the location of the drug administration (e.g., resident’s room, nurses’ station or activities room). Appropriate notation of these determinations should be placed in the resident’s care plan.

The decision that a resident has the ability to self-administer medication(s) is subject to periodic re-evaluation based on change in the resident’s status. The facility may require that drugs be administered by the nurse or medication aide, if allowed by state law, until the care planning team has the opportunity to obtain information necessary to make an assessment of the resident’s ability to safely self-administer medications. If the resident chooses to self-administer drugs, this decision should be made at least by the time the care plan is completed within seven days after completion of the comprehensive assessment.

Medication errors occurring with residents who self-administer drugs should not be counted in the facility’s medication error rate (see Guidelines for §483.25(m)), but should call into question the judgment made by the facility in allowing self-administration for those residents.
§483.12 Admission, Transfer and Discharge Rights

§483.12(a) Transfer and Discharge

(1) Definition

Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.

F201

§483.12(a)(2) Transfer and Discharge Requirements

The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless —

(i) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

(ii) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;

(iii) The safety of individuals in the facility is endangered;

(iv) The health of individuals in the facility would otherwise be endangered;

(v) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a nursing facility, the nursing facility may charge a resident only allowable charges under Medicaid; or

(vi) The facility ceases to operate.

See Guidance Under Tag 202

F202

§483.12(a)(3) Documentation

When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident's clinical record must be documented. The documentation must be made by —

(i) The resident's physician when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and
(ii) A physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section.

Interpretive Guidelines §483.12(a)(2) and (3)

If transfer is due to a significant change in the resident's condition, but not an emergency requiring an immediate transfer, then prior to any action, the facility must conduct the appropriate assessment to determine if a new care plan would allow the facility to meet the resident's needs. (See §485.20(b)(4)(iv), F274, for information concerning assessment upon significant change.)

Conversion from a private pay rate to payment at the Medicaid rate does not constitute non-payment.

Refusal of treatment would not constitute grounds for transfer, unless the facility is unable to meet the needs of the resident or protect the health and safety of others.

Documentation of the transfer/discharge may be completed by a physician extender unless prohibited by state law or facility policy.
F221

Use Tag F221 for deficiencies concerning physical restraints.

Use Guidance Under Tag F222

F222

Use Tag F222 for deficiencies concerning chemical restraints.

§483.13(a) Restraints

The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident’s medical symptoms.

Intent §483.15(a)

The intent of this requirement is for each person to attain and maintain his or her highest practicable well-being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints.

Interpretive Guidelines §483.15(a)

Definitions of Terms

“Physical restraints” are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident’s body that the individual cannot remove easily which restricts freedom of movement or normal access to one’s body.

“Chemical restraints” is defined as any drug that is used for discipline or convenience and not required to treat medical symptoms.

“Discipline” is defined as any action taken by the facility for the purpose of punishing or penalizing residents.

“Medical symptom” is defined as an indication or characteristic of a physical or psychological condition.

Restraints may not be used for staff convenience. However, if the resident needs emergency care, restraints may be used for brief periods to permit medical treatment to proceed unless the facility has a notice indicating that the resident has previously made a valid refusal of the treatment in question. If a resident’s unanticipated violent or aggressive behavior places him or her or others in imminent danger, the resident does not have the right to refuse the use of restraints. In this situation, the use of restraints is a measure of last resort to protect the safety of the resident or others and must not extend beyond the immediate episode. The resident’s right to participate in care planning and the right to refuse treatment are addressed at §§483.20(k)(2)(ii) and 483.10(b)(4), respectively, and include the right to accept or refuse restraints.
“Physical restraints” include, but are not limited to, leg restraints, arm restraints, hand mitts, soft ties or vests, lap cushions and lap trays the resident cannot remove easily. Also included as restraints are facility practices that meet the definition of a restraint, such as:

- Using side rails that keep a resident from voluntarily getting out of bed;
- Tucking in or using Velcro to hold a sheet, fabric or clothing tightly so that a resident’s movement is restricted;
- Using devices in conjunction with a chair, such as trays, tables, bars or belts, that the resident can not remove easily, that prevent the resident from rising;
- Placing a resident in a chair that prevents a resident from rising; and
- Placing a chair or bed so close to a wall that the wall prevents the resident from rising out of the chair or voluntarily getting out of bed.

Side rails sometimes restrain residents. The use of side rails as restraints is prohibited unless they are necessary to treat a resident’s medical symptoms. Residents who attempt to exit a bed through, between, over or around side rails are at risk of injury or death.

The potential for serious injury is more likely from a fall from a bed with raised side rails than from a fall from a bed where side rails are not used. They also potentially increase the likelihood that the resident will spend more time in bed and fall when attempting to transfer from the bed.

As with other restraints, for residents who are restrained by side rails, it is expected that the process facilities employ to reduce the use of side rails as restraints is systematic and gradual to ensure the resident’s safety while treating the resident’s medical symptom.

The same device may have the effect of restraining one individual but not another, depending on the individual resident’s condition and circumstances. For example, partial rails may assist one resident to enter and exit the bed independently while acting as a restraint for another.

Orthotic body devices may be used solely for therapeutic purposes to improve the overall functional capacity of the resident.

An enclosed framed wheeled walker, with or without a posterior seat, would not meet the definition of a restraint if the resident could easily open the front gate and exit the device. If the resident cannot open the front gate (due to cognitive or physical limitations that prevent him or her from exiting the device or because the device has been altered to prevent the resident from exiting the device), the enclosed framed wheeled walker would meet the definition of a restraint since the device would restrict the resident’s freedom of movement (e.g., transferring to another chair, to the commode or into the bed). The decision on whether framed wheeled walkers are a restraint must be made on an individual basis.

“Medical symptom” is defined as an indication or characteristic of a physical or psychological condition.
The resident's medical symptoms should not be viewed in isolation, rather the symptoms should be viewed in the context of the resident's condition, circumstances and environment. Objective findings derived from clinical evaluation and the resident's subjective symptoms should be considered to determine the presence of the medical symptom. The resident's subjective symptoms may not be used as the sole basis for using a restraint. Before a resident is restrained, the facility must determine the presence of a specific medical symptom that would require the use of restraints and how the use of restraints would treat the medical symptom, protect the resident's safety, and assist the resident in attaining or maintaining his or her highest practicable level of physical and psychosocial well-being.

Medical symptoms that warrant the use of restraints must be documented in the resident’s medical record, ongoing assessments and care plans. While there must be a physician’s order reflecting the presence of a medical symptom, CMS will hold the facility ultimately accountable for the appropriateness of that determination. The physician's order alone is not sufficient to warrant the use of the restraint. It is further expected, for those residents whose care plans indicate the need for restraints, that the facility engage in a systematic and gradual process toward reducing restraints (e.g., gradually increasing the time for ambulation and muscle strengthening activities). This systematic process would also apply to recently admitted residents for whom restraints were used in the previous setting.

**Consideration of Treatment Plan**

In order for the resident to be fully informed, the facility must explain, in the context of the individual resident's condition and circumstances, the potential risks and benefits of all options under consideration including using a restraint, not using a restraint, and alternatives to restraint use. Whenever restraint use is considered, the facility must explain to the resident how the use of restraints would treat the resident's medical symptoms and assist the resident in attaining or maintaining his or her highest practicable level of physical or psychological well-being. In addition, the facility must also explain the potential negative outcomes of restraint use which include, but are not limited to, declines in the resident’s physical functioning (e.g., ability to ambulate) and muscle condition, contractures, increased incidence of infections and development of pressure sores/ulcers, delirium, agitation, and incontinence. Moreover, restraint use may constitute an accident hazard. Restraints have been found in some cases to increase the incidence of falls or head trauma due to falls and other accidents (e.g., strangulation, entrapment). Finally, residents who are restrained may face a loss of autonomy, dignity and self respect, and may show symptoms of withdrawal, depression, or reduced social contact. In effect, restraint use can reduce independence, functional capacity and quality of life. Alternatives to restraint use should be considered and discussed with the resident. Alternatives to restraint use might include modifying the resident’s environment and/or routine.

In the case of a resident who is incapable of making a decision, the legal surrogate or representative may exercise this right based on the same information that would have been provided to the resident. (See §485.10(a)(3) and (4).) However, the legal surrogate or representative cannot give permission to use restraints for the sake of discipline or staff convenience or when the restraint is not necessary to treat the resident’s medical symptoms. That is, the facility may not use restraints in violation of the regulation solely based on a legal surrogate or representative’s request or approval.
Assessment and Care Planning for Restraint Use

There are instances where, after assessment and care planning, a least restrictive restraint may be deemed appropriate for an individual resident to attain or maintain his or her highest practicable physical and psychosocial well-being. This does not alter the facility’s responsibility to assess and care plan restraint use on an ongoing basis.

Before using a device for mobility or transfer, assessment should include a review of the resident's:

- Bed mobility (e.g., would the use of a device assist the resident to turn from side to side? Is the resident totally immobile and unable to change position without assistance?); and

- Ability to transfer between positions, to and from bed or chair, to stand and toilet (e.g., does the raised side rail add risk to the resident’s ability to transfer?).

The facility must design its interventions not only to minimize or eliminate the medical symptom, but also to identify and address any underlying problems causing the medical symptom.

Interventions that the facility might incorporate in care planning include:

- Providing restorative care to enhance abilities to stand, transfer and walk safely;
- Providing a device such as a trapeze to increase a resident’s mobility in bed;
- Placing the bed lower to the floor and surrounding the bed with a soft mat;
- Equipping the resident with a device that monitors his or her attempts to arise;
- Providing frequent monitoring by staff with periodic assisted toileting for residents who attempt to arise to use the bathroom;
- Furnishing visual and verbal reminders to use the call bell for residents who are able to comprehend this information and are able to use the call bell device; and/or
- Providing exercise and therapeutic interventions, based on individual assessment and care planning, that may assist the resident in achieving proper body position, balance and alignment, without the potential negative effects associated with restraint use.
ABUSE

F223

§483.13(b) Abuse

The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.

Intent §483.15(b)

Each resident has the right to be free from abuse, corporal punishment and involuntary seclusion. Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the resident, family members or legal guardians, friends, or other individuals.

Interpretive Guidelines §483.15(b) and (c)

“Abuse” means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. (42 CFR §488.301)

This also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish.

“Verbal abuse” is defined as the use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. Examples of verbal abuse include, but are not limited to: threats of harm; saying things to frighten a resident, such as telling a resident that he or she will never be able to see his or her family again.

“Sexual abuse” includes, but is not limited to, sexual harassment, sexual coercion or sexual assault.

“Physical abuse” includes hitting, slapping, pinching and kicking. It also includes controlling behavior through corporal punishment.

“Mental abuse” includes, but is not limited to, humiliation, harassment, threats of punishment or deprivation.

“Involuntary seclusion” is defined as separation of a resident from other residents or from her or his room or confinement to her or his room (with or without roommates) against the resident’s will or the will of the resident’s legal representative. Emergency or short-term monitored separation from other residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident’s needs.

Investigation of possible involuntary seclusion, may involve one of two types of situations: that in which residents are living in an area of the facility that restricts their freedom of movement throughout the facility or that in which a resident is temporarily separated from other residents.
• If the stated purpose of a unit which prevents residents from free movement throughout the facility is to provide specialized care for residents who are cognitively impaired, then placement in the unit is not considered involuntary seclusion, as long as care and services are provided in accordance with each resident's individual needs and preferences rather than for staff convenience, and as long as the resident, surrogate, or representative (if any) participates in the placement decision, and is involved in continuing care planning to assure placement continues to meet resident needs and preferences.

• If a resident is receiving emergency short-term monitored separation due to temporary behavioral symptoms (such as brief catastrophic reactions or combative or aggressive behaviors which pose a threat to the resident, other residents, staff or others in the facility), this is not considered involuntary seclusion as long as this is the least restrictive approach for the minimum amount of time, and is being done according to resident needs and not for staff convenience.

If a resident is being temporarily separated from other residents (i.e., for less than 24 hours) as an emergency short-term intervention, answer these questions:

1. What are the symptoms that led to the consideration of the separation?
2. Are these symptoms caused by failure to:
   a. Meet individual needs?
   b. Provide meaningful activities?
   c. Manipulate the resident's environment?
3. Can the cause(s) be removed?
4. If the cause(s) cannot be removed, has the facility attempted to use alternatives short of separation?
5. If these alternatives have been tried and found ineffective, does the facility use separation for the least amount of time?
6. To what extent has the resident, surrogate or representative (if any) participated in care planning and made an informed choice about separation?
7. Does the facility monitor and adjust care to reduce negative outcomes, while continually trying to find and use less restrictive alternatives?

If, during the course of the survey, you identify the possibility of abuse according to the definitions above, investigate through interviews, observations and record review. (For investigative options, refer to the Guidelines for Complaint Investigation which outlines the steps of investigations for various types of suspected abuse and misappropriation of property.)

Report and record any instances where the survey team observes an abusive incident. Completely document who committed the abusive act, the nature of the abuse and where and when it occurred. Ensure that the facility addresses the incident immediately.
Properly trained staff should be able to respond appropriately to resident behavior. The CMS does not consider striking a combative resident an appropriate response in any situation. Retaliation by staff is abuse and should be cited as such.
§483.13(c) Staff Treatment of Residents (F224* and F226**)

The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.

§483.13(c)(1)(i) Staff Treatment of Residents

(1) The facility must —

(i) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;

* Intent §483.13(c) (F224)

Each resident has the right to be free from mistreatment, neglect and misappropriation of property. This includes the facility's identification of residents whose personal histories render them at risk for abusing other residents, and development of intervention strategies to prevent occurrences, monitoring for changes that would trigger abusive behavior, and reassessment of the interventions on a regular basis.

Guidelines §483.13(c) (F224)

“Neglect” means failure to provide goods and services necessary to avoid physical harm, mental anguish or mental illness. (42 CFR 488.301)

“Misappropriation of resident property” means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident’s belongings or money without the resident’s consent. (42 CFR 488.301)

** Guidelines §483.13(c), F226

The facility must develop and implement policies and procedures that include the seven components: screening, training, prevention, identification, investigation, protection and reporting/response.

§483.13(c)(1)(ii) Not employ individuals who have been —

(A) Found guilty of abusing, neglecting or mistreating residents by a court of law; or

(B) Have had a finding entered into the state nurse aide registry concerning abuse, neglect, mistreatment of residents or
misappropriation of their property; and
(iii) Report any knowledge it has of actions by a court of law against
an employee, which would indicate unfitness for service as a nurse
aide or other facility staff to the state nurse aide registry or licensing
authorities.

§483.13(c)(2) The facility must ensure that all alleged violations involving
mistreatment, neglect, or abuse, including injuries of unknown source and
misappropriation of resident property are reported immediately to the
administrator of the facility and to other officials in accordance with state law
through established procedures (including to the state survey and certification
agency).

§483.13(c)(3) The facility must have evidence that all alleged violations are
thoroughly investigated, and must prevent further potential abuse while the
investigation is in progress.

§483.13(c)(4) The results of all investigations must be reported to the
administrator or his designated representative and to other officials in
accordance with state law (including to the state survey and certification
agency) within five working days of the incident, and if the alleged
violation is verified appropriate corrective action must be taken.
QUALITY OF LIFE

F240

§483.15 Quality of Life

A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.

Interpretive Guidelines §483.15

The intention of the quality of life requirements is to specify the facility’s responsibilities toward creating and sustaining an environment that humanizes and individualizes each resident. Compliance decisions here are driven by the quality of life each resident experiences.
§483.15(a) Dignity

The facility must promote care for residents in a manner and in an environment that maintains or enhances each resident’s dignity and respect in full recognition of his or her individuality.

Interpretive Guidelines §483.15(a)

“Dignity” means that in their interactions with residents, staff carries out activities that assist the resident to maintain and enhance his or her self-esteem and self-worth. For example:

- Grooming residents as they wish to be groomed (e.g., hair combed and styled, beards shaved/trimmed, nails clean and clipped);
- Assisting residents to dress in their own clothes appropriate to the time of day and individual preferences;
- Assisting residents to attend activities of their own choosing;
- Labeling each resident’s clothing in a way that respects his or her dignity;
- Promoting resident independence and dignity in dining (such as avoidance of day-to-day use of plastic cutlery and paper/plastic dishware, bibs instead of napkins, dining room conducive to pleasant dining, aides not yelling);
- Respecting resident's private space and property (e.g., not changing radio or television station without resident’s permission, knocking on doors and requesting permission to enter, closing doors as requested by the resident, not moving or inspecting resident’s personal possessions without permission);
- Respecting resident's social status, speaking respectfully, listening carefully, treating residents with respect (e.g., addressing the resident with a name of the resident’s choice, not excluding residents from conversations or discussing residents in community setting); and
- Focusing on residents as individuals when they talk to them and addressing residents as individuals when providing care and services.
F271

§483.20(a) Admission Orders

At the time each resident is admitted, the facility must have physician orders for the resident’s immediate care.

Interpretive Guidelines §483.20(a)

“Physician orders for immediate care” are those written orders facility staff need to provide essential care to the resident, consistent with the resident’s mental and physical status upon admission. These orders should, at a minimum, include dietary, drugs (if necessary) and routine care to maintain or improve the resident’s functional abilities until staff can conduct a comprehensive assessment and develop an interdisciplinary care plan.


PRESSURE SORES

F314

§483.25(c) Pressure Sores

Based on the comprehensive assessment of a resident, the facility must ensure that —

(1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and

(2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

NOTE: Although the regulatory language refers to pressure sores, the nomenclature widely accepted presently refers to pressure ulcers, and the guidance provided in this document will refer to pressure ulcers.

Definitions

Definitions are provided to clarify clinical terms related to pressure ulcers and their evaluation and treatment.

- “Pressure ulcer” refers to any lesion caused by unrelieved pressure that results in damage to the underlying tissue(s). Although friction and shear are not primary causes of pressure ulcers, friction and shear are important contributing factors to the development of pressure ulcers.

- “Avoidable/Unavoidable” Pressure Ulcers
  - “Avoidable” means that the resident developed a pressure ulcer and that the facility did not do one or more of the following: evaluate the resident’s clinical condition and pressure ulcer risk factors; define and implement interventions that are consistent with resident needs, resident goals, and recognized standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate.
  
  - “Unavoidable” means that the resident developed a pressure ulcer even though the facility had evaluated the resident’s clinical condition and pressure ulcer risk factors; defined and implemented interventions that are consistent with resident needs, goals, and recognized standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate.

- “Cleansing/Irrigation”
  - “Cleansing” refers to the use of an appropriate device and solution to clean the surface of the wound bed and to remove the looser foreign debris or contaminants in order to decrease microbial growth.
– “Irrigation” refers to a type of mechanical debridement, which uses an appropriate solution delivered under pressure to the wound bed to vigorously attempt to remove debris from the wound bed.3

• “Colonized/Infected” Wound4, 5

– “Colonized” refers to the presence of bacteria on the surface or in the tissue of a wound without the signs and symptoms of an infection.

– “Infected” refers to the presence of micro-organisms in sufficient quantity to overwhelm the defenses of viable tissues and produce the signs and symptoms of infection.

• “Debridement” refers to the removal of devitalized/necrotic tissue and foreign matter from a wound to improve or facilitate the healing process.6, 7, 8 Various debridement methods include:

  – “Autolytic debridement” refers to the use of moisture retentive dressings to cover a wound and allow devitalized tissue to self-digest by the action of enzymes present in the wound fluids.

  – “Enzymatic (chemical) debridement” refers to the topical application of substances (e.g., enzymes to break down devitalized tissue).

  – “Mechanical debridement” refers to the removal of foreign material and devitalized or contaminated tissue from a wound by physical rather than by chemical or autolytic means.

  – “Sharp or surgical debridement” refers to removal of foreign material or devitalized tissue by a surgical instrument.

  – “Maggot debridement therapy (MDT)” or medicinal maggots refers to a type of sterile intentional biological larval or biosurgical debridement that uses disinfected (sterile) maggots to clean wounds by dissolving the dead and infected tissue and by killing bacteria.9

• “Eschar/Slough”

  – “Eschar” is described as thick, leathery, frequently black or brown in color, necrotic (dead) or devitalized tissue that has lost its usual physical properties and biological activity. Eschar may be loose or firmly adhered to the wound.

  – “Slough” is necrotic/avascular tissue in the process of separating from the viable portions of the body and is usually light colored, soft, moist and stringy (at times).

• “Exudate”

  – “Exudate” is any fluid that has been forced out of the tissues or its capillaries because of inflammation or injury. It may contain serum, cellular debris, bacteria and leukocytes.

  – “Purulent exudate/drainage/discharge” is any product of inflammation that contains pus (e.g., leukocytes, bacteria and liquefied necrotic debris).
• “Serous drainage or exudate” is watery, clear or slightly yellow/tan/pink fluid that has separated from the blood and presents as drainage.

• “Friction/Shearing”
  – “Friction” is the mechanical force exerted on skin that is dragged across any surface.
  – “Shearing” is the interaction of both gravity and friction against the surface of the skin. Friction is always present when shear force is present. Shear occurs when layers of skin rub against each other or when the skin remains stationary and the underlying tissue moves and stretches and angulates or tears the underlying capillaries and blood vessels causing tissue damage.

• “Granulation Tissue”
  – “Granulation tissue” is the pink-red moist tissue that fills an open wound when it starts to heal. It contains new blood vessels, collagen, fibroblasts and inflammatory cells.

• “Tunnel/Sinus Tract/Undermining” (Tunnel and sinus tract are often used interchangeably.)
  – “Tunneling” is a passageway of tissue destruction under the skin surface that has an opening at the skin level from the edge of the wound.
  – A “sinus tract” is a cavity or channel underlying a wound that involves an area larger than the visible surface of the wound.
  – “Undermining” is the destruction of tissue or ulceration extending under the skin edges (margins) so that the pressure ulcer is larger at its base than at the skin surface. Undermining often develops from shearing forces and is differentiated from tunneling by the larger extent of the wound edge involved in undermining and the absence of a channel or tract extending from the pressure ulcer under the adjacent intact skin.

Overview

A pressure ulcer can occur wherever pressure has impaired circulation to the tissue. Critical steps in pressure ulcer prevention and healing include: identifying the individual resident at risk for developing pressure ulcers; identifying and evaluating the risk factors and changes in the resident’s condition; identifying and evaluating factors that can be removed or modified; implementing individualized interventions to attempt to stabilize, reduce or remove underlying risk factors; monitoring the impact of the interventions; and modifying the interventions as appropriate. It is important to recognize and evaluate each resident’s risk factors and to identify and evaluate all areas at risk of constant pressure.

A complete assessment is essential to an effective pressure ulcer prevention and treatment program. A comprehensive individual evaluation helps the facility to:

• Identify the resident at risk of developing pressure ulcers, the level and nature of risk(s); and
• Identify the presence of pressure ulcers.

This information allows the facility to develop and implement a comprehensive care plan that reflects each resident’s identified needs.

The care process should include efforts to stabilize, reduce or remove underlying risk factors; to monitor the impact of the interventions; and to modify the interventions as appropriate.

The facility should have a system/procedure to assure: assessments are timely and appropriate; interventions are implemented, monitored, and revised as appropriate; and changes in condition are recognized, evaluated, reported to the practitioner, and addressed. The quality assessment and assurance committee may help the facility evaluate existing strategies to reduce the development and progression of pressure ulcers, monitor the incidence and prevalence of pressure ulcers within the facility, and ensure that facility policies and procedures are consistent with current standards of practice.

Research into appropriate practices for the prevention, management and treatment of pressure ulcers continues to evolve. As such, there are many recognized clinical resources regarding the prevention and management of pressure ulcers, including wound care and complications such as infections and pain. Some of these resources include:

- The Clinical Practice Guidelines from the Agency for Healthcare Research and Quality (AHRQ) www.ahrq.gov (Guideline No. 15: Treatment of Pressure Ulcers and Guideline No. 5: Pressure Ulcers in Adults: Prediction and Prevention)(AHRQ was previously known as the Agency for Health Care Policy and Research [AHCPR]);
- The National Pressure Ulcer Advisory Panel (NPUAP) www.npuap.org;
- The American Medical Directors Association (AMDA) www.amda.com (Clinical Practice Guidelines: Pressure Ulcers, 1996 and Pressure Ulcer Therapy Companion, 1999);
- The Quality Improvement Organizations, Medicare Quality Improvement Community Initiatives www.medqic.org;
- The Wound, Ostomy, and Continence Nurses Society (WOCN) www.wocn.org; and

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.
Prevention of Pressure Ulcers

42 CFR 483.25 (c) requires that a resident who is admitted without a pressure ulcer doesn’t develop a pressure ulcer unless clinically unavoidable, and that a resident who has an ulcer receives care and services to promote healing and to prevent additional ulcers.

The first step in prevention is the identification of the resident at risk of developing pressure ulcers. This is followed by implementation of appropriate individualized interventions and monitoring for the effectiveness of the interventions.

Assessment

An admission evaluation helps identify the resident at risk of developing a pressure ulcer, and the resident with existing pressure ulcer(s) or areas of skin that are at risk for breakdown. Because a resident at risk can develop a pressure ulcer within two to six hours of the onset of pressure, the at-risk resident needs to be identified and have interventions implemented promptly to attempt to prevent pressure ulcers. The admission evaluation helps define those initial care approaches.

In addition, the admission evaluation may identify pre-existing signs, such as a purple or very dark area that is surrounded by profound redness, edema or induration, suggesting that deep tissue damage has already occurred and additional deep tissue loss may occur.

This deep tissue damage could lead to the appearance of an unavoidable Stage III or IV pressure ulcer or progression of a Stage I pressure ulcer to an ulcer with eschar or exudate within days after admission. Some situations, which may have contributed to this tissue damage, include pressure resulting from immobility during hospitalization or surgical procedures, during prolonged ambulance transport, or while waiting to be discovered or assisted after a debilitating event, such as a fall or a cerebral vascular accident.

Some evidence suggests that because it may be harder to identify erythema in an older adult with darkly pigmented skin, older individuals with darkly pigmented skin may be more at risk for developing pressure ulcers. It may be necessary, therefore, in a darker skinned individual to focus more on other evidence of pressure ulcer development, such as bogginess, induration, coolness, or increased warmth as well as signs of skin discoloration.

Multiple factors, including pressure intensity, pressure duration and tissue tolerance, significantly affect the potential for the development and healing of pressure ulcers. An individual may also have various intrinsic risks due to aging, for example: decreased subcutaneous tissue and lean muscle mass, decreased skin elasticity, and impaired circulation or innervation.

The comprehensive assessment, which includes the Resident Assessment Instrument (RAI), evaluates the resident’s intrinsic risks, the resident’s skin condition, other factors (including causal factors) which place the resident at risk for developing pressure ulcers and/or experiencing delayed healing, and the nature of the pressure to which the resident may be subjected. The assessment should identify which risk factors can be removed or modified.

The assessment also helps identify the resident who has multi-system organ failure or an end-of-life condition or who is refusing care and treatment. If the resident is refusing care, an evaluation of the basis for the refusal and the identification and evaluation of potential alternatives is indicated.
This comprehensive assessment should address those factors that have been identified as having an impact on the development, treatment and/or healing of pressure ulcers, including, at a minimum: risk factors, pressure points, under-nutrition and hydration deficits, and moisture and the impact of moisture on skin. Each of these factors is discussed in additional detail in the following sections.

**Risk Factors**

Many studies and professional documents identify risk factors that increase a resident’s susceptibility to develop or to not heal pressure ulcers. Examples of these risk factors include, but are not limited to:

- Impaired/decreased mobility and decreased functional ability;
- Co-morbid conditions, such as end-stage renal disease, thyroid disease or diabetes mellitus;
- Drugs, such as steroids, that may affect wound healing;
- Impaired diffuse or localized blood flow, for example, generalized atherosclerosis or lower extremity arterial insufficiency;
- Resident refusal of some aspects of care and treatment;
- Cognitive impairment;
- Exposure of skin to urinary and fecal incontinence;
- Under nutrition, malnutrition and hydration deficits; and
- A healed ulcer. The history of a healed pressure ulcer and its stage [if known] is important, since areas of healed Stage III or IV pressure ulcers are more likely to have recurrent breakdown.

Some residents have many risk factors for developing pressure ulcers, such as diabetic neuropathy, frailty, cognitive impairment and under nutrition. Not all factors are fully modifiable and some potentially modifiable factors (e.g., under-nutrition) may not be corrected immediately, despite prompt intervention, while other factors such as pressure may be modified promptly. It may be necessary to stabilize, when possible, the underlying causes (e.g., control blood sugars or ensure adequate food and fluid intake).

Although the requirements do not mandate any specific assessment tool, other than the RAI, validated instruments are available to assess risk for developing pressure ulcers. Research has shown that a significant number of pressure ulcers develop within the first four weeks after admission to a long-term care facility. Therefore, many clinicians recommend using a standardized pressure ulcer risk assessment tool to assess a resident’s pressure ulcer risks upon admission, weekly for the first four weeks after admission for each resident at risk, then quarterly, or whenever there is a change in cognition or functional ability. A resident’s risk may increase due to an acute illness or condition change (e.g., upper respiratory infection, pneumonia or exacerbation of underlying congestive heart failure) and may require additional evaluation.
Regardless of any resident’s total risk score, the clinicians responsible for the resident’s care should review each risk factor and potential cause(s) individually to: a) Identify those that increase the potential for the resident to develop pressure ulcers; b) Decide whether and to what extent the factor(s) can be modified, stabilized, removed, etc., and c) Determine whether targeted management protocols need to be implemented. In other words, an overall risk score indicating the resident is not at high risk of developing pressure ulcers does not mean that existing risk factors or causes should be considered less important or addressed less vigorously than those factors or causes in the resident whose overall score indicates he or she is at a higher risk of developing a pressure ulcer.

Pressure Points and Tissue Tolerance

Assessment of a resident’s skin condition helps define prevention strategies. The skin assessment should include an evaluation of the skin integrity and tissue tolerance (ability of the skin and its supporting structures to endure the effects of pressure without adverse effects) after pressure to that area has been reduced or redistributed.

Tissue closest to the bone may be the first tissue to undergo necrosis. Pressure ulcers are usually located over a bony prominence, such as the sacrum, heel, the greater trochanter, ischial tuberosity, fibular head, sacrum and ankle (malleolus).

An at-risk resident who sits too long on a static surface may be more prone to get ischial ulceration. Slouching in a chair may predispose an at-risk resident to pressure ulcers of the spine, scapula or elbow (elbow ulceration is often related to arm rests or lap boards). Friction and shearing are also important factors in tissue ischemia, necrosis and pressure ulcer formation.

Pressure ulcers may develop at other sites where pressure has impaired the circulation to the tissue, such as pressure from positioning or use of medical devices. For example, pressure ulcers may develop from pressure on an ear lobe related to positioning of the head; pressure or friction on areas (e.g., nares, urinary meatus, extremities) caused by tubes, casts, orthoses, braces, cervical collars or other medical devices; pressure on the labia or scrotum related to positioning (e.g., against a pommel type cushion); pressure on the foot related to ill-fitting shoes causing blistering; or pressure on legs, arms and fingers due to contractures or deformity resulting from rheumatoid arthritis, etc.

While pressure ulcers on the sacrum remain the most common location, pressure ulcers on the heel are occurring more frequently are difficult to assess and heal, and require early identification of skin compromise over the heel.

It is therefore important for clinical staff to regularly conduct thorough skin assessments on each resident who is at risk for developing pressure ulcers.

Under-Nutrition and Hydration Deficits

Adequate nutrition and hydration are essential for overall functioning. Nutrition provides vital energy and building blocks for all of the body’s structures and processes. Any organ or body system may require additional energy or structural materials for repair or function. The skin is the body’s largest organ system. It may affect, and be affected by, other body processes and organs. Skin condition reflects overall body function; skin breakdown may be the most visible evidence of a general catabolic state.
Weight reflects a balance between intake and utilization of energy. Significant unintended weight loss may indicate under-nutrition or worsening health status. Weight stability (in the absence of fluid excess or loss) is a useful indicator of overall caloric balance. Severely impaired organs (heart, lungs, kidneys, liver, etc.) may be unable to use nutrients effectively. A resident with a pressure ulcer who continues to lose weight either needs additional caloric intake or correction (where possible) of conditions that are creating a hypermetabolic state. Continuing weight loss and failure of a pressure ulcer to heal despite reasonable efforts to improve caloric and nutrient intake may indicate the resident is in multi-system failure or an end-stage or end-of-life condition warranting an additional assessment of the resident’s overall condition.

Before instituting a nutritional care plan, it helps to summarize resident-specific evidence, including: severity of nutritional compromise, rate of weight loss or appetite decline, probable causes, the individual’s prognosis and projected clinical course, and the resident’s wishes and goals. Because there are no wound-specific nutritional measures, the interdisciplinary team should develop nutritional goals for the whole person. Unless contraindicated, nutritional goals for a resident with nutritional compromise who has a pressure ulcer or is at risk of developing pressure ulcers should include protein intake of approximately 1.2-1.5 gm/kg body weight daily (higher end of the range for those with larger, more extensive, or multiple wounds). A simple multivitamin is appropriate, but unless the resident has a specific vitamin or mineral deficiency, supplementation with additional vitamins or minerals may not be indicated.

NOTE: Although some laboratory tests may help clinicians evaluate nutritional issues in a resident with pressure ulcers, no laboratory test is specific or sensitive enough to warrant serial/repeated testing. Serum albumin, pre-albumin and cholesterol may be useful to help establish overall prognosis; however, they may not correlate well with clinical observation of nutritional status. At his or her discretion, a practitioner may order test(s) that provide useful additional information or help with management of treatable conditions.

Water is essential to maintain adequate body functions. As a major component of blood, water dissolves vitamins, minerals, glucose, amino acids, etc.; transports nutrients into cells; removes waste from the cells; and helps maintain circulating blood volume as well as fluid and electrolyte balance. It is critical that each resident at risk for hydration deficit or imbalance, including the resident with a pressure ulcer or at risk of developing an ulcer, be identified and that hydration needs be addressed.

(The surveyor should refer to the Guidance at 42 CFR 483.25 (i), F525, Nutrition, and 483.25(j), F327 Hydration for investigation of potential non-compliance with the nutrition and hydration requirements. A low albumin level combined with the facility’s lack of supplementation, for example, is not sufficient to cite a pressure ulcer deficiency.)

Moisture and Its Impact

Both urine and feces contain substances that may irritate the epidermis and may make the skin more susceptible to breakdown. Some studies have found that fecal incontinence may pose a greater threat to skin integrity most likely due to bile acids and enzymes in the feces. Irritation or maceration resulting from prolonged exposure to urine and feces may hasten skin breakdown, and moisture may make skin more susceptible to damage from friction and shear during repositioning.
It may be difficult to differentiate dermatitis related to incontinence from partial thickness skin loss (pressure ulcer). This differentiation should be based on the clinical evidence and review of presenting risk factors. A Stage I pressure ulcer usually presents as a localized area of erythema or skin discoloration, while perineal dermatitis may appear as a more diffuse area of erythema or discoloration where the urine or stool has come into contact with the skin. The dermatitis may occur in the area where the incontinence brief or underpad has been used. Also, the dermatitis/rash more typically presents as intense erythema, scaling, itching, papules, weeping and eruptions.28

Interventions

The comprehensive assessment should provide the basis for defining approaches to address residents at risk of developing or already having a pressure ulcer. A determination that a resident is at high risk to develop a pressure ulcer has significant implications for preventive and treatment strategies, but does not by itself indicate that development of a pressure ulcer was unavoidable. Effective prevention and treatment are based upon consistently providing routine and individualized interventions.

In the context of the resident’s choices, clinical condition and physician input, the resident’s plan of care should establish relevant goals and approaches to stabilize or improve co-morbidities, such as attempts to minimize clinically significant blood sugar fluctuations and other interventions aimed at limiting the effects of risk factors associated with pressure ulcers. Alternatively, facility staff and practitioners should document clinically valid reasons why such interventions were not appropriate or feasible. Repeated hospitalizations or emergency room visits within a six-month period may indicate overall decline or instability.

Resident Choice

In order for a resident to exercise his or her right appropriately to make informed choices about care and treatment or to refuse treatment, the facility and the resident (or the resident’s legal representative) must discuss the resident’s condition, treatment options, expected outcomes, and consequences of refusing treatment. The facility is expected to address the resident’s concerns and offer relevant alternatives, if the resident has refused specific treatments. (See Resident Rights at 42 CFR 483.10(b)(3) and (4), F154 and F155.)

Advance Directive

A resident at the end of life, in terminal stages of an illness or having multiple system failures may have written directions for his or her treatment goals (or a decision has been made by the resident’s surrogate or representative, in accordance with state law).

If a resident has a valid advance directive, the facility’s care must reflect a resident’s wishes as expressed in the directive, in accordance with state law. However, the presence of an advance directive does not absolve the facility from giving supportive and other pertinent care that is not prohibited by the advance directive. If the facility has implemented individualized approaches for end-of-life care in accordance with the resident’s wishes and has implemented appropriate efforts to try to stabilize the resident’s condition (or indicated why the condition cannot or should not be stabilized) and to provide care to prevent or treat the pressure ulcer (including pertinent, routine, lesser aggressive approaches, such as, cleaning, turning,
repositioning), then the development, continuation or progression of a pressure ulcer may be consistent with regulatory requirements.

NOTE: The presence of a “Do Not Resuscitate” (DNR) order is not sufficient to indicate the resident is declining other appropriate treatment and services. It only indicates that the resident should not be resuscitated if respirations and/or cardiac function cease.

Based upon the assessment and the resident’s clinical condition, choices and identified needs, basic or routine care should include interventions to: a) Redistribute pressure, such as repositioning, protecting heels, etc.; b) Minimize exposure to moisture and keep skin clean, especially of fecal contamination; c) Provide appropriate, pressure-redistributing, support surfaces; d) Provide non-irritating surfaces; and e) Maintain or improve nutrition and hydration status, where feasible. Adverse drug reactions related to the resident’s drug regimen may worsen risk factors for development of pressure ulcers or for non-healing pressure ulcers (i.e., by causing lethargy or anorexia or creating/increasing confusion) and should be identified and addressed. These interventions should be incorporated into the plan of care and revised as the condition of the resident indicates.

Repositioning

Repositioning is a common, effective intervention for an individual with a pressure ulcer or who is at risk of developing one.\textsuperscript{29, 30} Assessment of a resident’s skin integrity after pressure has been reduced or redistributed should guide the development and implementation of repositioning plans. Such plans should be addressed in the comprehensive plan of care consistent with the resident’s need and goals. Repositioning is critical for a resident who is immobile or dependent upon staff for repositioning. The care plan for a resident at risk of friction or shearing during repositioning may require the use of lifting devices for repositioning. Positioning the resident on an existing pressure ulcer should be avoided since it puts additional pressure on tissue that is already compromised and may impede healing.

Surveyors should consider the following repositioning issues:

- A resident who can change positions independently may need supportive devices to facilitate position changes. The resident also may need instruction about why repositioning is important and how to do it, encouragement to change positions regularly, and monitoring of frequency of repositioning.

- The care plan for a resident who is reclining and is dependent on staff for repositioning should address position changes to maintain the resident’s skin integrity. This may include repositioning at least every two hours or more frequently depending upon the resident’s condition and tolerance of the tissue load (pressure). Depending on the individualized assessment, more frequent repositioning may be warranted for individuals who are at higher risk for pressure ulcer development or who show evidence (e.g., Stage I pressure ulcers) that repositioning at two-hour intervals is inadequate. With rare exception (e.g., both sacral and ischial pressure ulcers are present) the resident should not be placed directly on the greater trochanter for more than momentary placement. Elevating the head of the bed or the back of a reclining chair to or above a 30 degree angle creates pressure comparable to that exerted while sitting and requires the same
considerations regarding repositioning as those for a dependent resident who is seated.

- Many clinicians recommend a position change “off loading” hourly for dependent residents who are sitting or who are in a bed or a reclining chair with the head of the bed or back of the chair raised 30 degrees or more. Based upon an assessment including evidence of tissue tolerance while sitting (checking for Stage I ulcers as noted above), the resident may not tolerate sitting in a chair in the same position for one hour at a time and may require a more frequent position change.

- Postural alignment, weight distribution, sitting balance and stability, and pressure redistribution should all be considered when positioning a resident in a chair. A teachable resident should be taught to shift his or her weight approximately every 15 minutes while sitting in a chair.

- Wheelchairs are often used for transporting residents, but they may severely limit repositioning options and increase the risk of pressure ulcer development. Therefore, wheelchairs with sling seats may not be optimal for prolonged sitting during activities or meals, etc. However, available modifications to the seating can provide a more stable surface and provide better pressure reduction.

- There isn’t evidence that momentary pressure relief followed by return to the same position (that is a “microshift” of five or 10 degrees or a 10-15 second lift from a seated position) is beneficial. This approach does not allow sufficient capillary refill and tissue perfusion for a resident at risk of developing pressure ulcers. Ongoing monitoring of the resident’s skin integrity and tissue tolerance is critical to prevent development or deterioration of pressure ulcers.

**Support Surfaces and Pressure Redistribution**

Pressure redistribution refers to the function or ability to distribute a load over a surface or contact area. Redistribution results in shifting pressure from one area to another and requires attention to all affected areas. Pressure redistribution has incorporated the concepts of both pressure reduction (reduction of interface pressure, not necessarily below capillary closure pressure) and pressure relief (reduction of interface pressure below capillary closure pressure).

Appropriate support surfaces or devices should be chosen by matching a device’s potential therapeutic benefit with the resident’s specific situation (i.e., multiple ulcers, limited turning surfaces, ability to maintain position). The effectiveness of pressure redistribution devices (e.g., four-inch convoluted foam pads, gels, air fluidized mattresses and low-loss air mattresses) is based on their potential to address the individual resident’s risk, the resident’s response to the product, and the characteristics and condition of the product. For example, an overinflated overlay product, or one that “bottoms out” (completely compressing the overlay, when, for example, the caregiver can feel less than one inch between the resident and support material) is unlikely to effectively reduce the pressure risk. These products are more likely to reduce pressure effectively if they are used in accord with the manufacturer’s instructions. The effectiveness of each product used needs to be evaluated on an ongoing basis. Surveyors should consider the following pressure redistribution issues:

- Static pressure redistribution devices (e.g., solid foam, convoluted foam, gel mattress) may be indicated when a resident is at risk for pressure ulcer
development or delayed healing. A specialized pressure redistribution cushion or surface, for example, might be used to extend the time a resident is sitting in a chair; however, the cushion does not eliminate the necessity for periodic repositioning.

- Dynamic pressure reduction surfaces may be helpful when: 1) The resident cannot assume a variety of positions without bearing weight on a pressure ulcer; 2) The resident completely compresses a static device that has retained its original integrity; or 3) The pressure ulcer is not healing as expected, and it is determined that pressure may be contributing to the delay in healing.

- Because the heels and elbows have relatively little surface area, it is difficult to redistribute pressure on these two surfaces. Therefore, it is important to pay particular attention to reducing the pressure on these areas for the resident at risk in accord with resident’s overall goals and condition. Pillows used to support the entire lower leg may effectively raise the heel from contact with the bed, but use of the pillows needs to take into account the resident’s other conditions. The use of donut-type cushions is not recommended by the clinicians.

- A resident with severe flexion contractures also may require special attention to effectively reduce pressure on bony prominences or prevent breakdown from skin-to-skin contact.

Some products serve mainly to provide comfort and reduce friction and shearing forces (e.g., sheepskin, heel and elbow protectors). Although these products are not effective at redistributing pressure, they (in addition to pillows, foam wedges or other measures) may be employed to prevent bony prominences from rubbing together.

**Monitoring**

At least daily, staff should remain alert to potential changes in the skin condition and should evaluate and document identified changes. For example, a resident's complaint about pain or burning at a site where there has been pressure or a nursing assistant’s observation during the resident’s bath that there is a change in skin condition should be reported so that the resident may be evaluated further.

After completing a thorough evaluation, the interdisciplinary team should develop a relevant care plan to include prevention and management interventions with measurable goals. Many clinicians recommend evaluating skin condition (e.g., skin color, moisture, temperature, integrity and turgor) at least weekly, or more often if indicated, such as when the resident is using a medical device that may cause pressure.

The resident should be monitored for condition changes that might increase the risk for breakdown and the defined interventions should be implemented and monitored for effectiveness.

**Assessment and Treatment of Pressure Ulcer(s)**

It is important that each existing pressure ulcer be identified, whether present on admission or developed after admission, and that factors that influenced its development, the potential for development of additional ulcers or for the
deterioration of the pressure ulcer(s) be recognized, assessed and addressed (see discussion under Prevention regarding overall assessment and interventions). Any new pressure ulcer suggests a need to reevaluate the adequacy of the plan for preventing pressure ulcers.

When assessing the ulcer itself, it is important to:

- Differentiate the type of ulcer (pressure-related versus non-pressure-related) because interventions may vary depending on the specific type of ulcer;
- Determine the ulcer’s stage;
- Describe and monitor the ulcer’s characteristics;
- Monitor the progress toward healing and for potential complications;
- Determine if infection is present;
- Assess, treat and monitor pain, if present; and
- Monitor dressings and treatments.

Types of Ulcers

Three of the more common types of ulcers are pressure, vascular insufficiency/ischemia (venous stasis and arterial ischemic ulcers) and neuropathic. See Guidance to Surveyors at 42 CFR 483.25 (F309) for definition and description of ulcer types other than pressure ulcers.

At the time of the assessment, clinicians (physicians, advance practice nurses, physician assistants, and certified wound care specialists, etc.) should document the clinical basis (i.e., type of skin injury/ulcer, location, shape, ulcer edges and wound bed, condition of surrounding tissues) for any determination that an ulcer is not pressure-related, especially if the injury/ulcer has characteristics consistent with a pressure ulcer, but is determined not to be one.

Ulcer Characteristics

It is important that the facility have a system in place to assure that the protocols for daily monitoring and for periodic documentation of measurements, terminology, frequency of assessment, and documentation are implemented consistently throughout the facility. When a pressure ulcer is present, daily monitoring (with accompanying documentation, when a complication or change is identified), should include:

- An evaluation of the ulcer, if no dressing is present;
- An evaluation of the status of the dressing, if present (whether it is intact and whether drainage, if present, is or is not leaking);
- The status of the area surrounding the ulcer (that can be observed without removing the dressing);
- The presence of possible complications, such as signs of increasing area of ulceration or soft tissue infection (i.e., increased redness or swelling around the wound or increased drainage from the wound); and
• Whether pain, if present, is being adequately controlled.

The amount of observation possible will depend upon the type of dressing that is used, since some dressings are meant to remain in place for several days, according to manufacturers’ guidelines.

With each dressing change or at least weekly (and more often when indicated by wound complications or changes in wound characteristics), an evaluation of the pressure ulcer wound should be documented. At a minimum, documentation should include the date observed and:

• Location and staging;

• Size (perpendicular measurements of the greatest extent of length and width of the ulceration), depth; and the presence, location and extent of any undermining or tunneling/sinus tract;

• Exudate, if present: type (such as purulent/serous), color, odor and approximate amount;

• Pain, if present: nature and frequency (e.g., whether episodic or continuous);

• Wound bed: color and type of tissue/character including evidence of healing (e.g., granulation tissue), or necrosis (slough or eschar); and

• Description of wound edges and surrounding tissue (e.g., rolled edges, redness, hardness/induration, maceration) as appropriate.

Photographs may be used to support this documentation, if the facility has developed a protocol consistent with accepted standards (e.g., frequency, consistent distance from the wound, type of equipment used, means to assure digital images are accurate and not modified, inclusion of the resident identification, ulcer location, dates, etc. within the photographic image, and parameters for comparison).

Stages of Pressure Ulcers

The staging system is one method of summarizing certain characteristics of pressure ulcers, including the extent of tissue damage. This is the system used within the RAI.

Stage I pressure ulcers may be difficult to identify because they are not readily visible, and they present with greater variability. Advanced technology (not commonly available in nursing homes) has shown that a Stage I pressure ulcer may have minimal to substantial tissue damage in layers beneath the skin’s surface, even when there is no visible surface penetration. The Stage I indicators identified below will generally persist or be evident after the pressure on the area has been removed for 30-45 minutes.

The definitions for the stages of pressure ulcers identified below are from the NPUAP and used with permission.

• “Stage I” - An observable, pressure-related alteration of intact skin, whose indicators as compared to an adjacent or opposite area on the body may include changes in one or more of the following parameters:
– Skin temperature (warmth or coolness);
– Tissue consistency (firm or boggy);
– Sensation (pain, itching); and/or
– A defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue or purple hues.

*“Stage II”* - Partial thickness skin loss involving epidermis, dermis or both. The ulcer is superficial and presents clinically as an abrasion, blister or shallow crater.

*“Stage III”* - Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.

*“Stage IV”* - Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.

NOTE: If eschar and necrotic tissue are covering and preventing adequate staging of a pressure ulcer, the RAI User’s Manual Version 2 instructs the assessor to code the pressure ulcer as a Stage IV. These instructions must be followed for MDS coding purposes until they are revised. Although the AHCPR and NPUAP system for staging pressure ulcers indicates that the presence of eschar precludes accurate staging of the ulcer, the facility must use the RAI directions in order to code the MDS, but not necessarily to render treatment.

**The Healing Pressure Ulcer**

Ongoing evaluation and research have indicated that pressure ulcers do not heal in a reverse sequence, that is, the body does not replace the types and layers of tissue (e.g., muscle, fat and dermis) that were lost during the pressure ulcer development.

There are different types of clinical documentation to describe the progression of the healing pressure ulcer(s). The regulation at 42 CFR 483.20(b)(1), F272, requires that facilities use the Resident Assessment Instrument (RAI), which includes direction to describe the healing of the pressure ulcer(s) for coding purposes for the MDS: The RAI User's Manual Version 2.0, instructs staff to identify the stages of pressure ulcer(s) by describing depth in reverse order from deepest to lesser stages to describe the healing or improvement of a pressure ulcer (e.g., a Stage IV becomes a Stage III and so forth. This has been referred to as “reverse staging” or “back staging”).

Some clinicians utilize validated instruments to describe the healing of a pressure ulcer. Although such instruments are appropriate for making treatment decisions, they may not be utilized for coding the MDS. Until the MDS is revised, the present coding system (reverse staging) must be used for completion of the RAI.
Clinicians may use the National Pressure Ulcer Advisory Panel - Pressure Ulcer Scale for Healing (NPUAP-PUSH) tool. The NPUAP always refers to a healed pressure ulcer as a healed ulcer at the deepest stage of its development (e.g., a healed Stage IV or a healing Stage IV). The NPUAP cautions that the tool does not represent a comprehensive pressure ulcer assessment, and other factors may need to be considered when selecting pressure ulcer treatment options.

Since surveyors may encounter clinician’s notes in which the NPUAP-PUSH tool is used as part of the facility’s documentation protocol, the following description of the tool is provided. The NPUAP-PUSH tool documents pressure ulcer healing consistent with the healing process, describes a healing pressure ulcer in terms of three ulcer characteristics, and assigns a numeric value to the characteristics: length (cm) x width (cm), exudate amount, and type of tissue (closed with epithelium; new pink, shiny epithelial tissue; clean, pink or beefy red, shiny, moist granulation tissue; slough tissue; or necrotic, eschar tissue).

The 1994 AHCPR Guidelines and current literature indicate that a clean pressure ulcer with adequate blood supply and innervation should show evidence of stabilization or some healing within two to four weeks. Evidence accumulating since 1962 indicates that management of wound exudate coupled with a clean, moist wound environment allows a chronic wound (e.g., pressure ulcer) to lay down healthy granulating tissue more efficiently.

If a pressure ulcer fails to show some evidence of progress toward healing within two to four weeks, the pressure ulcer (including potential complications) and the resident’s overall clinical condition should be reassessed. Re-evaluation of the treatment plan, including determining whether to continue or modify the current interventions, is also indicated. Results may vary depending on the resident's condition and interventions/treatments used. The complexity of the resident’s condition may limit responsiveness to treatment or tolerance for certain treatment modalities. The clinicians, if deciding to retain the current regimen, should document the rationale for continuing the present treatment (i.e., why some, or all, of the plan’s interventions remain relevant despite little or no apparent healing).

Pressure ulcers may progress or may be associated with complications such as infection of the soft tissues around the wound (cellulitis), infection of the bone (osteomyelitis), infection of a joint (septic arthritis), abscess, spread of bacteria into the bloodstream (bacteremia/sepsis), chronic infection, or development of a sinus tract. Sometimes these complications may occur despite apparent improvement in the pressure ulcer itself. The physician's involvement is integral whenever significant changes in the nature of the wound or overall resident condition are identified.

Infections Related to Pressure Ulcers

Current literature reports that all Stage II, III and IV pressure ulcers are colonized with bacteria but may not be infected. Identification, diagnosis and treatment of infection, when present, are critical to healing a pressure ulcer. The infection occurs when the bacteria have invaded the tissue surrounding or within the pressure ulcer.

As with any infection, classic signs and symptoms of infection may include purulent exudate, peri-wound warmth, swelling, induration or erythema (erythema may not be readily determined in individuals with dark skin pigmentation), increasing pain or tenderness around the site or delayed wound healing. These classic signs may not be as evident in someone with a granulating, chronic wound or an immuno-
compromised or aged resident. Some infections may present primarily with pain or delayed healing without other typical clinical signs of infection. Clinicians have developed some tools, which may facilitate identifying and assessing an infection, and documenting progress toward healing.

Wounds may be classified as infected if the signs and symptoms of infection are present and/or a wound culture (obtained in accord with accepted standards, such as sterile tissue aspirate, a “quantitative surface swab” using the Levine technique or semi-quantitative swab) contains 100,000 ($10^5$) or greater micro-organisms per gram of tissue. A superficial swab may show the presence of bacteria, but is not a reliable method to identify infection.

Findings, such as an elevated white blood cell count, bacteremia, sepsis or fever, may signal an infection related to a pressure ulcer area or a co-existing infection from a different source.

Pain

The assessment and treatment of a resident’s pain are integral components of pressure ulcer prevention and management. “The goal of pain management in the pressure ulcer patient is to eliminate the cause of pain, to provide analgesia, or both.” Pain that interferes with movement and/or affects mood may contribute to immobility and contribute to the potential for developing a pressure ulcer or for delayed healing or non-healing of an already existing ulcer.

It may be difficult to assess the degree of pain in a resident who is cognitively impaired. Some strategies and tools exist to help determine the presence and characteristics of pain (e.g., nature, intensity and frequency). Recent research suggests that a resident with a Stage IV pressure ulcer can feel as much pain as those with a Stage I or II ulcer. The relationship of pain to the pressure ulcer healing process is not yet clear. Pain is an individual perception and response and an individual’s report of pain is a generally valid indicator of pain. One resident may experience pain of varying intensity and frequency (e.g., continually or periodically) or episodically in association with treatments (e.g., debridement, dressing changes) or movement or infection, while another resident may not have or report pain.

Dressings and Treatments

Research has found that chronic wounds such as pressure ulcers heal differently from acute wounds, primarily because of differing biochemical and cellular characteristics. Current clinical practice indicates that Stage III and Stage IV ulcers should be covered. Determination of the need for a dressing for a Stage I or Stage II ulcer is based upon the individual practitioner’s clinical judgment and facility protocols based upon current clinical standards of practice. No particular dressing promotes healing of all pressure ulcers within an ulcer classification.

For those pressure ulcers with significant exudate, management of the exudate is critical for healing. A balance is needed to assure that the wound is moist enough to support healing but not too moist to interfere with healing. Since excess wound exudate generally impairs wound healing, selecting an appropriate absorptive dressing is an important part of managing chronic wound exudate.

Product selection should be based upon the relevance of the specific product to the identified pressure ulcer(s) characteristics, the treatment goals and the manufacturer’s recommendations for use. Current literature does not indicate
significant advantages of any single specific product over another, but does confirm that not all products are appropriate for all pressure ulcers. Wound characteristics should be assessed throughout the healing process to assure that the treatments and dressings being used are appropriate to the nature of the wound.

Present literature suggests that pressure ulcer dressing protocols may use clean technique rather than sterile, but that appropriate sterile technique may be needed for those wounds that recently have been surgically debrided or repaired.48

Debridement of non-viable tissue is frequently performed to reduce the amount of wound debris or non-viable tissue and to reduce the risk of sepsis. A variety of debridement methods (e.g., mechanical, sharp or surgical, enzymatic, autolytic, MDT) are available. Removal of necrotic tissue should enhance wound healing. Ongoing monitoring (and timely intervention in case of change in the character of the wound) is critical for areas with eschar and those areas that have been debrided.49 Many clinicians believe that stable, dry, adherent and intact eschar on the foot/heel should not be debrided, unless signs and symptoms of local infection or instability are detected.50

Some facilities may use “wet-to-dry gauze dressings” or irrigation with chemical solutions to remove slough. The use of wet-to-dry dressings or irrigations may be appropriate in limited circumstances, but repeated use may damage healthy granulation tissue in healing ulcers and may lead to excessive bleeding and increased resident pain.

A facility should be able to show that its treatment protocols are based upon current standards of practice and are in accord with the facility’s policies and procedures as developed with the medical director’s review and approval.

End Notes

For more information on the references below, visit the CMS Sharing Innovations in Quality website: www.cms.hhs.gov/medicaid/survey-cert/siqhome.asp


§483.25(d) Urinary Incontinence

Based on the resident's comprehensive assessment, the facility must ensure that –

§483.25(d) (1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary; and

§483.25(d) (2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

Definitions

Definitions are provided to clarify clinical terms related to evaluation and treatment of urinary incontinence and catheter use.

- “Bacteremia” is the presence of bacteria in the bloodstream.
- “Bacteriuria” is defined as the presence of bacteria in the urine.
- “Urinary incontinence” is the involuntary loss or leakage of urine. There are several types of urinary incontinence, and the individual resident may experience more than one type at a time. Some of the more common types include:
  - “Functional incontinence” refers to loss of urine that occurs in residents whose urinary tract function is sufficiently intact that they should be able to maintain continence, but who cannot remain continent because of external factors (e.g., inability to utilize the toilet facilities in time);
  - “Mixed incontinence” is the combination of stress incontinence and urge incontinence;
  - “Overflow incontinence” is associated with leakage of small amounts of urine when the bladder has reached its maximum capacity and has become distended;
  - “Stress incontinence” (outlet incompetence) is associated with impaired urethral closure (malfunction of the urethral sphincter) which allows small amounts of urine leakage when intra-abdominal pressure on the bladder is increased by sneezing, coughing, laughing, lifting, standing from a sitting position, climbing stairs, etc.;
  - “Transient incontinence” refers to temporary episodes of urinary incontinence that are reversible once the cause(s) of the episode(s) is (are) identified and treated; and
“Urge incontinence” (overactive bladder) is associated with detrusor muscle overactivity (excessive contraction of the smooth muscle in the wall of the urinary bladder resulting in a sudden, strong urge (also known as urgency) to expel moderate to large amounts of urine before the bladder is full).

- “Urinary retention” is the inability to completely empty the urinary bladder by micturition.

- “Urinary tract infection” (UTI) is a clinically detectable condition associated with invasion by disease causing microorganisms of some part of the urinary tract, including the urethra (urethritis), bladder (cystitis), ureters (ureteritis), and/or kidney (pyelonephritis). An infection of the urethra or bladder is classified as a lower tract UTI and infection involving the ureter or kidney is classified as an upper tract UTI.

- “Urosepsis” refers to the systemic inflammatory response to infection (sepsis) that appears to originate from a urinary tract source. It may present with symptoms such as fever, hypotension, reduced urine output or acute change in mental status.

Overview

Urinary incontinence is not normal. Although aging affects the urinary tract and increases the potential for urinary incontinence, urinary incontinence is not a normal part of aging. In the younger person, urinary incontinence may result from a single cause. In the older individual, urinary incontinence generally involves psychological, physiological, pharmacological and/or pathological factors or co-morbid conditions (e.g., later stages of dementia, diabetes, prostatectomy, medical conditions involving dysfunction of the central nervous system, urinary tract infections, etc.). Because urinary incontinence is a symptom of a condition and may be reversible, it is important to understand the causes and to address incontinence to the extent possible. If the underlying condition is not reversible, it is important to treat or manage the incontinence to try to reduce complications.

Many older adults are incontinent of urine prior to admission to a nursing home. Urinary incontinence and related loss of independence are prominent reasons for a nursing home admission. Articles and data currently available, including CMS data (e.g., MDS Active Resident Information Report (Item H1b) at www.cms.hhs.gov/states/mdsreports), indicate that more than 50% of the nursing home population experience some degree of urinary incontinence. Whether the resident is incontinent of urine on admission or develops incontinence after admission, the steps of assessment, monitoring, reviewing and revising approaches to care (as needed) are essential to managing urinary incontinence and to restoring as much normal bladder function as possible.

Various conditions or situations may aggravate the severity of urinary incontinence in nursing home residents. In addition, urinary incontinence may be associated with changes in skin integrity, skin irritation or breakdown, urinary tract infections, falls and fractures, sleep disturbances, and psychosocial complications including social withdrawal, embarrassment, loss of dignity, feelings of isolation and interference with participation in activities.

Various factors common to elderly individuals may increase the risk of infection including: underlying diseases (e.g., diabetes mellitus), medications that affect immune responses to infection (e.g., steroids and chemotherapy, history of multiple
antibiotic usage), conditions that cause incontinence and indwelling urinary catheters.

The urinary tract is a common source of bacteremia in nursing home residents. A urinary tract infection (UTI) is one of the most common infections occurring in nursing homes and is often related to an indwelling urinary catheter. Without a valid clinical rationale for an indwelling catheter, its use is not an acceptable approach to manage urinary incontinence. Although UTIs can result from the resident’s own flora, they may also be the result of microorganisms transmitted by staff when handling the urinary catheter drainage system and/or providing incontinence care. Hand washing remains one of the most effective infection control tools available.

Resources

It is important for the facility to have in place systems/procedures to assure: assessments are timely and appropriate; interventions are defined, implemented, monitored and revised as appropriate in accordance with current standards of practice; and changes in condition are recognized, evaluated, reported to the practitioner and addressed. The Medical Director and the quality assessment and assurance committee may help the facility evaluate existing strategies for identifying and managing incontinence, catheter use, and UTIs, and ensure that facility policies and procedures are consistent with current standards of practice.

Research into appropriate practices to prevent, manage, and treat urinary incontinence, urinary catheterization, and UTI continues to evolve. Many recognized clinical resources on the prevention and management of urinary incontinence, infection and urinary catheterization exist. Some of these resources include:

- The American Medical Directors Association (AMDA) at www.amda.com (Clinical Practice Guidelines: Urinary Incontinence, 1996);
- The Quality Improvement Organizations, Medicare Quality Improvement Community Initiatives at www.medqic.org;
- The CMS Sharing Innovations in Quality at www.cms.hhs.gov/medicaid/survey-cert/siqhome.asp;
- Association for Professionals in Infection Control and Epidemiology (APIC) at www.apic.org;
- Centers for Disease Control at www.cdc.gov;
- The Annals of Long-Term Care publications at www.mmhc.com;
- American Foundation for Urologic Disease, Inc. at www.afud.org; and

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.
Resident Choice

In the course of developing and implementing care plan interventions for treatment and services related to achieving the highest practicable level of urinary continence, preventing and treating urinary tract infections, and avoiding the use of indwelling catheters without medical justification, it is important to involve the resident and/or her or his surrogate in care decisions and to consider whether the resident has an advance directive in place.

In order for a resident to exercise his or her right appropriately to make informed choices about care and treatment or to refuse treatment, the facility and the resident (or the resident’s legal representative) must discuss the resident's condition, treatment options, expected outcomes, and consequences of refusing treatment. The facility should address the resident's concerns and offer relevant alternatives, if the resident has refused specific treatments. (See Resident Rights 483.10(b) (3) and (4) (F154 and F155).)

Advance Directive. A resident who is at the end of life or in terminal stages of an illness or who has multiple organ system failures may have written directions for his or her treatment goals (or a decision has been made by the resident’s surrogate or representative, in accordance with state law).

Although a facility's care must reflect a resident's wishes as expressed in the directive, in accordance with state law, the presence of an advance directive does not absolve the facility from giving supportive and other pertinent care that is not prohibited by the advance directive. The presence of a “Do Not Resuscitate” (DNR) order does not indicate that the resident is declining appropriate treatment and services. It only indicates that the resident should not be resuscitated if respirations and/or cardiac function cease.

If the facility has implemented individualized approaches for end-of-life care in accordance with the resident's wishes and has implemented appropriate efforts to try to stabilize the resident's condition (or indicated why the condition cannot or should not be stabilized) and has provided care based on the assessed needs of the resident, then the development, continuation, or progression of urinary incontinence; the insertion and prolonged use of an indwelling urinary catheter; the development of infection or skin-related complications from urine or an indwelling catheter may be consistent with regulatory requirements.

Urinary Incontinence

42 CFR 483.25 (d) (2) Urinary incontinence requires that a resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

Urinary incontinence generally involves a number of transitory or chronic progressive factors that affect the bladder and/or the urethral sphincter. Any condition, medication, or factor that affects lower urinary tract function, bladder capacity, urination, or the ability to toilet can predispose residents to urinary incontinence and may contribute to incomplete bladder emptying.

The first steps toward assuring that a resident receives appropriate treatment and services to restore as much bladder function as possible or to treat and manage the incontinence are to identify the resident already experiencing some level of incontinence or at risk of developing urinary incontinence and to complete an accurate, thorough assessment of factors that may predispose the resident to
having urinary incontinence. This is followed by implementing appropriate, individualized interventions that address the incontinence, including the resident’s capabilities and underlying factors that can be removed, modified, or stabilized, and by monitoring the effectiveness of the interventions and modifying them, as appropriate. The practitioner may, at his or her option, refer residents to various practitioners who specialize in diagnosing and treating conditions that affect urinary function.

**Assessment**

Factors contributing to urinary incontinence sometimes may be resolved after a careful examination and review of history. In addition, for a resident who is incontinent of urine, determining the type of urinary incontinence can allow staff to provide more individualized programming or interventions to enhance the resident’s quality of life and functional status. A resident should be evaluated at admission and whenever there is a change in cognition, physical ability or urinary tract function. This evaluation is to include identification of individuals with reversible and irreversible (e.g., bladder tumors and spinal cord disease) causes of incontinence. If the resident has urinary incontinence that has already been investigated, documented and determined to be irreversible or not significantly improvable, additional studies may be of limited value, unless there has been advancement in available treatments.

Documentation of assessment information may be found throughout the medical record, such as in an admission assessment, hospital records, history and physical, and the Resident Assessment Instrument (RAI). The location of RAI assessment information is identified on the Resident Assessment Protocol (RAP) summary form. It is important that staff, when completing the comprehensive assessment, consider the following:

- Prior history of urinary incontinence, including onset, duration and characteristics, precipitants of urinary incontinence, associated symptoms (e.g., dysuria, polyuria, hesitancy), and previous treatment and/or management, including the response to the interventions and the occurrence of persistent or recurrent UTI;
- Voiding patterns (i.e., frequency, volume, nighttime or daytime, quality of stream) and, for those already experiencing urinary incontinence, voiding patterns over several days;
- Medication review, particularly those that might affect continence, such as medications with anticholinergic properties (may cause urinary retention and possible overflow incontinence), sedative/hypnotics (may cause sedation leading to functional incontinence), diuretics (may cause urgency, frequency, overflow incontinence), narcotics, alpha-adrenergic agonists (may cause urinary retention in men) or antagonists (may cause stress incontinence in women) calcium channel blockers (may cause urinary retention);¹
- Patterns of fluid intake, such as amounts, time of day, alterations and potential complications, such as decreased or increased urine output;
- Use of urinary tract stimulants or irritants (e.g., frequent caffeine intake);¹
- Pelvic and rectal examination to identify physical features that may directly affect urinary incontinence, such as prolapsed uterus or bladder, prostate...
enlargement, significant constipation or fecal impaction, use of a urinary catheter, atrophic vaginitis, distended bladder or bladder spasms;

- Functional and cognitive capabilities that could enhance urinary continence and limitations that could adversely affect continence, such as impaired cognitive function or dementia, impaired immobility, decreased manual dexterity, the need for task segmentation, decreased upper and lower extremity muscle strength, decreased vision, and pain with movement;

- Type and frequency of physical assistance necessary to assist the resident to access the toilet, commode, urinal, etc. and the types of prompting needed to encourage urination;

- Pertinent diagnoses such as congestive heart failure, stroke, diabetes mellitus, obesity, and neurological disorders (e.g., Multiple Sclerosis, Parkinson's Disease or tumors that could affect the urinary tract or its function);

- Identification of and/or potential of developing complications such as skin irritation or breakdown;

- Tests or studies indicated to identify the type(s) of urinary incontinence (e.g., post-void residual(s) for residents who have, or are at risk of, urinary retention, results of any urine culture if the resident has clinically significant systemic or urinary symptoms), or evaluations assessing the resident's readiness for bladder rehabilitation programs; and

- Environmental factors and assistive devices that may restrict or facilitate a resident's ability to access the toilet (e.g., grab bars, raised or low toilet seats, inadequate lighting, distance to toilet or bedside commodes, availability of urinals, use of bed rails or restraints, or fear of falling).

**Types of Urinary Incontinence**

Identifying the nature of the incontinence is a key aspect of the assessment and helps identify the appropriate program/interventions to address incontinence.

- “Urge incontinence” is characterized by abrupt urgency, frequency and nocturia (part of the overactive bladder diagnosis). It may be age-related or have neurological causes (e.g., stroke, diabetes mellitus, Parkinson's Disease, Multiple Sclerosis) or other causes such as bladder infection, urethral irritation, etc. The resident can feel the need to void, but is unable to inhibit voiding long enough to reach and sit on the commode. It is the most common cause of urinary incontinence in elderly persons.

- “Stress incontinence” is the loss of a small amount of urine with physical activity such as coughing, sneezing, laughing, walking stairs or lifting. Urine leakage results from an increase in intra-abdominal pressure on a bladder that is not over distended and is not the result of detrusor contractions. It is the second most common type of urinary incontinence in older women.

- “Mixed incontinence” is the combination of urge incontinence and stress incontinence. Many elderly persons (especially women) will experience symptoms of both urge and stress called mixed incontinence.
“Overflow incontinence” occurs when the bladder is distended from urine retention. Symptoms of overflow incontinence may include: weak stream, hesitancy, or intermittency; dysuria; nocturia; frequency; incomplete voiding; frequent or constant dribbling. Urine retention may result from outlet obstruction (e.g., benign prostatic hypertrophy (BPH), prostate cancer and urethral stricture), hypotonic bladder (detrusor under activity) or both. Hypotonic bladder may be caused by outlet obstruction, impaired or absent contractility of the bladder (neurogenic bladder) or other causes. Neurogenic bladder may also result from neurological conditions such as diabetes mellitus, spinal cord injury, or pelvic nerve damage from surgery or radiation therapy. In overflow incontinence, post-void residual (PVR) volume (the amount of urine remaining in the bladder within five to 10 minutes following urination) exceeds 200 milliliters (ml). Normal PVR is usually 50 ml or less. A PVR of 150 to 200 may suggest a need for retesting to determine if this finding is clinically significant. Overflow incontinence may mimic urge or stress incontinence but is less common than either of those.

“Functional incontinence” refers to incontinence that is secondary to factors other than inherently abnormal urinary tract function. It may be related to physical weakness or poor mobility/dexterity (e.g., due to poor eyesight, arthritis, deconditioning, stroke, contracture), cognitive problems (e.g., confusion, dementia, unwillingness to toilet), various medications (e.g., anti-cholinergics, diuretics) or environmental impediments (e.g., excessive distance of the resident from the toilet facilities, poor lighting, low chairs that are difficult to get out of, physical restraints and toilets that are difficult to access). Refer to 42 CFR 483.15(e) (1) for issues regarding unmet environmental needs (e.g., handicap toilet, lighting, assistive devices).

NOTE: Treating the physiological causes of incontinence, without attending to functional components that may have an impact on the resident’s continence, may fail to solve the incontinence problem.

“Transient incontinence” refers to temporary or occasional incontinence that may be related to a variety of causes, (for example: delirium, infection, atrophic urethritis or vaginitis, some pharmaceuticals (such as sedatives/hypnotics, diuretics, anticholinergic agents), increased urine production, restricted mobility or fecal impaction). The incontinence is transient because it is related to a potentially improvable or reversible cause.

Interventions

It is important that the facility follow the care process (accurate assessment, care planning, consistent implementation and monitoring of the care plan with evaluation of the effectiveness of the interventions, and revision, as appropriate). Recording and evaluating specific information (such as frequency and times of incontinence and toileting and response to specific interventions) is important for determining progress, changes, or decline.

A number of factors may contribute to the decline or lack of improvement in urinary continence, for example: underlying medical conditions, an inaccurate assessment of the resident’s type of incontinence (or lack of knowledge about the resident’s voiding patterns) may contribute to inappropriate interventions or unnecessary use of an indwelling catheter. Facility practices that may promote achieving the
highest practicable level of functioning, may prevent or minimize a decline or lack of improvement in degree of continence include providing treatment and services to address factors that are potentially modifiable, such as:

- Managing pain and/or providing adaptive equipment to improve function for residents suffering from arthritis, contractures, neurological impairments, etc;
- Removing or improving environmental impediments that affect the resident’s level of continence (e.g., improved lighting, use of a bedside commode or reducing the distance to the toilet);
- Treating underlying conditions that have a potentially negative impact on the degree of continence (e.g., delirium causing urinary incontinence related to acute confusion);
- Possibly adjusting medications affecting continence (e.g., medication cessation, dose reduction, selection of an alternate medication, change in time of administration); and
- Implementing a fluid and/or bowel management program to meet the assessed needs.

Options for managing urinary incontinence in nursing home residents include primarily behavioral programs and medication therapy. Other measures and supportive devices used in the management of urinary incontinence and/or urinary retention may include intermittent catheterization; pelvic organ support devices (pessaries); the use of incontinence products, garments and an external collection system for men and women; and environmental accommodation and/or modification.

**Behavioral Programs**

Interventions involving the use of behavioral programs are among the least invasive approaches to address urinary incontinence and have no known adverse complications. Behavior programs involve efforts to modify the resident’s behavior and/or environment. Critical aspects of a successful behavioral program include education of the caregiver and the resident, availability of the staff and the consistent implementation of the interventions.

NOTE: It is important for the comprehensive assessment to identify the essential skills the resident must possess to be successful with specific interventions being attempted. These skills include the resident’s ability to: comprehend and follow through on education and instructions; identify urinary urge sensation; learn to inhibit or control the urge to void until reaching a toilet; contract the pelvic floor muscle (Kegel exercises) to lessen urgency and/or urinary leakage; and/or respond to prompts to void. Voiding records help detect urinary patterns or intervals between incontinence episodes and facilitate planning care to avoid or reduce the frequency of episodes.

Programs that require the resident’s cooperation and motivation in order for learning and practice to occur include the following:

- “Bladder rehabilitation/bladder retraining” is a behavioral technique that requires the resident to resist or inhibit the sensation of urgency (the
strong desire to urinate), to postpone or delay voiding, and to urinate according to a timetable rather than to the urge to void. Depending upon the resident’s successful ability to control the urge to void, the intervals between voiding may be increased progressively. Bladder training generally consists of education, scheduled voiding with systematic delay of voiding and positive reinforcement. This program is difficult to implement in cognitively impaired residents and may not be successful in frail, elderly or dependent residents. The resident who may be appropriate for a bladder rehabilitation (retraining) program is usually fairly independent in activities of daily living, has occasional incontinence, is aware of the need to urinate (void), may wear incontinence products for episodic urine leakage, and has a goal to maintain his or her highest level of continence and decrease urine leakage. Successful bladder retraining usually takes at least several weeks. Residents who are assessed with urge or mixed incontinence and are cognitively intact may be candidates for bladder retraining; and

- “Pelvic floor muscle rehabilitation,” also called Kegel and pelvic floor muscle exercise, is performed to strengthen the voluntary periurethral and perivaginal muscles that contribute to the closing force of the urethra and the support of the pelvic organs. These exercises are helpful in dealing with urge and stress incontinence. Pelvic floor muscle exercises (PFME) strengthen the muscular components of urethral supports and are the cornerstone of noninvasive treatment of stress urinary incontinence. PFME requires residents who are able and willing to participate and the implementation of careful instructions and monitoring provided by the facility. Poor resident adherence to the exercises may occur even with close monitoring.

Programs that are dependent on staff involvement and assistance, as opposed to resident function, include the following:

- “Prompted voiding” is a behavioral technique appropriate for use with dependent or more cognitively impaired residents. Prompted voiding techniques have been shown to reduce urinary incontinence episodes up to 40% for elderly incontinent nursing home residents, regardless of their type of urinary incontinence or cognitive deficit — provided that they at least are able to say their name or reliably point to one of two objects. Prompted voiding has three components: regular monitoring with encouragement to report continence status; prompting to toilet on a scheduled basis; and praise and positive feedback when the resident is continent and attempts to toilet. These methods require training, motivation and continued effort by the resident and caregivers to ensure continued success. Prompted voiding focuses on teaching the resident, who is incontinent, to recognize bladder fullness or the need to void, to ask for help, or to respond when prompted to toilet.

Residents who are assessed with urge or mixed incontinence and are cognitively impaired may be candidates for prompted voiding. As the resident’s cognition changes, the facility should consider other factors, such as mobility, when deciding to conduct a voiding trial to determine feasibility of an ongoing toileting program; and

- “Habit training/scheduled voiding” is a behavioral technique that calls for scheduled toileting at regular intervals on a planned basis to match the resident’s voiding habits. Unlike bladder retraining, there is no systematic
effort to encourage the resident to delay voiding and resist urges. Habit training includes timed voiding with the interval based on the resident’s usual voiding schedule or pattern. Scheduled voiding is timed voiding, usually every three to four hours while awake. Residents who cannot self-toilet may be candidates for habit training or scheduled voiding programs.

**Intermittent Catheterization** - Sterile insertion and removal of a catheter through the urethra every three to six hours for bladder drainage may be appropriate for the management of acute or chronic urinary retention. See additional discussion below in “Catheterization”.

**Medication Therapy** - Medications are often used to treat specific types of incontinence, including stress incontinence and those categories associated with an overactive bladder, which may involve symptoms including urge incontinence, urinary urgency, frequency and nocturia. The current literature identifies classifications and names of medications used for various types of incontinence. When using medications, potentially problematic anticholinergic and other side effects must be recognized. The use of medication therapy to treat urinary incontinence may not be appropriate for some residents because of potential adverse interactions with their other medications or other co-morbid conditions. Therefore, it is important to weigh the risks and benefits before prescribing medications for continence management and to monitor for both effectiveness and side effects. As with all approaches attempting to improve control or management of incontinence, the education and discussion with the resident (or the resident’s surrogate) regarding the benefits and risks of pharmacologic therapies is important.

**Pessary** - A pessary is an intra-vaginal device used to treat pelvic muscle relaxation or prolapse of pelvic organs. Women whose urine retention or urinary incontinence is exacerbated by bladder or uterine prolapse may benefit from placement of a pessary. Female residents may be admitted to the nursing home with a pessary device. The assessment should note whether the resident has a pessary in place or has had a history of successful pessary use. If a pessary is to be used, it is important to develop a plan of care for ongoing management and for the prevention of and monitoring for complications.

**Absorbent Products, Toileting Devices and External Collection Devices** - Absorbent incontinence products include perineal pads or panty liners for slight leakage, undergarments and protective underwear for moderate to heavy leakage, guards and drip collection pouches for men, and products (called adult briefs) for moderate or heavy loss. Absorbent products can be a useful, rational way to manage incontinence; however, every absorbent product has a saturation point. Factors contributing to the selection of the type of product to be used should include the severity of incontinence, gender, fit and ease of use.

Advantages of using absorbent products to manage urinary incontinence include the ability to contain urine (some may wick the urine away from the skin), provide protection for clothing, and preserve the resident’s dignity and comfort.

**NOTE:** Although many residents have used absorbent products prior to admission to the nursing home and the use of absorbent products may be appropriate, absorbent products should not be used as the primary long term approach to continence management until the resident has been appropriately evaluated and other alternative approaches have been considered.

The potential disadvantages of absorbent products are the impact on the resident’s dignity, cost, the association with skin breakdown and irritation, and the amount of time needed to check and change them.6
It is important that residents using various toileting devices, absorbent products, external collection devices, etc., be checked (and changed as needed) on a schedule based upon the resident's voiding pattern, accepted standards of practice, and the manufacturer's recommendations.

**Skin-Related Complications**

Skin problems associated with incontinence and moisture can range from irritation to increased risk of skin breakdown. Moisture may make the skin more susceptible to damage from friction and shear during repositioning.

One form of early skin breakdown is maceration or the softening of tissue by soaking. Macerated skin has a white appearance and a very soft, sometimes “soggy” texture.

The persistent exposure of perineal skin to urine and/or feces can irritate the epidermis and can cause severe dermatitis or skin erosion. Skin erosion is the loss of some or all of the epidermis (comparable to a deep chemical peel) leaving a slightly depressed area of skin.

One key to preventing skin breakdown is to keep the perineal skin clean and dry. Research has shown that a soap and water regimen alone may be less effective in preventing skin breakdown compared with moisture barriers and no-rinse incontinence cleansers. Because frequent washing with soap and water can dry the skin, the use of a perineal rinse may be indicated. Moisturizers help preserve the moisture in the skin by either sealing in existing moisture or adding moisture to the skin. Moisturizers include creams, lotions or pastes. However, moisturizers should be used sparingly — if at all — on already macerated or excessively moist skin.

**Catheterization**

42 CFR 483.25 (d) (1) Urinary incontinence requires that a resident who enters the facility without an indwelling catheter is not catheterized unless the resident’s clinical condition demonstrates that catheterization was necessary. Some residents are admitted to the facility with indwelling catheters that were placed elsewhere (e.g., during a recent acute hospitalization). The facility is responsible for the assessment of the resident at risk for urinary catheterization and/or the ongoing assessment for the resident who currently has a catheter. This is followed by implementation of appropriate individualized interventions and monitoring for the effectiveness of the interventions.

**Assessment**

A resident may be admitted to the facility with or without an indwelling urinary catheter (urethral or suprapubic) and may be continent or incontinent of urine. Regardless of the admission status, a comprehensive assessment should address those factors that predispose the resident to the development of urinary incontinence and the use of an indwelling urinary catheter.

An admission evaluation of the resident’s medical history and a physical examination helps identify the resident at risk for requiring the use of an indwelling urinary catheter. This evaluation is to include detection of reversible causes of incontinence and identification of individuals with incontinence caused by conditions that may not be reversible, such as bladder tumors and spinal cord
diseases. (See the assessment factors discussed under incontinence.) The assessment of continence/incontinence is based upon an interdisciplinary review. The comprehensive assessment should include underlying factors supporting the medical justification for the initiation and continuing need for catheter use, determination of which factors can be modified or reversed (or rationale for why those factors should not be modified), and the development of a plan for removal. The clinician’s decision to use an indwelling catheter in the elderly should be based on valid clinical indicators.

For the resident with an indwelling catheter, the facility’s documented assessment and staff knowledge of the resident should include information to support the use of an indwelling catheter. Because of the risk of substantial complications with the use of indwelling urinary catheters, they should be reserved primarily for short-term decompression of acute urinary retention. The assessment should include consideration of the risks and benefits of an indwelling (suprapubic or urethral) catheter; the potential for removal of the catheter; and consideration of complications resulting from the use of an indwelling catheter, such as symptoms of blockage of the catheter with associated bypassing of urine, expulsion of the catheter, pain, discomfort and bleeding.

**Intermittent Catheterization**

Intermittent catheterization can often manage overflow incontinence effectively. Residents who have new onset incontinence from a transient, hypotonic/atonic bladder (usually seen following indwelling catheterization in the hospital) may benefit from intermittent bladder catheterization until the bladder tone returns (e.g., up to approximately seven days). A voiding trial and post void residual can help identify when bladder tone has returned.

**Indwelling Catheter Use**

The facility’s documented assessment and staff approach to the resident should be based on evidence to support the use of an indwelling catheter. Appropriate indications for continuing use of an indwelling catheter beyond 14 days may include:

- Urinary retention that cannot be treated or corrected medically or surgically, for which alternative therapy is not feasible, and which is characterized by:
  - Documented post-void residual (PVR) volumes in a range over 200 milliliters (ml);
  - Inability to manage the retention/incontinence with intermittent catheterization; and
  - Persistent overflow incontinence, symptomatic infections, and/or renal dysfunction.

- Contamination of Stage III or IV pressure ulcers with urine which has impeded healing, despite appropriate personal care for the incontinence; and

- Terminal illness or severe impairment, which makes positioning or clothing changes uncomfortable, or which is associated with intractable pain.
Catheter-Related Complications

An indwelling catheter may be associated with significant complications, including bacteremia, febrile episodes, bladder stones, fistula formation, erosion of the urethra, epididymitis, chronic renal inflammation and pyelonephritis. In addition, indwelling catheters are prone to blockage. Risk factors for catheter blockage include alkaline urine, poor urine flow, proteinuria, and preexisting bladder stones. In the absence of evidence indicating blockage, catheters need not be changed routinely as long as monitoring is adequate. Based on the resident’s individualized assessment, the catheter may need to be changed more or less often than every 50 days.

Some residents with indwelling catheters experience persistent leakage around the catheter. Examples of factors that may contribute to leakage include irritation by a large balloon or by catheter materials, excessive catheter diameter, fecal impaction, and improper catheter positioning. Because leakage around the catheter is frequently caused by bladder spasm, leakage should generally not be treated by using increasingly larger catheter sizes, unless medically justified. Current standards indicate that catheterization should be accomplished with the narrowest, softest tube that will serve the purpose of draining the bladder. Additional care practices related to catheterization include:

- Educating the resident or responsible party on the risks and benefits of catheter use;
- Recognizing and assessing for complications and their causes, and maintaining a record of any catheter-related problems;
- Attempts to remove the catheter as soon as possible when no indications exist for its continuing use;
- Monitoring for excessive post-void residual, after removing a catheter that was inserted for obstruction or overflow incontinence;
- Keeping the catheter anchored to prevent excessive tension on the catheter, which can lead to urethral tears or dislodging the catheter; and
- Securing the catheter to facilitate flow of urine.

Research has shown that catheterization is an important, potentially modifiable, risk factor for UTI. By the 30th day of catheterization, bacteriuria is nearly universal. The potential for complications can be reduced by:

- Identifying specific clinical indications for the use of an indwelling catheter;
- Assessing whether other treatments and services would appropriately address those conditions; and
- Assessing whether residents are at risk for other possible complications resulting from the continuing use of the catheter, such as obstruction resulting from catheter encrustation, urethral erosion, bladder spasms, hematuria and leakage around the catheter.
Urinary Tract Infections

Catheter-Related Bacteriuria and UTIs/Urosepsis

Most individuals with indwelling catheters for more than seven days have bacteriuria. Bacteriuria alone in a catheterized individual should not be treated with antibiotics.

A long-term indwelling catheter (>two to four weeks) increases the chances of having a symptomatic UTI and urosepsis. The incidence of bacteremia is 40 times greater in individuals with a long term indwelling catheter than in those without one. For suspected UTIs in a catheterized individual, the literature recommends removing the current catheter and inserting a new one and obtaining a urine sample via the newly inserted catheter.10

Clinical Evidence That May Suggest UTI

Clinically, an acute deterioration in stable chronic symptoms may indicate an acute infection. Multiple co-existing findings, such as fever with hematuria, are more likely to be from a urinary source.

No one lab test alone proves that a UTI is present. For example, a positive urine culture will show bacteriuria but that alone is not enough to diagnose a symptomatic UTI. However, several test results in combination with clinical findings can help to identify UTIs such as the presence of pyuria (more than minimal white cells in the urine) on microscopic urinalysis or a positive urine dipstick test for leukocyte esterase (indicating significant pyuria) or for nitrites (indicating the presence of Enterobacteriaceae). A negative leukocyte esterase or the absence of pyuria strongly suggests that a UTI is not present. A positive leukocyte esterase test alone does not prove that the individual has a UTI.11

In someone with nonspecific symptoms, such as a change in function or mental status, bacteriuria alone does not necessarily warrant antibiotic treatment. Additional evidence that could confirm a UTI may include hematuria, fever (which could include a variation from the individual’s normal or usual temperature range), or evidence of pyuria (either by microscopic examination or by dipstick test). In the absence of fever, hematuria, pyuria, or local urinary tract symptoms, other potential causes of nonspecific general symptoms, such as fluid and electrolyte imbalance or adverse drug reactions, should be considered instead of, or in addition to, a UTI. Although sepsis, including urosepsis, can cause dizziness or falling, there is not clear evidence linking bacteriuria or a localized UTI to an increased fall risk.12

Indications to Treat a UTI

Because many residents have chronic bacteriuria, the research-based literature suggests treating only symptomatic UTIs. Symptomatic UTIs are based on the following criteria:13

- Residents without a catheter should have at least three of the following signs and symptoms:
  - Fever (increase in temperature of >two degrees F (1.1 degrees C) or rectal temperature >99.5 degrees F (37.5 degrees C) or single measurement of temperature >100 degrees F (57.8 degrees C ));14
  - New or increased burning pain on urination, frequency or urgency;
– New flank or suprapubic pain or tenderness;
– Change in character of urine (e.g., new bloody urine, foul smell or amount of sediment) or as reported by the laboratory (new pyuria or microscopic hematuria); and/or
– Worsening of mental or functional status (e.g., confusion, decreased appetite, unexplained falls, incontinence of recent onset, lethargy, decreased activity).\textsuperscript{15}

• Residents with a catheter should have at least two of the following signs and symptoms:
  – Fever or chills;
  – New flank pain or suprapubic pain or tenderness;
  – Change in character of urine (e.g., new bloody urine, foul smell or amount of sediment) or as reported by the laboratory (new pyuria or microscopic hematuria); and/or
  – Worsening of mental or functional status. Local findings such as obstruction, leakage or mucosal trauma (hematuria) may also be present.\textsuperscript{16}

\textbf{Follow-Up of UTIs}

The goal of treating a UTI is to alleviate systemic or local symptoms, not to eradicate all bacteria. Therefore, a post-treatment urine culture is not routinely necessary but may be useful in select situations. Continued bacteriuria without residual symptoms does not warrant repeat or continued antibiotic therapy. Recurrent UTIs (two or more in six months) in a noncatheterized individual may warrant additional evaluation (such as a determination of an abnormal post-void residual (PVR) urine volume or a referral to a urologist) to rule out structural abnormalities such as enlarged prostate, prolapsed bladder, periurethral abscess, strictures, bladder calculi, polyps and tumors.

Recurrent symptomatic UTIs in a catheterized or noncatheterized individual should lead the facility to check whether perineal hygiene is performed consistently to remove fecal soiling in accordance with accepted practices. Recurrent UTIs in a catheterized individual should lead the facility to look for possible impairment of free urine flow through the catheter, to re-evaluate the techniques being used for perineal hygiene and catheter care, and to reconsider the relative risks and benefits of continuing the use of an indwelling catheter.

Because the major factors (other than an indwelling catheter) that predispose individuals to bacteriuria, including physiological aging changes and chronic co-morbid illnesses, cannot be modified readily, the facility should demonstrate that they:

• Employ standard infection control practices in managing catheters and associated drainage system;
• Strive to keep the resident and catheter clean of feces to minimize bacterial migration into the urethra and bladder (e.g., cleaning fecal material away from, rather than towards, the urinary meatus);
• Take measures to maintain free urine flow through any indwelling catheter; and
• Assess for fluid needs and implement a fluid management program (using alternative approaches as needed) based on those assessed needs.

End Notes


RANGE OF MOTION

§483.25(e) Range of motion.

F317

§483.25(e)(1) A resident who enters the facility without a limited range of motion does not experience reduction in range of motion unless the resident’s clinical condition demonstrates that a reduction in range of motion is unavoidable; and

See Interpretive Guidelines At Tag F318

F318

§483.25(e)(2) A resident with a limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion

Intent §483.25(e)

The intent of this regulation is to ensure that the resident reaches and maintains his or her highest level of range of motion and to prevent avoidable decline of range of motion.

Interpretive Guidelines §483.25(e)

This corresponds to MDS 2.0 sections G and P when specified for use by the state.

“Range of motion (ROM)” is defined as the extent of movement of a joint.

The clinical condition that may demonstrate that a reduction in ROM is unavoidable is: limbs or digits immobilized because of injury or surgical procedures (e.g., surgical adhesions).

Adequate preventive care may include active ROM performed by the resident; passive ROM performed by staff; active-assistive ROM exercise performed by the resident and staff; and application of splints and braces, if necessary.

Examples of clinical conditions that are the primary risk factors for a decreased range of motion are:

- Immobilization (e.g., bedfast);
- Deformities arising out of neurological deficits (e.g., strokes, multiple sclerosis, cerebral palsy and polio); and
- Pain, spasms and immobility associated with arthritis or late-stage Alzheimer’s disease. This clinical condition may demonstrate that a reduction in ROM is unavoidable only if adequate assessment, appropriate care planning, and preventive care was provided and resulted in limitation in ROM or muscle atrophy.
§483.25(l) Unnecessary Drugs

1. General. Each resident’s drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

   (i) In excessive dose (including duplicate therapy); or
   (ii) For excessive duration; or
   (iii) Without adequate monitoring; or
   (iv) Without adequate indications for its use; or
   (v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
   (vi) Any combinations of the reasons above.

2. Antipsychotic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that:

   (i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and
   (ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

INTENT: §483.25(l) Unnecessary drugs

The intent of this requirement is that each resident’s entire drug/medication regimen be managed and monitored to achieve the following goals:

- The medication regimen helps promote or maintain the resident’s highest practicable mental, physical, and psychosocial well-being, as identified by the resident and/or representative(s) in collaboration with the attending physician and facility staff;
- Each resident receives only those medications, in doses and for the duration clinically indicated to treat the resident’s assessed condition(s);
- Non-pharmacological interventions (such as behavioral interventions) are considered and used when indicated, instead of, or in addition to, medication;
- Clinically significant adverse consequences are minimized; and
- The potential contribution of the medication regimen to an unanticipated decline or newly emerging or worsening symptom is recognized and evaluated, and the regimen is modified when appropriate.

NOTE: This guidance applies to all categories of medications including antipsychotic medications.

Although the regulatory language refers to “drugs,” the guidance in this document generally will refer to “medications,” except in those situations...
where the term “drug” has become part of an established pharmaceutical term (e.g., adverse drug event, and adverse drug reaction or consequence).

For purposes of this guidance, references to “the pharmacist” mean the facility's licensed pharmacist, whether employed directly by the facility or through arrangement.

The surveyor’s review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents.

DEFINITIONS

Definitions are provided to clarify terminology related to medications and to the evaluation and treatment of residents.

- “Adverse consequence” is an unpleasant symptom or event that is due to or associated with a medication, such as impairment or decline in an individual’s mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease)

NOTE: Adverse drug reaction (ADR) is a form of adverse consequences. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or treatment. The term “side effect” is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.

- “Anticholinergic side effect” is an effect of a medication that opposes or inhibits the activity of the parasympathetic (cholinergic) nervous system to the point of causing symptoms such as dry mouth, blurred vision, tachycardia, urinary retention, constipation, confusion, delirium, or hallucinations

- “Behavioral interventions” are individualized non-pharmacological approaches (including direct care and activities) that are provided as part of a supportive physical and psychosocial environment, and are directed toward preventing, relieving, and/or accommodating a resident's distressed behavior

- “Clinically significant” refers to effects, results, or consequences that materially affect or are likely to affect an individual's mental, physical, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status

- “Distressed behavior” is behavior that reflects individual discomfort or emotional strain. It may present as crying, apathetic or withdrawn behavior, or as verbal or physical actions such as: pacing, cursing, hitting, kicking, pushing, scratching, tearing things, or grabbing others
• “Dose” is the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.

  – “Excessive dose” means the total amount of any medication (including duplicate therapy) given at one time or over a period of time that is greater than the amount recommended by the manufacturer’s label, package insert, current standards of practice for a resident's age and condition, or clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals and that lacks evidence of:
    – A review for the continued necessity of the dose;
    – Attempts at, or consideration of the possibility of, tapering a medication; and
    – A documented clinical rationale for the benefit of, or necessity for, the dose or for the use of multiple medications from the same pharmacological class.

• “Duplicate therapy” refers to multiple medications of the same pharmacological class/category or any medication therapy that substantially duplicates a particular effect of another medication that the individual is taking.

• “Duration” is the total length of time the medication is being received.

  – “Excessive Duration” means the medication is administered beyond the manufacturer's recommended time frames or facility-established stop order policies, beyond the length of time advised by current standards of practice, clinical practice guidelines, clinical studies or evidence-based review articles, and/or without either evidence of additional therapeutic benefit for the resident or clinical evidence that would warrant the continued use of the medication.

• “Extrapyramidal symptoms (EPS)” are neurological side effects that can occur at any time from the first few days of treatment to years later. EPS includes various syndromes such as:

  – Akathisia, which refers to a distressing feeling of internal restlessness that may appear as constant motion, the inability to sit still, fidgeting, pacing, or rocking.
  – Medication-induced Parkinsonism, which refers to a syndrome of Parkinson-like symptoms including tremors, shuffling gait, slowness of movement, expressionless face, drooling, postural unsteadiness and rigidity of muscles in the limbs, neck and trunk.
  – Dystonia, which refers to an acute, painful, spastic contraction of muscle groups (commonly the neck, eyes and trunk) that often occurs soon after initiating treatment and is more common in younger individuals.

• “Gradual Dose Reduction (GDR)” is the stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued.

• “Indications for use” is the identified, documented clinical rationale for administering a medication that is based upon an assessment of
the resident's condition and therapeutic goals and is consistent with manufacturer’s recommendations and/or clinical practice guidelines, clinical standards of practice, medication references, clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.

- “Insomnia” is the inability to sleep characterized by difficulty falling asleep, difficulty staying asleep, early waking, or non-restorative sleep, which may result in impaired physical, social, or cognitive function.

- “Medication Interaction” is the impact of another substance (such as another medication, nutritional supplement including herbal products, food, or substances used in diagnostic studies) upon a medication. The interactions may alter absorption, distribution, metabolism, or elimination. These interactions may decrease the effectiveness of the medication or increase the potential for adverse consequences.

- “Medication Regimen Review” (MRR) is a thorough evaluation of the medication regimen by a pharmacist, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication. The review includes preventing, identifying, reporting, and resolving medication-related problems, medication errors, or other irregularities in collaboration with other members of the interdisciplinary team.51

- “Monitoring” is the ongoing collection and analysis of information (such as observations and diagnostic test results) and comparison to baseline data in order to:
  - Ascertain the individual's response to treatment and care, including progress or lack of progress toward a therapeutic goal;
  - Detect any complications or adverse consequences of the condition or of the treatments; and
  - Support decisions about modifying, discontinuing, or continuing any interventions.

- “Neuroleptic Malignant Syndrome” (NMS) is a syndrome related to the use of medications, mainly antipsychotics, that typically presents with a sudden onset of diffuse muscle rigidity, high fever, labile blood pressure, tremor, and notable cognitive dysfunction. It is potentially fatal if not treated immediately, including stopping the offending medications.

- “Non-pharmacological interventions” refers to approaches to care that do not involve medications, generally directed towards stabilizing or improving a resident’s mental, physical or psychosocial well-being.

- “Psychopharmacological medication” is any medication used for managing behavior, stabilizing mood, or treating psychiatric disorders.

- “Serotonin Syndrome” is a potentially serious clinical condition resulting from overstimulation of serotonin receptors. It is commonly related to the use of multiple serotonin-stimulating medications (e.g., SSRIs, SNRIs, triptans, certain antibiotics). Symptoms may include restlessness, hallucinations, confusion, loss of coordination, fast heart beat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting and diarrhea.
“Tardive dyskinesia” refers to abnormal, recurrent, involuntary movements that may be irreversible and typically present as lateral movements of the tongue or jaw, tongue thrusting, chewing, frequent blinking, brow arching, grimacing, and lip smacking, although the trunk or other parts of the body may also be affected.

**Overview**

Medications are an integral part of the care provided to residents of nursing facilities. They are administered to try to achieve various outcomes, such as curing an illness, diagnosing a disease or condition, arresting or slowing a disease process, reducing or eliminating symptoms, or preventing a disease or symptom.

A study of 33,301 nursing facility residents found that an average of 6.7 medications were ordered per resident, with 27 percent of residents taking nine or more medications. Analysis of antipsychotic use by 693,000 Medicare nursing home residents revealed that 28.5 percent of the doses received were excessive and 32.2 percent lacked appropriate indications for use.

Proper medication selection and prescribing (including dose, duration, and type of medication(s)) may help stabilize or improve a resident's outcome, quality of life and functional capacity. Any medication or combination of medications—or the use of a medication without adequate indications, in excessive dose, for an excessive duration, or without adequate monitoring—may increase the risk of a broad range of adverse consequences such as medication interactions, depression, confusion, immobility, falls, and related hip fractures.

Intrinsic factors including physiological changes accompanying the aging process, multiple comorbidities, and certain medical conditions may affect the absorption, distribution, metabolism or elimination of medications from the body and may also increase an individual’s risk of adverse consequences.

While assuring that only those medications required to treat the resident's assessed condition are being used, reducing the need for and maximizing the effectiveness of medications are important considerations for all residents. Therefore, as part of all medication management (including antipsychotics), it is important for the interdisciplinary team to consider non-pharmacological approaches. Educating facility staff and providers in addition to implementing non-pharmacological approaches to resident conditions prior to, and/or in conjunction with, the use of medications may minimize the need for medications or reduce the dose and duration of those medications.

Examples of non-pharmacological interventions may include:

- Increasing the amount of resident exercise, intake of liquids and dietary fiber in conjunction with an individualized bowel regimen to prevent or reduce constipation and the use of medications (e.g. laxatives and stool softeners);
- Identifying, addressing, and eliminating or reducing underlying causes of distressed behavior such as boredom and pain;
- Using sleep hygiene techniques and individualized sleep routines;
- Accommodating the resident's behavior and needs by supporting and encouraging activities reminiscent of lifelong work or activity patterns,
such as providing early morning activity for a farmer used to awakening early;

- Individualizing toileting schedules to prevent incontinence and avoid the use of incontinence medications that may have significant adverse consequences (e.g., anticholinergic effects);

- Developing interventions that are specific to resident’s interests, abilities, strengths and needs, such as simplifying or segmenting tasks for a resident who has trouble following complex directions;

- Using massage, hot/warm or cold compresses to address a resident’s pain or discomfort; or

- Enhancing the taste and presentation of food, assisting the resident to eat, addressing food preferences, and increasing finger foods and snacks for an individual with dementia, to improve appetite and avoid the unnecessary use of medications intended to stimulate appetite.

The indications for initiating, withdrawing, or withholding medication(s), as well as the use of non-pharmacological approaches, are determined by assessing the resident’s underlying condition, current signs and symptoms, and preferences and goals for treatment. This includes, where possible, the identification of the underlying cause(s), since a diagnosis alone may not warrant treatment with medication.

Orders from multiple prescribers can increase the resident’s chances of receiving unnecessary medications. Many residents receive orders for medications from several practitioners, for example, attending and on-call physicians, consultants, and nurse practitioner(s). It is important that the facility clearly identify who is responsible for prescribing and identifying the indications for use of medication(s), for providing and administering the medication(s), and for monitoring the resident for the effects and potential adverse consequence of the medication regimen. This is also important when care is delivered or ordered by diverse sources such as consultants, providers, or suppliers (e.g., hospice or dialysis programs).

Staff and practitioner access to current medication references and pertinent clinical protocols helps to promote safe administration and monitoring of medications. One of the existing mechanisms to warn prescribers about risks associated with medications is the Food and Drug Administration (FDA) requirement that manufacturers include within the medication labeling warnings about adverse reactions and potential safety hazards identified both before and after approval of a medication, and what to do if they occur (Visit: www.fda.gov/medwatch/safety.htm). Manufacturers are required to update labels to warn about newly identified safety hazards—regardless of whether causation has been proven and whether the medication is prescribed for a disease or condition that is not included in the “Indications and Usage” section of the labeling (so-called “off-label” or unapproved use). The FDA may require manufacturers to place statements about serious problems in a prominently displayed box (so-called boxed or “black box” warnings), which indicates a need to closely evaluate and monitor the potential benefits and risks of that medication.

The facility’s pharmacist is a valuable source of information about medications. Listings or descriptions of most significant risks, recommended doses, medication interactions, cautions, etc. can be found in widely available, standard references, and computer software and systems that provide up-to-date information. It is important
to note that some of the medication information found in many of these references is not specific to older adults or institutionalized individuals.

Clinical standards of practice and clinical guidelines established by professional groups are useful to guide clinicians. Some of the recognized clinical resources available for understanding the overall treatment and management of medical problems, symptoms and medication consequences and precautions include the:

- American Geriatrics Society [www.americangeriatrics.org](http://www.americangeriatrics.org) and [www.geriatricsatyourfingertips.org](http://www.geriatricsatyourfingertips.org);
- American Medical Directors Association [www.amda.com](http://www.amda.com);
- American Psychiatric Association [www.psych.org](http://www.psych.org);
- American Society of Consultant Pharmacists [www.ASCP.com](http://www.ASCP.com);
- Agency for Healthcare Research and Quality (AHRQ) [www.ahrq.gov](http://www.ahrq.gov);
- American Association for Geriatric Psychiatry [www.aagp.org](http://www.aagp.org);
- Association for Practitioners in Infection Control and Epidemiology [www.apic.org](http://www.apic.org);
- CMS Sharing Innovations in Quality Web site maintained at: [http://siq.air.org](http://siq.air.org);
- National Guideline Clearinghouse [www.guideline.gov](http://www.guideline.gov);
- Quality Improvement Organizations, Medicare Quality Improvement Community Initiatives [www.medqic.org](http://www.medqic.org);
- U.S. Department of Health and Human Services, Food and Drug Administration Web site [www.fda.gov/medwatch/safety.htm](http://www.fda.gov/medwatch/safety.htm);
- U.S. Department of Health and Human Services, National Institute of Mental Health Web site, which includes publications and clinical research information [www.nimh.nih.gov](http://www.nimh.nih.gov);
- Mace N, Rabins P. The 36-Hour Day: A Family Guide to Caring for Persons with Alzheimer’s Disease, Related Dementing Illnesses, and Memory Loss in Later Life; and
- “Bathing without a battle” [www.bathingwithoutabattle.unc.edu](http://www.bathingwithoutabattle.unc.edu)

NOTE: References to non-CMS sources or sites on the Internet included above or later in this document 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.

Although these guidelines generally emphasize the older adult resident, adverse consequences can occur in anyone at any age; therefore, these requirements apply to residents of all ages.
Medication Management

Medication management is based in the care process and includes recognition or identification of the problem/need, assessment, diagnosis/cause identification, management/treatment, monitoring, and revising interventions, as warranted. The attending physician plays a key leadership role in medication management by developing, monitoring, and modifying the medication regimen in conjunction with residents and/or representative(s) and other professionals and direct care staff (the interdisciplinary team).

When selecting medications and non-pharmacological interventions, members of the interdisciplinary team participate in the care process to identify, assess, address, advocate for, monitor, and communicate the resident’s needs and changes in condition.

This guidance is intended to help the surveyor determine whether the facility’s medication management supports and promotes:

- Selection of medications(s) based on assessing relative benefits and risks to the individual resident;
- Evaluation of a resident’s signs and symptoms, in order to identify the underlying cause(s), including adverse consequences of medications;
- Selection and use of medications in doses and for the duration appropriate to each resident’s clinical conditions, age, and underlying causes of symptoms;
- The use of non-pharmacological interventions, when applicable, to minimize the need for medications, permit use of the lowest possible dose, or allow medications to be discontinued; and
- The monitoring of medications for efficacy and clinically significant adverse consequences.

The resident’s clinical record documents and communicates to the entire team the basic elements of the care process. Information about aspects of the care process related to medications may be found in various locations within the record, such as: hospital discharge summaries and transfer notes, progress notes and interdisciplinary notes, history and physical examination, Resident Assessment Instrument (RAI), plan of care, laboratory reports, professional consults, medication orders, Medication Regimen Review (MRR) reports, and Medication Administration Records (MAR).

Resident Choice – A resident and/or representative(s) has the right to be informed about the resident’s condition; treatment options, relative risks and benefits of treatment, required monitoring, expected outcomes of the treatment; and has the right to refuse care and treatment. If a resident refuses treatment, the facility staff and physician should inform the resident about the risks related to the refusal, and discuss appropriate alternatives such as offering the medication at another time or in another dosage form, or offer an alternative medication or non-pharmacological approach, if available.

Advance Directives – A resident may have written or verbal directions related to treatment choices (or a decision has been made by the resident’s surrogate or representative) in accordance with state law. An advance directive is a means for
the resident to communicate his or her wishes, which may include withdrawing or withholding medications. Whether or not a resident has an advanced directive, the facility is responsible for giving treatment, support, and other care that is consistent with the resident’s condition and applicable care instructions.

NOTE: Choosing not to be resuscitated (reflected in a “Do Not Resuscitate” (DNR) order) indicates that the resident should not be resuscitated if respirations and/or cardiac function cease. A DNR order by itself does not indicate that the resident has declined other appropriate treatment and services.

Under these regulations, medication management includes consideration of:

I. Indications for use of medication (including initiation or continued use of antipsychotic medication);

II. Monitoring for efficacy and adverse consequences;

III. Dose (including duplicate therapy);

IV. Duration;

V. Tapering of a medication dose/gradual dose reduction for antipsychotic medications; and

VI. Prevention, identification, and response to adverse consequences.

I. Indications for Use of Medication (including Initiation or Continued Use of an Antipsychotic Medication)

An evaluation of the resident helps to identify his/her needs, comorbid conditions, and prognosis to determine factors (including medications and new or worsening medical conditions) that are affecting signs, symptoms, and test results. This evaluation process is important when making initial medication/intervention selections and when deciding whether to modify or discontinue a current medication intervention. Regarding “as needed” (PRN) medications, it is important to evaluate and document the indication(s), specific circumstance(s) for use, and the desired frequency of administration. As part of the evaluation, gathering and analyzing information helps define clinical indications and provide baseline data for subsequent monitoring. The evaluation also clarifies:

- Whether other causes for the symptoms (including behavioral distress that could mimic a psychiatric disorder) have been ruled out;
- Whether the signs, symptoms, or related causes are persistent or clinically significant enough (e.g., causing functional decline) to warrant the initiation or continuation of medication therapy;
- Whether non-pharmacological interventions are considered;
- Whether a particular medication is clinically indicated to manage the symptom or condition; and
- Whether the intended or actual benefit is sufficient to justify the potential risk(s) or adverse consequences associated with the selected medication, dose, and duration.
The content and extent of the evaluation may vary with the situation and may employ various assessment instruments and diagnostic tools. Examples of information to be considered and evaluated may include, but are not limited to, the following:

- An appropriately detailed evaluation of mental, physical, psychosocial, and functional status, including comorbid conditions and pertinent psychiatric symptoms and diagnoses and a description of resident complaints, symptoms, and signs (including the onset, scope, frequency, intensity, precipitating factors, and other important features);

- Each resident’s goals and preferences;

- Allergies to medications and foods and potential for medication interactions;

- A history of prior and current medications and non-pharmacological interventions (including therapeutic effectiveness and any adverse consequences);

- Recognition of the need for end-of-life or palliative care; and

- The refusal of care and treatment, including the basis for declining it, and the identification of pertinent alternatives

NOTE: The Resident Assessment Protocols (RAPs), an integral part of the comprehensive resident assessment, help identify some possible categories of causes of various symptoms including: behavioral symptoms of distress, delirium, and changes in functional status. Refer to 42 CFR 483.20 and the Minimum Data Set (MDS) and RAPs.

Circumstances that warrant evaluation of the resident and medication(s) may include:

- Admission or re-admission;

- A clinically significant change in condition/status;

- A new, persistent, or recurrent clinically significant symptom or problem;

- A worsening of an existing problem or condition;

- An unexplained decline in function or cognition;

- A new medication order or renewal of orders; and

- An irregularity identified in the pharmacist’s monthly medication regimen review.

Specific considerations related to these circumstances may include the following:

- **Admission (or Readmission)** – Some residents may be admitted on medications for an undocumented chronic condition or without a clear indication as to why a medication was begun or should be continued. It is expected that the attending physician, pharmacist, and staff subsequently determine if continuing the medication is justified by evaluating the
resident’s clinical condition, risks, existing medication regimen, and related factors. If the indications for continuing the medication are unclear, or if the resident’s symptoms could represent a clinically significant adverse consequence, additional consideration of the rationale for the medication(s) is warranted.

- **Multiple prescribers** – Regardless of who the prescribers are, the continuation of a medication needs to be evaluated to determine if the medication is still warranted in the context of the resident’s other medications and comorbidities. Medications prescribed by a specialist or begun in another care setting, such as the hospital, need to have a clinically pertinent documented rationale.

- **New medication order as an emergency measure** – When a resident is experiencing an acute medical problem or psychiatric emergency (e.g., the resident’s behavior poses an immediate risk to the resident or others), medications may be required. In these situations, it is important to identify and address the underlying causes of the problem or symptoms. Once the acute phase has stabilized, the staff and prescriber consider whether medications are still relevant. Subsequently, the medication is reduced or discontinued as soon as possible or the clinical rationale for continuing the medication is documented.

When psychopharmacological medications are used as an emergency measure, adjunctive approaches, such as behavioral interventions and techniques should be considered and implemented as appropriate. Longer term management options should be discussed with the resident and/or representative(s).

- **Psychiatric disorders or distressed behavior** – As with all symptoms, it is important to seek the underlying cause of distressed behavior, either before or while treating the symptom. Examples of potential causes include:
  
  - Delirium;
  - Pain;
  - Chronic psychiatric illness such as schizophrenia or schizoaffective disorder;
  - Acute psychotic illness such as brief reactive psychosis;
  - Substance intoxication or withdrawal;
  - Psychological stressors (e.g., disruption of the resident’s customary daily routine, grief over nursing home admission or health status, abuse, taunting, intimidation);
  - Neurological illnesses such as Huntington’s disease or Tourette’s syndrome; or
  - Environmental stressors (e.g., excessive heat, noise, overcrowding);
  - Medical illnesses such as Alzheimer’s disease, Lewy body disease, vascular dementia, or frontotemporal dementia.

See Table I on page 150 in these guidelines for key issues related to indications for use of antipsychotic agents, monitoring, and adverse consequences.
II. Monitoring for Efficacy and Adverse Consequences

The information gathered during the initial and ongoing evaluations is essential to:

- Incorporate into a comprehensive care plan that reflects appropriate medication related goals and parameters for monitoring the resident’s condition, including the likely medication effects and potential for adverse consequences. Examples of this information may include the FDA boxed warnings or adverse consequences that may be rare, but have sudden onset or that may be irreversible. If the facility has established protocols for monitoring specific medications and the protocols are accessible for staff use, the care plan may refer staff to these protocols;

- Optimize the therapeutic benefit of medication therapy and minimize or prevent potential adverse consequences;

- Establish parameters for evaluating the ongoing need for the medication; and

- Verify or differentiate the underlying diagnoses or other underlying causes of signs and symptoms.

The key objectives for monitoring the use of medications are to track progress towards the therapeutic goal(s) and to detect the emergence or presence of any adverse consequences. Effective monitoring relies upon understanding the indications and goals for using the medication, identifying relevant baseline information, identifying the criteria for evaluating the benefit(s) of the medication, and recognizing and evaluating adverse consequences. Monitoring parameters are based on the resident’s condition, the pharmacologic properties of the medication being used and its associated risks, individualized therapeutic goals, and the potential for clinically significant adverse consequences.

Adverse consequences related to medications are common enough to warrant serious attention and close monitoring. For example, a study reported that 538 (42%) of 815 adverse drug events were judged preventable, and that common omissions included inadequate monitoring and either lack of response or a delayed response to signs, symptoms, or laboratory evidence of medication toxicity.\(^{55}\)

Sources of information to facilitate defining the monitoring criteria or parameters may include cautions, warnings, and identified adverse consequences from:

- Manufacturers’ package inserts and black-box warnings;

- Facility policies and procedures;

- Pharmacists;

- Clinical practice guidelines or clinical standards of practice;

- Medication references; and

- Clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.

Monitoring of the resident’s response to any medication(s) is essential to evaluate
the ongoing benefits as well as risks of various medications. It is important, for example, to monitor the effectiveness of medications used to address behavioral symptoms (e.g., behavioral monitoring) or to treat hypertension (e.g., periodic pulse and blood pressure). Monitoring for adverse consequences involves ongoing vigilance and may periodically involve objective evaluation (e.g., assessing vital signs may be indicated if a medication is known to affect blood pressure, pulse rate and rhythm, or temperature). Using quantitative and qualitative monitoring parameters facilitates consistent and objective collection of information by the facility.

Examples of tools that may be used by facility staff, practitioners, or consultants to determine baseline status as well as to monitor for effectiveness and potential adverse consequences may include, but are not limited to the following:

<table>
<thead>
<tr>
<th>Common Conditions/ Symptoms</th>
<th>Examples of Tools</th>
<th>Potential Applications</th>
<th>Source/Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alzheimer’s Disease/ Dementia</td>
<td>Mini Mental Status Exam (MMSE)</td>
<td>Determine degree of cognitive impairment</td>
<td><a href="http://www.emedicine.com/med/topic3558.htm">www.emedicine.com/med/topic3558.htm</a> <a href="http://www.fpnotebook.com/NEU75.htm">www.fpnotebook.com/NEU75.htm</a></td>
</tr>
<tr>
<td></td>
<td>Resident Assessment Instrument (RAI)</td>
<td>Assess aspects of nursing home resident’s behavior and function</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Functional Alzheimer’s Screening Test (FAST)</td>
<td>Assess level of function in individuals with dementia</td>
<td><a href="http://geriatrics.uthscsa.edu/educational/med_students/fastscale_admin.htm">http://geriatrics.uthscsa.edu/educational/med_students/fastscale_admin.htm</a></td>
</tr>
<tr>
<td>Common Conditions/ Symptoms</td>
<td>Examples of Tools</td>
<td>Potential Applications</td>
<td>Source/Reference</td>
</tr>
<tr>
<td>-----------------------------</td>
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<td>------------------</td>
</tr>
<tr>
<td>Pain</td>
<td>List of pain scales</td>
<td>Assess pain characteristics (e.g., intensity, impact, timing)</td>
<td><a href="http://www.chcr.brown.edu/pcoc/Physical.htm">www.chcr.brown.edu/pcoc/Physical.htm</a></td>
</tr>
<tr>
<td></td>
<td>Cornell Depression in Dementia Scale</td>
<td>Screen or monitor for depression in individuals with cognitive impairment</td>
<td><a href="http://www.emoryhealthcare.org/departments/fuqua/CornellScale.pdf">www.emoryhealthcare.org/departments/fuqua/CornellScale.pdf</a></td>
</tr>
<tr>
<td>Common Conditions/ Symptoms</td>
<td>Examples of Tools</td>
<td>Potential Applications</td>
<td>Source/Reference</td>
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<tr>
<td>----------------------------</td>
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<td>------------------</td>
</tr>
<tr>
<td>Behavioral Symptoms associated with Dementia</td>
<td>Neuro-psychiatric Inventory-Nursing Home Version (NPI-NH)</td>
<td>Screen or monitor for behavior associated with dementia (e.g., hallucinations, agitation or anxiety)</td>
<td><a href="http://www.alzheimer-insights.com/insights/vol2no3/vol2no5.htm">www.alzheimer-insights.com/insights/vol2no3/vol2no5.htm</a></td>
</tr>
<tr>
<td>Behavioral Symptoms associated with Dementia</td>
<td>Behavioral Pathology in Alzheimer’s Disease Rating Scale (Behave AD)</td>
<td>Provide a global rating of non-cognitive symptoms.</td>
<td><a href="http://www.alzforum.org/dis/dia/tes/neuropsychological.asp">www.alzforum.org/dis/dia/tes/neuropsychological.asp</a></td>
</tr>
</tbody>
</table>

Monitoring involves several steps, including:

- **Identifying the essential information and how it will be obtained and reported.** It is important to consider who is responsible for obtaining the information, which information should be collected, and how the information will be documented. The information that is collected depends on therapeutic goals, detection of potential or actual adverse consequences, and consideration of risk factors, such as:
  - Medication—medication, medication—food interactions;
  - Clinical condition (for example renal disease);
  - Properties of the medication;
  - Black-box warnings; and
  - History of adverse consequences related to a similar medication.
• **Determining the frequency of monitoring.** The frequency and duration of monitoring needed to identify therapeutic effectiveness and adverse consequences will depend on factors such as clinical standards of practice, facility policies and procedures, manufacturer's specifications, and the resident’s clinical condition. Monitoring involves three aspects:
  – Periodic planned evaluation of progress toward the therapeutic goals;
  – Continued vigilance for adverse consequences; and
  – Evaluation of identified adverse consequences.
For example, when monitoring all psychopharmacological medications and sedative/hypnotics, the facility should review the continued need for them, at least quarterly (i.e., a 3 month period), and document the rationale for continuing the medication, including evidence that the following had been evaluated:

  • The resident’s target symptoms and the effect of the medication on the severity, frequency, and other characteristics of the symptoms;
  
  • Any changes in the resident's function during the previous quarter (e.g., as identified in the Minimum Data Set); and
  
  • Whether the resident experienced any medication-related adverse consequences during the previous quarter.

An important aspect of the review would include whether the pharmacological management of the resident’s medical and/or psychiatric disorder is consistent with recommendations from relevant clinical practice guidelines, current standards of practice, and/or manufacturer’s specifications.

• **Defining the methods for communicating, analyzing, and acting upon relevant information.** The monitoring process needs to identify who is to communicate with the prescriber, what information is to be conveyed, and when to ask the prescriber to evaluate and consider modifying the medication regimen.

It is important to consider whether a resident's medications are promoting or maintaining a resident's highest practicable level of function. If the therapeutic goals are not being met or the resident is experiencing adverse consequences, it is essential for the prescriber in collaboration with facility staff and pharmacist to consider whether current medications and doses continue to be appropriate or should be reduced, changed, or discontinued.

• **Re-evaluating and updating monitoring approaches.** Modification of monitoring may be necessary when the resident experiences changes, such as:
  – Acute onset of signs or symptoms or worsening of chronic disease;
  – Decline in function or cognition;
  – Addition or discontinuation of medications and/or non pharmacological interventions;
  – Addition or discontinuation of care and services such as enteral feedings; and
  – Significant changes in diet that may affect medication absorption or effectiveness or increase adverse consequences.

Additional examples of circumstances that may indicate a need to modify the monitoring include: changes in manufacturer’s specifications, FDA warnings,
pertinent clinical practice guidelines, or other literature about how and what to monitor.

III. Dose (Including Duplicate Therapy)

A prescriber orders medication(s) based on a variety of factors including the resident’s diagnoses, signs and symptoms, current condition, age, coexisting medication regimen, review of lab and other test results, input from the interdisciplinary team about the resident, the type of medication(s), and therapeutic goals being considered or used.

Factors influencing the appropriateness of any dose include the resident’s clinical response, possible adverse consequences, and other resident and medication-related variables. Often, lab test results such as serum medication concentrations are only a rough guide to dosing. Significant adverse consequences can occur even when the concentration is within the therapeutic range. Serum concentrations alone may not necessarily indicate a need for dose adjustments, but may warrant further evaluation of a dose or the medication regimen.

The route of administration influences a medication’s absorption and ultimately the dose received. Examples of factors that can affect the absorption of medications delivered by transdermal patches include skin temperature and moisture, and the integrity of the patch. Similarly, the flow rate of intravenous solutions affects the amount received at a given time.

Duplicate therapy is generally not indicated, unless current clinical standards of practice and documented clinical rationale confirm the benefits of multiple medications from the same class or with similar therapeutic effects. Some examples of potentially problematic duplicate therapy include:

- Use of more than one product containing the same medication can lead to excessive doses of a medication, such as concomitant use of acetaminophen/hydrocodone and acetaminophen, which may increase the risk of acetaminophen toxicity;
- Use of multiple laxatives to improve or maintain bowel movements, which may lead to abdominal pain or diarrhea;
- Concomitant use of multiple benzodiazepines such as lorazepam for anxiety and temazepam for sleep, which may increase fall risk; or
- Use of medications from different therapeutic categories that have similar effects or properties, such as multiple medications with anticholinergic effects (e.g., oxybutynin and diphenhydramine), which may increase the risk of delirium or excessive sedation.

Documentation is necessary to clarify the rationale for and benefits of duplicate therapy and the approach to monitoring for benefits and adverse consequences. This documentation may be found in various areas of the resident’s clinical record.

IV. Duration

Many conditions require treatment for extended periods, while others may resolve and no longer require medication therapy. For example:

- Acute conditions such as cough and cold symptoms, upper respiratory
condition, nausea and/or vomiting, acute pain, psychiatric or behavioral symptoms;

- Proton pump inhibitors (PPIs)/H2 blockers used for prophylaxis during the acute phase of a medical illness should be tapered and possibly discontinued after the acute phase of the illness has resolved, unless there is a valid clinical indication for prolonged use.

Periodic re-evaluation of the medication regimen is necessary to determine whether prolonged or indefinite use of a medication is indicated. The clinical rationale for continued use of a medication(s) may have been demonstrated in the clinical record, or the staff and prescriber may present pertinent clinical reasons for the duration of use. Common considerations for appropriate duration may include:

- A medication initiated as a result of a time-limited condition (for example, delirium, pain, infection, nausea and vomiting, cold and cough symptoms, or itching) is then discontinued when the condition has resolved, or there is documentation indicating why continued use is still relevant. Failure to review whether the underlying cause has resolved may lead to excessive duration.

- A medication is discontinued when indicated by facility stop order policy or by the prescriber’s order, unless there is documentation of the clinical justification for its extended use. A medication administered beyond the stop date established in the prescriber’s order or by facility policy, without evidence of clinical justification for continued use of the medication, may be considered excessive duration.

V. Tapering of a Medication Dose/Gradual Dose Reduction (GDR)

The requirements underlying this guidance emphasize the importance of seeking an appropriate dose and duration for each medication and minimizing the risk of adverse consequences. The purpose of tapering a medication is to find an optimal dose or to determine whether continued use of the medication is benefiting the resident. Tapering may be indicated when the resident’s clinical condition has improved or stabilized, the underlying causes of the original target symptoms have resolved, and/or non-pharmacological interventions, including behavioral interventions, have been effective in reducing the symptoms.

There are various opportunities during the care process to evaluate the effects of medications on a resident’s function and behavior, and to consider whether the medications should be continued, reduced, discontinued, or otherwise modified. Examples of these opportunities include:

- During the monthly medication regimen review, the pharmacist evaluates resident-related information for dose, duration, continued need, and the emergence of adverse consequences for all medications;

- When evaluating the resident’s progress, the practitioner reviews the total plan of care, orders, the resident’s response to medication(s), and determines whether to continue, modify, or stop a medication; and

- During the quarterly MDS review, the facility evaluates mood, function, behavior, and other domains that may be affected by medications.

Sometimes, the decision about whether to continue a medication is clear; for
example, someone with a history of multiple episodes of depression or recurrent seizures may need an antidepressant or anticonvulsant medication indefinitely. Often, however, the only way to know whether a medication is needed indefinitely and whether the dose remains appropriate is to try reducing the dose and to monitor the resident closely for improvement, stabilization, or decline.

The time frames and duration of attempts to taper any medication depend on factors including the coexisting medication regimen, the underlying causes of symptoms, individual risk factors, and pharmacologic characteristics of the medications. Some medications (e.g., antidepressants, sedative/hypnotics, opioids) require more gradual tapering so as to minimize or prevent withdrawal symptoms or other adverse consequences.

NOTE: If the resident’s condition has not responded to treatment or has declined despite treatment, it is important to evaluate both the medication and the dose to determine whether the medication should be discontinued or the dosing should be altered, whether or not the facility has implemented GDR as required, or tapering.

**Considerations Specific to Antipsychotics.** The regulation addressing the use of antipsychotic medications identifies the process of tapering as a “gradual dose reduction (GDR)” and requires a GDR, unless clinically contraindicated.

Within the first year in which a resident is admitted on an antipsychotic medication or after the facility has initiated an antipsychotic medication, the facility must attempt a GDR in two separate quarters (with at least one month between the attempts), unless clinically contraindicated. After the first year, a GDR must be attempted annually, unless clinically contraindicated.

For any individual who is receiving an antipsychotic medication to treat behavioral symptoms related to dementia, the GDR may be considered clinically contraindicated if:

- The resident’s target symptoms returned or worsened after the most recent attempt at a GDR within the facility; and
- The physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident’s function or increase distressed behavior.

For any individual who is receiving an antipsychotic medication to treat a psychiatric disorder other than behavioral symptoms related to dementia (for example, schizophrenia, bipolar mania, or depression with psychotic features), the GDR may be considered contraindicated, if:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident’s function or cause psychiatric instability by exacerbating an underlying psychiatric disorder; or
- The resident’s target symptoms returned or worsened after the most recent attempt at a GDR within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident’s function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.
Attempted Tapering Relative to Continued Indication or Optimal Dose

As noted, attempted tapering is one way to determine whether a specific medication is still indicated, and whether target symptoms and risks can be managed with a lesser dose of a medication. As noted, many medications in various categories can be tapered safely. The following examples of tapering relate to two common categories of concern: sedatives / hypnotics and psychopharmacologic medications (other than antipsychotic and sedatives/hypnotics medications).

Tapering Considerations Specific to Sedatives/Hypnotics.

For as long as a resident remains on a sedative/hypnotic that is used routinely and beyond the manufacturer's recommendations for duration of use, the facility should attempt to taper the medication quarterly unless clinically contraindicated. Clinically contraindicated means:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder; or

- The resident’s target symptoms returned or worsened after the most recent attempt at tapering the dose within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

Considerations Specific to Psychopharmacological Medications (Other Than Antipsychotics and Sedatives/Hypnotics).

During the first year in which a resident is admitted on a psychopharmacological medication (other than an antipsychotic or a sedative/hypnotic), or after the facility has initiated such medication, the facility should attempt to taper the medication during at least two separate quarters (with at least one month between the attempts), unless clinically contraindicated. After the first year, a tapering should be attempted annually, unless clinically contraindicated. The tapering may be considered clinically contraindicated, if:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder; or

- The resident’s target symptoms returned or worsened after the most recent attempt at tapering the dose within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.
VI. Adverse Consequences

Any medication or combination of medications (for example interactions between multiple medications with sedative or anticholinergic effects) can cause adverse consequences. Some adverse consequences occur quickly or abruptly, while others are more insidious and develop over time. Adverse consequences may become evident at any time after the medication is initiated, e.g., when there is a change in dose or after another medication has been added.

When reviewing medications used for a resident, it is important to be aware of the medication’s recognized safety profile, tolerability, dosing, and potential medication interactions. Although a resident may have an unanticipated reaction to a medication that is not always preventable, many ADRs can be anticipated, minimized, or prevented. Some adverse consequences may be avoided by:

- Following relevant clinical guidelines and manufacturer’s specifications for use, dose, administration, duration, and monitoring of the medication;
- Defining appropriate indications for use; and
- Determining that the resident:
  - Has no known allergies to the medication;
  - Is not taking other medications, nutritional supplements including herbal products, or foods that would be incompatible with the prescribed medication; and
  - Has no condition, history, or sensitivities that would preclude use of that medication.

Published studies have sought to identify the frequency, severity, and preventability of adverse consequences. Neuropsychiatric, hemorrhagic, gastrointestinal, renal/electrolyte abnormalities and metabolic/endocrine complications were the most common overall and preventable adverse consequences identified in two nursing home studies. Specifically, a study of 18 community-based nursing homes reported that approximately 50 percent (276/546) of all the adverse consequences—and 72 percent of those characterized as fatal, life-threatening, or serious—were considered preventable. A second study of two academic-based nursing homes reported that inadequate monitoring, failure to act on the monitoring, and errors in ordering, including wrong dose, wrong medication, and medication–medication interactions were the most frequent causes for the preventable adverse consequences.

The risk for adverse consequences increases with both the number of medications being taken regularly and with medications from specific pharmacological classes, such as anticoagulants, diuretics, antipsychotics, anti-infectives, and anticonvulsants. See Tables I and II for classes of medications that are associated with frequent or severe adverse consequences. Adverse consequences can range from minimal harm to functional decline, hospitalization, permanent injury, and death.

Delirium (i.e., acute confusional state) is a common medication-related adverse consequence. In many facilities, a majority of the residents have dementia. Individuals who have dementia may be more sensitive to medication effects and may be at greater risk for delirium. Delirium may result from treatable underlying causes including medical conditions and the existing medication regimen. The presence of delirium is associated with higher morbidity and mortality. Some of the classic signs of delirium may be difficult to recognize and may be mistaken for the
natural progression of dementia, particularly in the late stages of dementia. Careful observation of the resident (including mental status and level of consciousness), review of the potential causes (e.g., medications, fluid and electrolyte imbalance, infections) of the mental changes and distressed behavior, and appropriate and timely management of delirium are essential.

End Notes


TABLE I

Medication Issues Of Particular Relevance

This table lists alphabetically, examples of some categories of medications that have the potential to cause clinically significant adverse consequences, that may have limited indications for use, require specific monitoring, and which warrant careful consideration of relative risks and benefit. Inclusion of a medication in this table does not imply that it is contraindicated for every resident. Medications are identified by generic rather than trade names.

NOTE: This table is based on review of a variety of pharmaceutical references. It does not include all categories of medications or all medications within a category, and does not address all issues or considerations related to medication use, such as dosages. Medications other than those listed in this table may present significant issues related to indications, dosage, duration, monitoring, or potential for clinically significant adverse consequences.

Since medication issues continue to evolve and new medications are being approved regularly, it is important to refer to a current authoritative source for detailed medication information such as indications and precautions, dosage, monitoring, or adverse consequences.

The listed doses for psychopharmacological medications are applicable to older individuals. The facility is encouraged to initiate therapy with lower doses and, when necessary, only gradually increase doses. The facility may exceed these doses if it provides evidence to show why higher doses were necessary to maintain or improve the resident's function and quality of life.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analgesics</td>
<td>Dosage/Adverse Consequences</td>
</tr>
<tr>
<td>acetaminophen</td>
<td>• Daily doses greater than 4 grams/day from all sources (alone or as part of combination products) may increase risk of liver toxicity</td>
</tr>
<tr>
<td></td>
<td>Monitoring</td>
</tr>
<tr>
<td></td>
<td>• For doses greater than the maximum recommended daily dose, documented assessment should reflect periodic monitoring of liver function and indicate that benefits outweigh risks</td>
</tr>
</tbody>
</table>
### Medication

#### Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-selective NSAIDs, e.g.,</strong></td>
<td></td>
</tr>
<tr>
<td>• aspirin</td>
<td></td>
</tr>
<tr>
<td>• diclofenac</td>
<td></td>
</tr>
<tr>
<td>• diflunisal</td>
<td></td>
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<tr>
<td>• ibuprofen</td>
<td></td>
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<tr>
<td>• indomethacin</td>
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<tr>
<td>• ketorolac</td>
<td></td>
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<tr>
<td>• meclofenamate</td>
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<tr>
<td>• naproxen</td>
<td></td>
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<tr>
<td>• piroxicam</td>
<td></td>
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<tr>
<td>• salicylates</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cyclooxygenase-II (COX-2) inhibitors, e.g.,</strong></td>
<td></td>
</tr>
<tr>
<td>• celecoxib</td>
<td></td>
</tr>
</tbody>
</table>

### Indications

- NSAID, including COX-2 inhibitors, should be reserved for symptoms and/or inflammatory conditions for which lower risk analgesics (e.g., acetaminophen) have either failed, or are not clinically indicated

**Exception:** Use of low dose aspirin (81–325 mg/day) as prophylactic treatment for cardiovascular events such as myocardial infarct or stroke may be appropriate

### Interactions

- Aspirin may increase the adverse effects of COX-2 inhibitors on the gastrointestinal (GI) tract
- Some NSAIDs (e.g., ibuprofen) may reduce the cardioprotective effect of aspirin

### Monitoring

- Monitor closely for bleeding when ASA > 325 mg/day is being used with another NSAID or when NSAIDS are used with other platelet inhibitors or anticoagulants (See 42 CFR 483.60(c) for Table of Common Medication-Medication Interactions in Long Term Care)

### Adverse Consequences

- May cause gastrointestinal (GI) bleeding in anyone with a prior history of, or with increased risk for, GI bleeding. Compared to nonselective NSAIDs, COX-2 inhibitors may reduce—but do not eliminate—risk of gastrointestinal bleeding
- May cause bleeding in anyone who is receiving warfarin, heparin, other anticoagulants, or platelet inhibitors (e.g., ticlopidine, clopidogrel, and dipyridamole)
- Any NSAID may cause or worsen renal failure, increase blood pressure, or exacerbate heart failure
- Prolonged use of indomethacin, piroxicam, tolmetin, and meclofenamate should be avoided because of central nervous system side effects, e.g., headache, dizziness, somnolence, confusion
<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Opioid analgesics</strong></td>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>Short-acting, e.g.,</td>
<td>• The initiation of longer-acting opioid analgesics is not recommended unless shorter-acting opioids have been tried unsuccessfully, or titration of shorter-acting doses has established a clear daily dose of opioid analgesic that can be provided by using a long-acting form</td>
</tr>
<tr>
<td>• codeine</td>
<td>• Meperidine is not an effective oral analgesic in doses commonly used in older individuals</td>
</tr>
<tr>
<td>• fentanyl</td>
<td><strong>Adverse Consequences</strong></td>
</tr>
<tr>
<td>• hydrocodone</td>
<td>• May cause constipation, nausea, vomiting, sedation, lethargy, weakness confusion, dysphoria, physical and psychological dependency, hallucinations and unintended respiratory depression, especially in individuals with compromised pulmonary function. These can lead to other adverse consequences such as falls</td>
</tr>
<tr>
<td>• hydromorphone</td>
<td>• Meperidine use (oral or injectable) may cause confusion, respiratory depression even with therapeutic analgesic doses</td>
</tr>
<tr>
<td>• meperidine</td>
<td>• Active metabolite of meperidine (normeperidine) accumulates with repeated use and has been associated with seizures</td>
</tr>
<tr>
<td>• morphine</td>
<td><strong>pentazocine</strong></td>
</tr>
<tr>
<td>• oxycodone</td>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>Long-acting, e.g.,</td>
<td>• Limited effectiveness because it is a partial opiate agonist-antagonist; is not recommended for use in older individuals</td>
</tr>
<tr>
<td>• fentanyl, transdermal</td>
<td><strong>Adverse Consequences</strong></td>
</tr>
<tr>
<td>• methadone</td>
<td>• This opioid analgesic causes central nervous system side effects (including confusion and hallucinations) more commonly than other opioid analgesics</td>
</tr>
<tr>
<td>• morphine</td>
<td>• May cause dizziness, lightheadedness, euphoria, sedation, hypotension, tachycardia, syncope</td>
</tr>
<tr>
<td>sustained release</td>
<td><strong>sustained release</strong></td>
</tr>
<tr>
<td>• oxycodone, sustained release</td>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>pentazocine</td>
<td><strong>Adverse Consequences</strong></td>
</tr>
<tr>
<td>Medication</td>
<td>Issues and Concerns</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------</td>
</tr>
<tr>
<td><strong>Analgesics (cont.)</strong></td>
<td></td>
</tr>
<tr>
<td>propoxyphene and combination products with aspirin or acetaminophen</td>
<td><strong>Indications</strong>&lt;br&gt;• Offers few analgesic advantages over acetaminophen, yet has the adverse effects, including addiction risk, of other opioid medications; is not recommended for use in older individuals</td>
</tr>
<tr>
<td></td>
<td><strong>Adverse Consequences</strong>&lt;br&gt;• May cause hypotension and central nervous system effects (e.g., confusion, drowsiness, dizziness) that can lead to other adverse consequences such as falls</td>
</tr>
<tr>
<td><strong>Antibiotics</strong></td>
<td></td>
</tr>
<tr>
<td>All antibiotics</td>
<td><strong>Indications</strong>&lt;br&gt;• Use of antibiotics should be limited to confirmed or suspected bacterial infection</td>
</tr>
<tr>
<td></td>
<td><strong>Adverse Consequences</strong>&lt;br&gt;• Any antibiotic may cause diarrhea, nausea, vomiting, anorexia, and hypersensitivity/allergic reactions&lt;br&gt;• Antibiotics are non-selective and may result in the eradication of beneficial microorganisms and the emergence of undesired ones, causing secondary infections such as oral thrush, colitis, and vaginitis</td>
</tr>
<tr>
<td>Parenteral vancomycin and aminoglycosides, e.g., amikacin, gentamycin/gentamicin, tobramycin</td>
<td><strong>Monitoring</strong>&lt;br&gt;• Use must be accompanied by monitoring of renal function tests (which should be compared with the baseline) and by serum medication concentrations&lt;br&gt;• Serious adverse consequences may occur insidiously if adequate monitoring does not occur&lt;br&gt;&lt;br&gt;<strong>Exception:</strong> Single dose administration prophylaxis&lt;br&gt;<strong>Adverse Consequences</strong>&lt;br&gt;• May cause or worsen hearing loss and renal failure</td>
</tr>
</tbody>
</table>
### Antibiotics (cont.)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>nitrofurantoin</td>
<td><strong>Indications</strong>&lt;br&gt;• It is not the anti-infective/antibiotic of choice for treatment of acute urinary tract infection or prophylaxis in individuals with impaired renal function (CrCl &lt;60 ml/min) because of ineffectiveness and the high risk of serious adverse consequences</td>
</tr>
<tr>
<td>Fluoroquinolones, e.g.,</td>
<td><strong>Adverse Consequences</strong>&lt;br&gt;• May cause pulmonary fibrosis (e.g., symptoms including dyspnea, cough) and peripheral neuropathy</td>
</tr>
<tr>
<td>ciprofloxacin</td>
<td></td>
</tr>
<tr>
<td>levofloxacin</td>
<td></td>
</tr>
<tr>
<td>moxifloxacin</td>
<td></td>
</tr>
<tr>
<td>ofloxacin</td>
<td></td>
</tr>
<tr>
<td><strong>Indications</strong></td>
<td><strong>Adverse Consequences</strong>&lt;br&gt;• May cause prolonged QTc interval&lt;br&gt;• May increase risk of hypo- or hyperglycemia in individuals age 65 or older, and in individuals with diabetes mellitus, renal insufficiency (CrCl &lt; 60 ml/min), or those receiving other glucose-altering medications&lt;br&gt;• May increase risk of acute tendonitis</td>
</tr>
<tr>
<td>**Fluoroquinolones, e.g.,</td>
<td></td>
</tr>
<tr>
<td>ciprofloxacin</td>
<td></td>
</tr>
<tr>
<td>levofloxacin</td>
<td></td>
</tr>
<tr>
<td>moxifloxacin</td>
<td></td>
</tr>
<tr>
<td>ofloxacin</td>
<td></td>
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</tbody>
</table>

### Anticoagulants

<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>warfarin</td>
<td><strong>Monitoring</strong>&lt;br&gt;• Use must be monitored by Prothrombin Time (PT)/International Normalization Ratio (INR), with frequency determined by clinical circumstances, duration of use, and stability of monitoring results&lt;br&gt;<strong>Adverse Consequences</strong>&lt;br&gt;• Multiple medication interactions exist (See 42 CFR 483.60(c) F428 for Table of Common Medication-Medication Interactions in Long Term Care), which may:&lt;br&gt;– Significantly increase PT/INR results to levels associated with life-threatening bleeding, or&lt;br&gt;– Decrease PT/INR results to ineffective levels, or&lt;br&gt;– Increase or decrease the serum concentration of the interacting medication</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticonvulsants</td>
<td>All anticonvulsants, e.g.,</td>
</tr>
<tr>
<td></td>
<td>• carbamazepine</td>
</tr>
<tr>
<td></td>
<td>• gabapentin</td>
</tr>
<tr>
<td></td>
<td>• lamotrigine</td>
</tr>
<tr>
<td></td>
<td>• levetiracetam</td>
</tr>
<tr>
<td></td>
<td>• oxcarbazepine</td>
</tr>
<tr>
<td></td>
<td>• phenobarbital</td>
</tr>
<tr>
<td></td>
<td>• phenytoin</td>
</tr>
<tr>
<td></td>
<td>• primidone</td>
</tr>
<tr>
<td></td>
<td>• valproic acid</td>
</tr>
<tr>
<td>Indications</td>
<td>• In addition to seizures, may also be used to treat other disorders, such as bipolar disorder, schizoaffective disorder, chronic neuropathic pain, and for prophylaxis of migraine headaches</td>
</tr>
<tr>
<td></td>
<td>• Need for indefinite continuation should be based on confirmation of the condition (for example, distinguish epilepsy from isolated seizure due to medical cause or distinguish migraine from other causes of headaches) and its potential causes (medications, electrolyte imbalance, hypocalcemia, etc.)</td>
</tr>
<tr>
<td>Duration</td>
<td>• If used to manage behavior, stabilize mood, or treat a psychiatric disorder, refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance</td>
</tr>
<tr>
<td>Monitoring</td>
<td>• Serum medication concentration monitoring is not required or available for all anticonvulsants. Only the following anticonvulsants should be monitored with periodic serum concentrations: phenytoin, phenobarbital, primidone, divalproex sodium (as valproic acid), and carbamazepine</td>
</tr>
<tr>
<td></td>
<td>• Serum medication concentrations may help identify toxicity, but significant signs and symptoms of toxicity can occur even at normal or low serum concentrations.</td>
</tr>
<tr>
<td></td>
<td>• When anticonvulsants are used for conditions other than seizure disorders (e.g., as mood stabilizers), the same concerns exist regarding the need for monitoring for effectiveness and side effects; but evaluation of symptoms—not serum concentrations—should be used to adjust doses. High or toxic serum concentrations should, however, be evaluated and considered for dosage adjustments</td>
</tr>
<tr>
<td></td>
<td>• Symptom control for seizures or behavior can occur with subtherapeutic serum medication concentrations</td>
</tr>
</tbody>
</table>
Medication | Issues and Concerns
--- | ---
**Anticonvulsants (cont.)** | **Adverse Consequences**
- May cause liver dysfunction, blood dyscrasias, and serious skin rashes requiring discontinuation of treatment
- May cause nausea/vomiting, dizziness, ataxia, somnolence/lethargy, incoordination, blurred or double vision, restlessness, toxic encephalopathy, anorexia, headaches. These effects can increase the risk for falls

**Antidepressants**

All antidepressants classes, e.g.,
- Alpha-adrenoceptor antagonist, e.g., mirtazapine
- Dopamine-reuptake blocking compounds, e.g., bupropion
- Monoamine oxidase inhibitors (MAOIs) Serotonin (5-HT2) antagonists, e.g., nefazodone, trazodone
- Selective serotonin-norepinephrine reuptake inhibitors (SNRIs), e.g., duloxetine, venlafaxine
- Selective serotonin reuptake inhibitors (SSRIs), e.g., citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline
- Tricyclic (TCA) and related compounds

<table>
<thead>
<tr>
<th><strong>Indications</strong></th>
<th><strong>Dosage</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Agents usually classified as “antidepressants” are prescribed for conditions other than depression including anxiety disorders, post-traumatic stress disorder, obsessive compulsive disorder, insomnia, neuropathic pain (e.g., diabetic peripheral neuropathy), migraine headaches, urinary incontinence, and others</td>
<td>Use of two or more antidepressants simultaneously may increase risk of side effects; in such cases, there should be documentation of expected benefits that outweigh the associated risks and monitoring for any increase in side effects</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Duration</strong></th>
<th><strong>Monitoring</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration should be in accordance with pertinent literature, including clinical practice guidelines</td>
<td>All residents being treated for depression with any antidepressant should be monitored closely for worsening of depression and/or suicidal behavior or thinking, especially during initiation of therapy and during any change in dosage</td>
</tr>
<tr>
<td>Prior to discontinuation, many antidepressants may need a gradual dose reduction or tapering to avoid a withdrawal syndrome (e.g., SSRIs, TCAs)</td>
<td>If used to manage behavior, stabilize mood, or treat a psychiatric disorder, refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance</td>
</tr>
<tr>
<td>Antidepressants (cont.)</td>
<td>Interactions/Adverse Consequences</td>
</tr>
<tr>
<td>-------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td></td>
<td>• May cause dizziness, nausea, diarrhea, anxiety, nervousness, insomnia, somnolence, weight gain, anorexia, or increased appetite. Many of these effects can increase the risk for falls</td>
</tr>
<tr>
<td></td>
<td>• Bupropion may increase seizure risk and be associated with seizures in susceptible individuals</td>
</tr>
<tr>
<td></td>
<td>• SSRIs in combination with other medications affecting serotonin (e.g., tramadol, St. John’s Wort, linezolid, other SSRI’s) may increase the risk for serotonin syndrome and seizures</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monoamine oxidase inhibitors (MAOIs), e.g.,</th>
<th>Indications/Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>• isocarboxazid</td>
<td>• Should not be administered to anyone with a confirmed or suspected cerebrovascular defect or to anyone with confirmed cardiovascular disease or hypertension</td>
</tr>
<tr>
<td>• phenelzine</td>
<td>• Should not be used in the presence of pheochromocytoma</td>
</tr>
<tr>
<td>• tranylcypromine</td>
<td>• MAO Inhibitors are rarely utilized due to their potential interactions with tyramine or tryptophan-containing foods, other medications, and their profound effect on blood pressure</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adverse Consequences</th>
<th>• May cause hypertensive crisis if combined with certain foods, cheese, wine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exception: Monoamine oxidase inhibitors such as selegiline (MAO-B inhibitors) utilized for Parkinson’s Disease, unless used in doses greater than 10 mg per day</td>
</tr>
</tbody>
</table>

| Interactions | • Should not be administered together or in rapid succession with other MAO inhibitors, tricyclic antidepressants, bupropion, SSRIs, buspirone, sympathomimetics, meperidine, triptans, and other medications that affect serotonin or norepinephrine |
### Tricyclic antidepressants (TCAs), e.g.,
- amitriptyline
- amoxapine
- doxepin
- combination products, e.g.,
  - amitriptyline and chlordiazepoxide
  - amitriptyline and perphenazine

### Indications
- Because of strong anticholinergic and sedating properties, TCAs and combination products are rarely the medication of choice in older individuals

**Exception**: Use of TCAs may be appropriate if:

- The resident is being treated for neurogenic pain (e.g., trigeminal neuralgia, peripheral neuropathy), based on documented evidence to support the diagnosis; and
- The relative benefits outweigh the risks and other, safer agents including nonpharmacological interventions or alternative therapies are not indicated or have been considered, attempted, and failed

### Adverse Consequences
- Compared to other categories of antidepressants, TCAs cause significant anticholinergic side effects and sedation (nortriptyline and desipramine are less problematic)
<table>
<thead>
<tr>
<th>Medication Issue</th>
<th>Antidiabetic medications</th>
</tr>
</thead>
</table>
| **Insulin and oral hypoglycemics, e.g.,** | - acarbose  
- acetohexamide  
- chlorpropamide  
- glimepiride  
- glipizide  
- glyburide  
- metformin  
- repaglinide  
- rosiglitazone  
- tolazamide  
- tolbutamide |
| Including combination products, e.g., | - rosiglitazone/metformin  
- glyburide/metformin  
- glipizide/metformin  
- pioglitazone/metformin |

### Monitoring

- Use of anti-diabetic medications should include monitoring (for example, periodic blood sugars) for effectiveness based on desired goals for that individual and to identify complications of treatment such as hypoglycemia, impaired renal function

**NOTE:** Continued or long-term need for sliding scale insulin for non-emergency coverage may indicate inadequate blood sugar control

- Residents on rosiglitazone should be monitored for visual deterioration due to new onset and/or worsening of macular edema in diabetic patients

### Adverse Consequences

- Metformin has been associated with the development of lactic acidosis (a potentially life-threatening metabolic disorder), which is more likely to occur in individuals with:
  - serum creatinine $\geq 1.5$ mg/dL in males or $\geq 1.4$ mg/dL in females
  - abnormal creatinine clearance from any cause, including shock, acute myocardial infarction, or septicemia
  - age $\geq 80$ years unless measurement of creatinine clearance verifies normal renal function
  - radiologic studies in which intravascular iodinated contrast materials are given
  - congestive heart failure requiring pharmacological management
  - acute or chronic metabolic acidosis with or without coma (including diabetic ketoacidosis)

- Rosiglitazone and pioglitazone have been associated with edema and weight gain; therefore, their use should be avoided in residents with Stage III or Stage IV heart failure

- Sulfonylureas can cause the syndrome of inappropriate antidiuretic hormone (SIADH) and result in hyponatremia
## Antidiabetic medications (cont.)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorpropamide</td>
<td></td>
</tr>
<tr>
<td>Glyburide</td>
<td></td>
</tr>
</tbody>
</table>

**Indications**
- Chlorpropamide and glyburide are not considered hypoglycemic agents of choice in older individuals because of the long half-life and/or duration of action and increased risk of hypoglycemia

**Adverse Consequences**
- May cause prolonged and serious hypoglycemia (with symptoms including tachycardia, palpitations, irritability, headache, hypothermia, visual disturbances, lethargy, confusion, seizures, and/or coma)

## Antifungals

<table>
<thead>
<tr>
<th>Imidazoles for systemic use, e.g.,</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluconazole</td>
<td></td>
</tr>
<tr>
<td>Itraconazole</td>
<td></td>
</tr>
<tr>
<td>Ketoconazole</td>
<td></td>
</tr>
</tbody>
</table>

**Indications**
- Should be used in lowest possible dose for shortest possible duration, especially in anyone receiving other medications known to interact with these medications

**Interactions/Adverse Consequences**
- Interaction with warfarin can cause markedly elevated PT/INR, increasing bleeding risk
- Multiple potentially significant medication interactions may occur, for example:
  - These medications when administered concurrently may increase the effect or toxicity of phenytoin, theophylline, sulfonylureas (hypoglycemics)
  - Other medications such as rifampin and cimetidine may decrease the effect of these antifungals
- May cause hepatotoxicity, headaches, GI distress

**Monitoring**
- Enhanced monitoring may be required to identify and minimize adverse consequences when these antifungals are given with the following:
  - Warfarin (PT/INR)
  - Phenytoin (serum phenytoin levels)
  - Theophylline (serum theophylline levels)
  - Sulfonylureas (fasting blood glucose)
### Medication Issues and Concerns

#### Antimanic medications

**Lithium**

**Indications**
- Should generally not be given to individuals with significant renal or cardiovascular disease, severe debilitation, dehydration, or sodium depletion

**Monitoring**
- Toxic levels are very close to therapeutic levels. Serum lithium concentration should be monitored periodically, and dosage adjusted accordingly

**Interactions/Adverse Consequences**
- May cause potentially dangerous sodium imbalance
- Adverse consequences may occur at relatively low serum concentrations (1–1.5 mEq/L)
- Serum lithium concentration levels can be affected by many other medications, e.g., thiazide diuretics, ACE inhibitors, NSAIDs

#### Antiparkinson medications

**All classes, e.g.**

- Catechol-O-Methyl Transferase (COMT) Inhibitors, e.g.,
  - entacapone

- Dopamine agonists, e.g.,
  - bromocriptine
  - ropinirole
  - pramipexole

- MAO inhibitors, e.g.,
  - selegiline

- Others, e.g.,
  - amantadine

- Various dopaminergic combinations, e.g.,
  - carbidopa/levodopa
  - carbidopa/levodopa/entacapone

**Adverse Consequences**
- May cause significant confusion, restlessness, delirium, dyskinesia, nausea, dizziness, hallucinations, agitation
- Increased risk of postural hypotension and falls, especially when given in conjunction with antihypertensive medications
<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antipsychotic medications</td>
<td>Indications</td>
</tr>
<tr>
<td>All classes, e.g.,</td>
<td>• An antipsychotic medication should be used only for the following conditions/diagnoses as documented in the record and as meets the definition(s) in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Training Revision (DSM-IV TR) or subsequent editions):</td>
</tr>
<tr>
<td>First generation (conventional) agents, e.g.</td>
<td>− Schizophrenia</td>
</tr>
<tr>
<td>• chlorpromazine</td>
<td>− Schizo-affective disorder</td>
</tr>
<tr>
<td>• fluphenazine</td>
<td>− Delusional disorder</td>
</tr>
<tr>
<td>• haloperidol</td>
<td>− Mood disorders (e.g. mania, bipolar disorder, depression with psychotic features, and treatment refractory major depression)</td>
</tr>
<tr>
<td>• loxapine</td>
<td>− Schizophreniform disorder</td>
</tr>
<tr>
<td>• mesoridazine</td>
<td>− Psychosis NOS</td>
</tr>
<tr>
<td>• molindone</td>
<td>− Atypical psychosis</td>
</tr>
<tr>
<td>• perphenazine</td>
<td>− Brief psychotic disorder</td>
</tr>
<tr>
<td>• promazine</td>
<td>− Dementing illnesses with associated behavioral symptoms</td>
</tr>
<tr>
<td>• thioridazine</td>
<td>− Medical illnesses or delirium with manic or psychotic symptoms and/or treatment-related psychosis or mania (e.g., thyrotoxicosis, neoplasms, high dose steroids)</td>
</tr>
<tr>
<td>• thiothixene</td>
<td></td>
</tr>
<tr>
<td>• trifluoperazine</td>
<td>• In addition, the use of an antipsychotic must meet the criteria and applicable, additional requirements listed below:</td>
</tr>
<tr>
<td>• triflupromazine</td>
<td>1. Criteria:</td>
</tr>
<tr>
<td>Second generation (atypical) agents, e.g.</td>
<td>− Since diagnoses alone do not warrant the use of antipsychotic medications, the clinical condition must also meet at least one of the following criteria (A or B or C):</td>
</tr>
<tr>
<td>• aripiprazole</td>
<td>A. The symptoms are identified as being due to mania or psychosis (such as: auditory, visual, or other hallucinations; delusions (such as paranoia or grandiosity)); OR</td>
</tr>
<tr>
<td>• clozapine</td>
<td>B. The behavioral symptoms present a danger to the resident or to others; OR</td>
</tr>
<tr>
<td>• olanzapine</td>
<td></td>
</tr>
<tr>
<td>• quetiapine</td>
<td></td>
</tr>
</tbody>
</table>
Medication Issues and Concerns

Antipsychotic medications (cont.)

| C. | The symptoms are significant enough that the resident is experiencing one or more of the following: inconsolable or persistent distress (e.g., fear, continuously yelling, screaming, distress associated with end-of-life, or crying); a significant decline in function; and/or substantial difficulty receiving needed care (e.g., not eating resulting in weight loss, fear and not bathing leading to skin breakdown or infection). |

2. Additional Requirements:
   - Acute Psychiatric Situations

   When an antipsychotic medication is being initiated or used to treat an acute psychiatric emergency (i.e., recent or abrupt onset or exacerbation of symptoms) related to one or more of the aforementioned conditions/diagnoses, that use must meet one of the above criteria and all of the following additional requirements:

   A. The acute treatment period is limited to seven days or less; and

   B. A clinician in conjunction with the interdisciplinary team must evaluate and document the situation within 7 days, to identify and address any contributing and underlying causes of the acute psychiatric condition and verify the continuing need for antipsychotic medication; and

   C. Pertinent non-pharmacological interventions must be attempted, unless contraindicated, and documented following the resolution of the acute psychiatric situation.
Antipsychotic medications (cont.)

- **Enduring Psychiatric Conditions**

  Antipsychotic medications may be used to treat an enduring (i.e., non-acute, chronic, or prolonged) condition, if the clinical condition/diagnosis meets the criteria in #1 above. In addition, before initiating or increasing an antipsychotic medication for enduring conditions, the target behavior must be clearly and specifically identified and monitored objectively and qualitatively, in order to ensure the behavioral symptoms are:

  A. Not due to a medical condition or problem (e.g., headache or joint pain, fluid or electrolyte imbalance, pneumonia, hypoxia, unrecognized hearing or visual impairment) that can be expected to improve or resolve as the underlying condition is treated; and

  B. Persistent or likely to reoccur without continued treatment; and

  C. Not sufficiently relieved by non-pharmacological interventions; and

  D. Not due to environmental stressors (e.g., alteration in the resident’s customary location or daily routine, unfamiliar care provider, hunger or thirst, excessive noise for that individual, inadequate or inappropriate staff response, physical barriers) that can be addressed to improve the psychotic symptoms or maintain safety; and

  E. Not due to psychological stressors (e.g., loneliness, taunting, abuse), or anxiety or fear stemming from misunderstanding related to his or her cognitive impairment (e.g., the mistaken belief that this is not where he/she lives or inability to find his or her clothes or glasses) that can be expected to improve or resolve as the situation is addressed
• After initiating or increasing the dose of an antipsychotic medication, the behavioral symptoms must be reevaluated periodically to determine the effectiveness of the antipsychotic and the potential for reducing or discontinuing the dose

**Exception:** When antipsychotic medications are used for behavioral disturbances related to Tourette’s disorder, or for non-psychiatric indications such as movement disorders associated with Huntington’s disease, hiccups, nausea and vomiting associated with cancer or cancer chemotherapy, or adjunctive therapy at end of life.

### Inadequate Indications

• In many situations, antipsychotic medications are not indicated. They should not be used if the only indication is one or more of the following: 1) wandering; 2) poor self-care; 3) restlessness; 4) impaired memory; 5) mild anxiety; 6) insomnia; 7) unsociability; 8) inattention or indifference to surroundings; 9) fidgeting; 10) nervousness; 11) uncooperativeness; or 12) verbal expressions or behavior that are not due to the conditions listed under “Indications” and do not represent a danger to the resident or others.

### Dosage

• Doses for acute indications (for example, delirium) may differ from those used for long-term treatment, but should be the lowest possible to achieve the desired therapeutic effects

*(dosage table on next page)*
Medication Issues and Concerns

Antipsychotic medications (cont.)

Daily Dose Thresholds for Antipsychotic Medications Used to Manage Behavioral Symptoms Related to Dementing Illnesses

<table>
<thead>
<tr>
<th>Generic Medication</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First Generation</strong></td>
<td></td>
</tr>
<tr>
<td>chlorpromazine</td>
<td>75 mg</td>
</tr>
<tr>
<td>fluphenazine</td>
<td>4 mg</td>
</tr>
<tr>
<td>haloperidol</td>
<td>2 mg</td>
</tr>
<tr>
<td>loxapine</td>
<td>10 mg</td>
</tr>
<tr>
<td>molindone</td>
<td>10 mg</td>
</tr>
<tr>
<td>perphenazine</td>
<td>8 mg</td>
</tr>
<tr>
<td>pimozide</td>
<td>*</td>
</tr>
<tr>
<td>prochlorperazine</td>
<td>*</td>
</tr>
<tr>
<td>thioridazine</td>
<td>75 mg</td>
</tr>
<tr>
<td>thiothixene</td>
<td>7 mg</td>
</tr>
<tr>
<td>trifluoperazine</td>
<td>8 mg</td>
</tr>
<tr>
<td><strong>Second Generation</strong></td>
<td></td>
</tr>
<tr>
<td>aripiprazole</td>
<td>10 mg</td>
</tr>
<tr>
<td>clozapine</td>
<td>50 mg</td>
</tr>
<tr>
<td>olanzapine</td>
<td>7.5 mg</td>
</tr>
<tr>
<td>quetiapine</td>
<td>150 mg</td>
</tr>
<tr>
<td>risperidone</td>
<td>2 mg</td>
</tr>
<tr>
<td>ziprasidone</td>
<td>*</td>
</tr>
</tbody>
</table>

* Not customarily used for the treatment of behavioral symptoms

References:


<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antipsychotic medications (cont.)</td>
<td><strong>Duration</strong></td>
</tr>
<tr>
<td></td>
<td>• If used to manage behavior, stabilize mood, or treat a psychiatric disorder, refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance</td>
</tr>
<tr>
<td></td>
<td><strong>Monitoring/Adverse Consequences</strong></td>
</tr>
<tr>
<td></td>
<td>• The facility assures that residents are being adequately monitored for adverse consequences such as:</td>
</tr>
<tr>
<td></td>
<td>– anticholinergic effects (see Table II)</td>
</tr>
<tr>
<td></td>
<td>– akathisia</td>
</tr>
<tr>
<td></td>
<td>– neuroleptic malignant syndrome (NMS)</td>
</tr>
<tr>
<td></td>
<td>– cardiac arrhythmias</td>
</tr>
<tr>
<td></td>
<td>– death secondary to heart-related events (e.g., heart failure, sudden death)</td>
</tr>
<tr>
<td></td>
<td>– falls</td>
</tr>
<tr>
<td></td>
<td>– lethargy</td>
</tr>
<tr>
<td></td>
<td>– increase in total cholesterol and triglycerides</td>
</tr>
<tr>
<td></td>
<td>– parkinsonism</td>
</tr>
<tr>
<td></td>
<td>– blood sugar elevation (including diabetes mellitus)</td>
</tr>
<tr>
<td></td>
<td>– orthostatic hypotension</td>
</tr>
<tr>
<td></td>
<td>– cerebrovascular event (e.g., stroke, transient ischemic attack (TIA)) in older individuals with dementia</td>
</tr>
<tr>
<td></td>
<td>– tardive dyskinesia</td>
</tr>
<tr>
<td></td>
<td>– excessive sedation</td>
</tr>
<tr>
<td></td>
<td>• When antipsychotics are used without monitoring they may be considered unnecessary medications because of inadequate monitoring</td>
</tr>
<tr>
<td>Medication</td>
<td>Issues and Concerns</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------</td>
</tr>
<tr>
<td><strong>Anxiolytics</strong></td>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>All Anxiolytics</td>
<td>• Anxiolytic medications should only be used when:</td>
</tr>
<tr>
<td>Benzodiazepines, Short-acting, e.g.,</td>
<td></td>
</tr>
<tr>
<td>• alprazolam</td>
<td>– Use is for one of the following indications as defined in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Training Revision (DSM-IV TR) or subsequent editions:</td>
</tr>
<tr>
<td>• estazolam</td>
<td>a. Generalized anxiety disorder</td>
</tr>
<tr>
<td>• lorazepam</td>
<td>b. Panic disorder</td>
</tr>
<tr>
<td>• oxazepam</td>
<td>c. Symptomatic anxiety that occurs in residents with another diagnosed psychiatric disorder</td>
</tr>
<tr>
<td>• temazepam</td>
<td>d. Sleep disorders (See Sedatives/Hypnotics)</td>
</tr>
<tr>
<td>Benzodiazepines, Long acting, e.g.,</td>
<td>e. Acute alcohol or benzodiazepine withdrawal</td>
</tr>
<tr>
<td>• chlordiazepoxide</td>
<td>f. Significant anxiety in response to a situational trigger</td>
</tr>
<tr>
<td>• clonazepam</td>
<td>g. Delirium, dementia, and other cognitive disorders with associated behaviors that:</td>
</tr>
<tr>
<td>• clorazepate</td>
<td>– Are quantitatively and objectively documented;</td>
</tr>
<tr>
<td>• diazepam</td>
<td>– Are persistent;</td>
</tr>
<tr>
<td>• flurazepam</td>
<td>– Are not due to preventable or correctable reasons; and</td>
</tr>
<tr>
<td>• quazepam</td>
<td>– Constiute clinically significant distress or dysfunction to the resident or represent a danger to the resident or others</td>
</tr>
<tr>
<td>buspirone</td>
<td>• Evidence exists that other possible reasons for the individual’s distress have been considered; and</td>
</tr>
<tr>
<td>Other antidepressants except bupropion</td>
<td>• Use results in maintenance or improvement in the individual’s mental, physical or psychosocial well-being (e.g., as reflected on the MDS or other assessment tools); or</td>
</tr>
</tbody>
</table>
Medication Issues and Concerns
Anxiolytics (cont.)

- There are clinical situations that warrant the use of these medications such as:
  - a long-acting benzodiazepine is being used to withdraw a resident from a short-acting benzodiazepine
  - used for neuromuscular syndromes (e.g., cerebral palsy, tardive dyskinesia, restless leg syndrome or seizure disorders)
  - symptom relief in end of life situations

Dosage

- Dosage is less than, or equal to, the following listed total daily doses unless higher doses (as evidenced by the resident’s response and/or the resident’s clinical record) are necessary to maintain or improve the resident’s function

Total Daily Dose Thresholds for Anxiolytic Medications

<table>
<thead>
<tr>
<th>Generic Medication</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>flurazepam</td>
<td>15 mg</td>
</tr>
<tr>
<td>chlordiazepoxide</td>
<td>20 mg</td>
</tr>
<tr>
<td>clorazepate</td>
<td>15 mg</td>
</tr>
<tr>
<td>diazepam</td>
<td>5 mg</td>
</tr>
<tr>
<td>clonazepam</td>
<td>1.5 mg</td>
</tr>
<tr>
<td>quazepam</td>
<td>7.5 mg</td>
</tr>
<tr>
<td>estazolam</td>
<td>0.5 mg</td>
</tr>
<tr>
<td>alprazolam</td>
<td>0.75 mg</td>
</tr>
<tr>
<td>oxazepam</td>
<td>30 mg</td>
</tr>
<tr>
<td>lorazepam</td>
<td>2 mg</td>
</tr>
</tbody>
</table>

Duration

- If used to manage behavior, stabilize mood, or treat a psychiatric disorder, refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance

Adverse Consequences

- May increase risk of confusion, sedation, and falls
<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anxiolytics (cont.)</strong></td>
<td></td>
</tr>
<tr>
<td>diphenhydramine and hydroxyzine</td>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>• Not appropriate for use as an anxiolytic</td>
<td></td>
</tr>
<tr>
<td>meprobamate</td>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>• Highly addictive and sedating medication; not indicated for use in older individuals</td>
<td><strong>Dosage/Duration</strong></td>
</tr>
<tr>
<td>• Those who have used meprobamate for prolonged periods may be physically and/or psychologically dependent and may need to be withdrawn slowly</td>
<td></td>
</tr>
<tr>
<td><strong>Cardiovascular medications (including antihypertensives)</strong></td>
<td></td>
</tr>
<tr>
<td>All antiarrhythmics</td>
<td><strong>Adverse Consequences</strong></td>
</tr>
<tr>
<td>• Cardiac antiarrhythmics can have serious adverse effects in older individuals, including impaired mental function, falls, appetite, behavior, and heart function</td>
<td></td>
</tr>
<tr>
<td>amiodarone</td>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>• Only approved indication for use is to treat documented life-threatening recurrent ventricular arrhythmias that do not respond to other antiarrhythmic agents or when alternative agents are not tolerated</td>
<td><strong>Common off-label use to treat atrial fibrillation; however, literature suggests that in many higher risk individuals, alternative approaches to managing atrial fibrillation (rate control and anticoagulation) are equally effective and less toxic</strong></td>
</tr>
</tbody>
</table>
### Medication Issues and Concerns

#### Cardiovascular medications (including antihypertensives) (cont.)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage/Monitoring</th>
<th>Interactions/Adverse Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• It is critical to carefully consider risks and benefits, to use the lowest possible dose for the shortest possible duration, to closely monitor individuals receiving long-term amiodarone, and to seek and identify adverse consequences</td>
<td>• May cause potentially fatal toxicities, including pulmonary toxicity (hypersensitivity pneumonitis or interstitial/alveolar pneumonitis) and hepatic injury. May cause hypothyroidism, exacerbate existing arrhythmia, and worsen heart failure. Can also impair mental function and behavior</td>
</tr>
<tr>
<td>disopyramide</td>
<td>• May cause clinically significant medication interactions; for example, with digoxin and warfarin</td>
<td>• Toxicity increases with higher doses and longer duration of use</td>
</tr>
<tr>
<td>All antihypertensives</td>
<td>• Doses of individual antihypertensives may require modification in order to achieve desired effects while minimizing adverse consequences, especially when multiple antihypertensives are prescribed simultaneously</td>
<td>• May cause dizziness, postural hypotension, fatigue, and an increased risk for falls</td>
</tr>
<tr>
<td></td>
<td>• When discontinuing some antihypertensives (e.g., clonidine, beta blockers), gradual tapering may be required to avoid adverse consequences caused by abrupt cessation</td>
<td>• Many other medications may interact with antihypertensives to potentiate their effect (e.g., levodopa, nitrates)</td>
</tr>
<tr>
<td>Medication</td>
<td>Issues and Concerns</td>
<td></td>
</tr>
<tr>
<td>------------</td>
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<td></td>
</tr>
<tr>
<td><strong>Cardiovascular medications (including antihypertensives) (cont.)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Alpha blockers, e.g.,</strong></td>
<td><strong>Adverse Consequences</strong></td>
<td></td>
</tr>
<tr>
<td>- alfuzosin</td>
<td>- Doxazosin, prazosin, and terazosin can cause significant hypotension and syncope during the first few doses. Therefore, these medications should be initiated at bedtime with a slow titration of dose</td>
<td></td>
</tr>
<tr>
<td>- doxazosin</td>
<td>- Prazosin can cause more CNS side effects and generally should be avoided in older individuals</td>
<td></td>
</tr>
<tr>
<td>- prazosin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- tamsulosin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- terazosin</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Angiotensin converting enzyme (ACE) inhibitors, e.g.,</strong></td>
<td><strong>Monitoring</strong></td>
<td></td>
</tr>
<tr>
<td>- benazepril</td>
<td>- Monitoring of serum potassium is necessary especially in individuals receiving ACE inhibitors with potassium, or potassium sparing diuretics</td>
<td></td>
</tr>
<tr>
<td>- captopril</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- enalapril</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- fosinopril</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- lisinopril</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- ramipril</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Angiotensin II receptor blockers, e.g.,</strong></td>
<td><strong>Adverse Consequences</strong></td>
<td></td>
</tr>
<tr>
<td>- candesartan</td>
<td>- May cause angioedema (signs and symptoms of immediate hypersensitivity), chronic persistent nonproductive cough, or may worsen renal failure</td>
<td></td>
</tr>
<tr>
<td>- eprosartan</td>
<td>- Potential for life-threatening elevation of serum potassium concentrations when used in combination with potassium supplements, potassium-sparing diuretics including spironolactone</td>
<td></td>
</tr>
<tr>
<td>- irbesartan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- losartan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- olmesartan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- valsartan</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Beta adrenergic blockers, e.g.,</strong></td>
<td><strong>Adverse Consequences</strong></td>
<td></td>
</tr>
<tr>
<td>Nonselective, e.g.,</td>
<td>- May cause or exacerbate:</td>
<td></td>
</tr>
<tr>
<td>- propranolol</td>
<td>- Bradycardia, especially in individuals receiving other medications that affect cardiac conduction (e.g., calcium channel blockers);</td>
<td></td>
</tr>
<tr>
<td><strong>Cardioselective, e.g.,</strong></td>
<td>- Dizziness, fatigue; depression, bronchospasm (especially, but not exclusively, propranolol); or</td>
<td></td>
</tr>
<tr>
<td>- atenolol</td>
<td>- Cardiac decompensation that may require adjusting dose in residents with acute heart failure</td>
<td></td>
</tr>
<tr>
<td>- esmolol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- metoprolol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- nadolol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- timolol</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Monitoring</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Adverse Consequences</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- May cause or exacerbate:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- May mask tachycardia associated with symptomatic hypoglycemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- May have increased effect or may accumulate in individuals with hepatic impairment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>Issues and Concerns</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>---------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Calcium channel blockers, e.g.,</td>
<td>Adverse consequences</td>
<td></td>
</tr>
<tr>
<td>- nifedipine</td>
<td>• May cause clinically significant constipation</td>
<td></td>
</tr>
<tr>
<td>- isradipine</td>
<td>• May cause peripheral edema</td>
<td></td>
</tr>
<tr>
<td>- amlodipine</td>
<td>• Some agents may cause generalized aching, headache, muscle pain</td>
<td></td>
</tr>
<tr>
<td>- nisoldipine</td>
<td>• Short acting/immediate release nifedipine increases the risk of cardiac complications and should not be used</td>
<td></td>
</tr>
<tr>
<td>- diltiazem</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- verapamil</td>
<td></td>
<td></td>
</tr>
<tr>
<td>methyldopa</td>
<td>Indications</td>
<td></td>
</tr>
<tr>
<td>Including combination products such as</td>
<td>• Alternate treatments for hypertension are preferred</td>
<td></td>
</tr>
<tr>
<td>methyldopa/hydrochlorothiazide</td>
<td>Adverse Consequences</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• May cause bradycardia and excessive sedation; may exacerbate depression in older individuals</td>
<td></td>
</tr>
<tr>
<td>digoxin</td>
<td>Indications</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Digoxin is indicated only for the following diagnoses: congestive heart failure, atrial fibrillation, paroxysmal supraventricular tachycardia, or atrial flutter</td>
<td></td>
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<tr>
<td></td>
<td>• Should be used with caution in individuals with impaired renal function</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dosage</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Daily doses in older individuals should ordinarily not exceed 0.125 mg/day except when used to control atrial arrhythmia and ventricular rate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monitoring</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Must be used cautiously in individuals with renal failure or fluid and electrolyte imbalance, with close monitoring for adverse consequences and monitoring, as indicated, of both renal function and serum medication concentration (“digoxin level”)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Adverse consequences may occur even with therapeutic serum concentration, especially in older individuals</td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>Issues and Concerns</td>
<td></td>
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<tr>
<td>------------</td>
<td>---------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Cardiovascular medications (including antihypertensives) (cont.)</strong></td>
<td><strong>Interactions/Adverse Consequences</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• May interact with many other medications, possibly resulting in digoxin toxicity or elevated serum concentrations of other medications</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• May cause significant bradycardia, especially when used in individuals taking other medications affecting cardiac conduction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Toxicity may cause fatigue, nausea, vomiting, anorexia, delirium, cardiac arrhythmia</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Diuretics, e.g.,</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• bumetanide</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• ethacrynic acid</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• furosemide</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• hydrochlorothiazide</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• metolazone</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• spironolactone</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• torsemide</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• triamterene</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Adverse Consequences</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• May cause fluid and electrolyte imbalance (hypo/hypernatremia, hypo/hyperkalemia, dehydration, etc.), hypotension; may precipitate or exacerbate urinary incontinence, falls</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Nitrates, e.g.,</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• isosorbide mononitrate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• isosorbide dinitrate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• nitroglycerin</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Adverse Consequences</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• May cause headaches, dizziness, lightheadedness, faintness, or symptomatic orthostatic hypotension, especially when initially started or when taken in combination with antihypertensive medications</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Cholesterol lowering medications</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>HMG-CoA Reductase Inhibitors (“statins”), e.g.,</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• atorvastatin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• fluvastatin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• lovastatin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• pravastatin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• rosuvastatin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• simvastatin</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Monitoring</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Liver function monitoring should be performed consistent with manufacturer’s recommendations, generally accepted as:</td>
<td></td>
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<tr>
<td></td>
<td>• Prior to initiation of therapy, at 12 weeks following both initiation of therapy and any increase in dose, and periodically (e.g., semiannually) thereafter</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Adverse Consequences</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• May impair liver function; liver function tests should be monitored as indicated above</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• May cause muscle pain, myopathy, and rhabdomyolysis (breakdown of skeletal muscle) that can precipitate kidney failure especially in combination with other cholesterol lowering medications.</td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>Issues and Concerns</td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>-----------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Cholesterol lowering medications (cont.)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cholestyramine</td>
<td><strong>Interactions</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• May reduce the absorption of other medications being taken concurrently. Other medications, including diuretics, beta-blockers, corticosteroids, thyroid hormones, digoxin, valproic acid, NSAIDs, sulfonylureas, and warfarin should be administered one hour before or four hours after cholestyramine administration to avoid this interaction</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Adverse Consequences</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• May cause constipation, dyspepsia, nausea or vomiting, abdominal pain</td>
<td></td>
</tr>
<tr>
<td>fibrates, e.g.,</td>
<td><strong>Monitoring</strong></td>
<td></td>
</tr>
<tr>
<td>• fenofibrate</td>
<td>• Fenofibrate and clofibrate require regular monitoring of liver tests as well as evaluating the complete blood count (CBC) prior to and after initiation</td>
<td></td>
</tr>
<tr>
<td>• clofibrate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>niacin</td>
<td><strong>Monitoring</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Monitor glucose and liver function tests regularly</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Adverse Consequences</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Interferes with glucose control and can aggravate diabetes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Can exacerbate active gallbladder disease and gout</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Flushing is common</td>
<td></td>
</tr>
</tbody>
</table>
### Medication Issues and Concerns

#### Cognitive Enhancers

**Cholinesterase inhibitors, e.g.,**
- donepezil
- galantamine
- rivastigmine

**Indications**
- As the underlying disorder progresses into advanced stages, the continued use of the medication should be reevaluated

**Adverse Consequences**
- May affect cardiac conduction, especially in individuals who already have a cardiac conduction disorder or who are taking other medications that affect heart rate
- May cause insomnia, dizziness, nausea, vomiting, diarrhea, anorexia, and weight loss
- Should be used with caution in individuals with severe asthma or obstructive pulmonary disease

**NMDA receptor antagonists, e.g.,**
- memantine

**Indications**
- As the underlying disorder progresses into advanced stages, the continued use of the medication should be reevaluated

**Adverse Consequences**
- May cause restlessness, distress, dizziness, somnolence, hypertension, headache, hallucinations, or increased confusion

#### Cough, cold, and allergy medications

**All cough, cold, allergy medications**

**Indications/Duration**
- Should be used only for a limited duration (less than 14 days) unless there is documented evidence of enduring symptoms that cannot otherwise be alleviated and for which a cause cannot be identified and corrected

**Antihistamine H-1 blockers, e.g.,**
- chlorpheniramine
- cyproheptadine
- diphenhydramine
- hydroxyzine
- meclizine
- promethazine

**Indications**
- H-1 blocker antihistamines have strong anticholinergic properties and are not considered medications of choice in older individuals
- If appropriate and effective, topical instead of oral diphenhydramine should be considered for allergic reactions involving the skin
## Medication Issues and Concerns

### Cough, cold, and allergy medications (cont.)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dosage/Duration</strong></td>
<td>Should be used in the smallest possible dosage for the shortest possible duration, especially in individuals who are susceptible to anticholinergic side effects or who are receiving other medications with anticholinergic properties (see Table II)</td>
</tr>
<tr>
<td><strong>Adverse Consequences</strong></td>
<td>May cause excessive sedation, confusion, cognitive impairment, distress, dry mouth, constipation, urinary retention. These may lead to other adverse consequences such as falls</td>
</tr>
<tr>
<td><strong>Oral decongestants, e.g.,</strong></td>
<td><strong>pseudoephedrine</strong></td>
</tr>
<tr>
<td><strong>Adverse Consequences</strong></td>
<td>May cause dizziness, nervousness, insomnia, palpitations, urinary retention, elevated blood pressure</td>
</tr>
<tr>
<td></td>
<td>Should be used with caution in individuals who have insomnia or hypertension</td>
</tr>
<tr>
<td><strong>Gastrointestinal medications</strong></td>
<td></td>
</tr>
</tbody>
</table>
| **Phenothiazine-related antiemetics, e.g.,** | **prochlorperazine**  
**promethazine** |
<p>| <strong>Indications</strong> | Use with caution in individuals with Parkinson’s disease, narrow-angle glaucoma, BPH, seizure disorder |
| <strong>Adverse Consequences</strong> | May cause sedation, dizziness, drowsiness, postural hypotension, and neuroleptic malignant syndrome |
|  | May lower seizure threshold |
|  | Promethazine and prochlorperazine may cause anticholinergic effects, such as constipation, dry mouth, blurred vision, urinary retention |
|  | May cause extrapyramidal symptoms, including medication-induced parkinsonism, acute dystonic reactions, akathisia, and tardive dyskinesia |
|  | May alter cardiac conduction or induce arrhythmias |</p>
<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gastrointestinal medications (cont.)</strong></td>
<td></td>
</tr>
<tr>
<td>trimethobenzamide</td>
<td><strong>Adverse Consequences</strong></td>
</tr>
<tr>
<td></td>
<td>• Relatively ineffective antiemetic that can cause significant extrapyramidal side effects in addition to lethargy, sedation, confusion</td>
</tr>
<tr>
<td></td>
<td><strong>Exception:</strong> May be indicated in patients with Parkinson’s Disease taking apomorphine</td>
</tr>
<tr>
<td>metoclopramide</td>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td></td>
<td>• High-risk medication with limited clinical indication and limited demonstrated effectiveness*</td>
</tr>
<tr>
<td></td>
<td>• Not recommended for first-line treatment of gastroesophageal reflux disease, especially in older individuals</td>
</tr>
<tr>
<td></td>
<td>• When used for diabetic gastroparesis, or other indications, relative benefits and risks should be assessed and documented</td>
</tr>
<tr>
<td></td>
<td><strong>Adverse Consequences</strong></td>
</tr>
<tr>
<td></td>
<td>• Especially in older individuals, metoclopramide may cause restlessness, drowsiness, insomnia, depression, distress, anorexia, and extrapyramidal symptoms, and may lower the seizure threshold</td>
</tr>
<tr>
<td></td>
<td>• May increase seizures in individuals with seizure disorders or exacerbate symptoms in individuals with Parkinson’s Disease</td>
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<tr>
<td></td>
<td><strong>Monitoring</strong></td>
</tr>
<tr>
<td></td>
<td>• It is essential to closely monitor at-risk individuals for adverse consequences</td>
</tr>
<tr>
<td>Medication</td>
<td>Issues and Concerns</td>
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<td>------------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Gastrointestinal medications (cont.)</td>
<td></td>
</tr>
<tr>
<td>Proton pump inhibitors (PPI), e.g.,</td>
<td>Indications</td>
</tr>
<tr>
<td>• esomeprazole</td>
<td>• Indication for use should be based on clinical symptoms and/or endoscopic findings</td>
</tr>
<tr>
<td>• lansoprazole</td>
<td>• When used to treat or prevent NSAID-induced gastritis or esophagitis, documentation should exist that other, less GI-toxic analgesics have been tried or were not indicated</td>
</tr>
<tr>
<td>• omeprazole</td>
<td></td>
</tr>
<tr>
<td>• rabeprazole</td>
<td></td>
</tr>
<tr>
<td>H-2 antagonists, e.g.,</td>
<td>Duration</td>
</tr>
<tr>
<td>• cimetidine</td>
<td>• If used for greater than 12 weeks, clinical rationale for continued need and/or documentation should support an underlying chronic disease (e.g., GERD) or risk factors (e.g., chronic NSAID use)</td>
</tr>
<tr>
<td>• famotidine</td>
<td></td>
</tr>
<tr>
<td>• ranitidine</td>
<td></td>
</tr>
<tr>
<td>Dosage</td>
<td></td>
</tr>
<tr>
<td>• Dosing of histamine-H2 antagonists should be based on renal function</td>
<td></td>
</tr>
<tr>
<td>Interactions</td>
<td></td>
</tr>
<tr>
<td>• Cimetidine has higher incidence of medication interactions and should be avoided in older individuals</td>
<td></td>
</tr>
<tr>
<td>Adverse Consequences</td>
<td></td>
</tr>
<tr>
<td>• May cause or exacerbate headache, nausea, vomiting, flatulence, dysphagia, abdominal pain, diarrhea, or other gastrointestinal symptoms</td>
<td></td>
</tr>
<tr>
<td>• H-2 antagonists may cause confusion</td>
<td></td>
</tr>
<tr>
<td>• PPIs may increase the risk of clostridium difficile colitis</td>
<td></td>
</tr>
<tr>
<td>Glucocorticoids</td>
<td>Duration/Monitoring</td>
</tr>
<tr>
<td>All glucocorticoids (except topical or inhaled dosage forms), e.g.,</td>
<td>• Necessity for continued use should be documented, along with monitoring for and management of adverse consequences</td>
</tr>
<tr>
<td>• dexamethasone</td>
<td></td>
</tr>
<tr>
<td>• hydrocortisone</td>
<td></td>
</tr>
<tr>
<td>• methylprednisolone</td>
<td></td>
</tr>
<tr>
<td>• prednisone</td>
<td></td>
</tr>
<tr>
<td>Adverse Consequences</td>
<td></td>
</tr>
<tr>
<td>• Intermediate- or longer-term use may cause hyperglycemia, psychosis, edema, insomnia, hypertension, osteoporosis, mood lability, or depression</td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>Issues and Concerns</td>
</tr>
<tr>
<td>------------</td>
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</tr>
<tr>
<td><strong>Hematinics</strong></td>
<td></td>
</tr>
<tr>
<td>Erythropoiesis stimulants, e.g.,</td>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>• darbepoetin</td>
<td>• Assessment of causes and categories of anemia should precede or accompany the use of this medication</td>
</tr>
<tr>
<td>• erythropoietin</td>
<td><strong>Monitoring</strong></td>
</tr>
<tr>
<td></td>
<td>• Use must be monitored according to specific manufacturer’s instructions including blood pressure, baseline serum iron or ferritin level, and frequent complete blood count (CBCs) to permit tapering or discontinuation when hemoglobin/hematocrit reaches or exceeds target ranges</td>
</tr>
<tr>
<td></td>
<td><strong>Adverse Consequences</strong></td>
</tr>
<tr>
<td></td>
<td>• May cause or worsen hypertension</td>
</tr>
<tr>
<td></td>
<td>• Excessive dose or duration can lead to polycythemia, dangerous thrombotic events including myocardial infarction and stroke</td>
</tr>
<tr>
<td><strong>Iron</strong></td>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td></td>
<td>• Iron therapy is not indicated in anemia of chronic disease when iron stores and transferrin levels are normal or elevated</td>
</tr>
<tr>
<td></td>
<td><strong>Dosage/Duration</strong></td>
</tr>
<tr>
<td></td>
<td>• Clinical rationale should be documented for long-term use (greater than two months) or administration more than once daily for greater than a week, because of side effects and the risk of iron accumulation in tissues</td>
</tr>
<tr>
<td></td>
<td><strong>Monitoring</strong></td>
</tr>
<tr>
<td></td>
<td>• Baseline serum iron or ferritin level and periodic CBC or hematocrit/hemoglobin</td>
</tr>
<tr>
<td></td>
<td><strong>Adverse Consequences</strong></td>
</tr>
<tr>
<td></td>
<td>• May cause constipation, dyspepsia</td>
</tr>
<tr>
<td></td>
<td>• Can accumulate in tissues and cause multiple complications if given chronically despite normal or high iron stores</td>
</tr>
<tr>
<td>Medication</td>
<td>Issues and Concerns</td>
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<td>--------------------------------</td>
<td>------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Laxatives</strong></td>
<td></td>
</tr>
<tr>
<td>All categories including</td>
<td><strong>Adverse Consequences</strong></td>
</tr>
<tr>
<td>bulk producing laxatives,</td>
<td>• May cause flatulence, bloating, abdominal pain</td>
</tr>
<tr>
<td>hyperosmolar agents, saline</td>
<td>• Bulk forming laxatives and stool softeners may cause accumulation of stool and</td>
</tr>
<tr>
<td>laxatives, stimulant laxatives,</td>
<td>possible bowel obstruction, if not used with adequate fluids or in individuals with</td>
</tr>
<tr>
<td>emollient laxatives</td>
<td>other causes of impaired bowel motility</td>
</tr>
<tr>
<td><strong>Muscle relaxants</strong></td>
<td></td>
</tr>
<tr>
<td>All muscle relaxants, e.g.,</td>
<td><strong>Indications/Adverse Consequences</strong></td>
</tr>
<tr>
<td>• baclofen</td>
<td>• Most are poorly tolerated by older individuals due to anticholinergic side effects</td>
</tr>
<tr>
<td>• carisoprodol</td>
<td>(see Table II), sedation, or weakness</td>
</tr>
<tr>
<td>• chlorzoxazone</td>
<td>• Long-term use in individuals with complications due to multiple sclerosis, spinal</td>
</tr>
<tr>
<td>• cyclobenzaprine</td>
<td>cord injuries, cerebral palsy, and other nonselect conditions may be indicated,</td>
</tr>
<tr>
<td>• dantrolene</td>
<td>although close monitoring is still warranted</td>
</tr>
<tr>
<td>• metaxalone</td>
<td>• Abrupt cessation of some muscle relaxants may cause or predispose individuals to</td>
</tr>
<tr>
<td>• methocarbamol</td>
<td>seizures or hallucinations</td>
</tr>
<tr>
<td>• orphenadrine</td>
<td><strong>Exception:</strong> Periodic use (once every three months) for a short duration (not</td>
</tr>
<tr>
<td></td>
<td>more than seven days) may be appropriate, when other interventions or alternative</td>
</tr>
<tr>
<td></td>
<td>medications are not effective or not indicated</td>
</tr>
<tr>
<td>**Orexigenics (appetite</td>
<td></td>
</tr>
<tr>
<td>stimulants)**</td>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>All appetite stimulants, e.g.,</td>
<td>• Use should be reserved for situations where assessment and management of</td>
</tr>
<tr>
<td>• megestrol acetate</td>
<td>underlying correctable causes of anorexia and weight loss is not feasible or</td>
</tr>
<tr>
<td>• oxandrolone</td>
<td>successful, and after evaluating potential benefits/risks</td>
</tr>
<tr>
<td>• dronabinol</td>
<td><strong>Monitoring</strong></td>
</tr>
<tr>
<td></td>
<td>• Appetite and weight should be monitored at least monthly and agent should be</td>
</tr>
<tr>
<td></td>
<td>discontinued if there is no improvement.</td>
</tr>
<tr>
<td></td>
<td><strong>Adverse Consequences</strong></td>
</tr>
<tr>
<td></td>
<td>• Megesterol acetate may cause fluid retention, adrenal suppression, and symptoms</td>
</tr>
<tr>
<td></td>
<td>of adrenal insufficiency</td>
</tr>
</tbody>
</table>
### Medication Issues and Concerns (cont.)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
</table>
| **Orexigenics (appetite stimulants)**<sup>(cont.)</sup> | Adverse Consequences  
• Oxandrolone may cause virilization of females and feminization of males, excessive sexual stimulation, and fluid retention  
• Dronabinol may cause tachycardia, orthostatic hypotension, dizziness, dysphoria, and impaired cognition, which may lead to falls |

<table>
<thead>
<tr>
<th><strong>Osteoporosis medications</strong></th>
<th></th>
</tr>
</thead>
</table>
| Bisphosphonates, e.g.,       | **Dosage**  
• alendronate  
• ibandronate  
• risedronate  

**Monitoring**  
• Individuals receiving these medications should be monitored closely for gastrointestinal complications, including esophageal or gastric erosion  

**Adverse Consequences**  
• Potential to cause gastrointestinal symptoms including dysphagia, esophagitis, gastritis, or esophageal and gastric ulcers, especially when given to individuals who are also taking oral corticosteroids, aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs) |

<table>
<thead>
<tr>
<th><strong>Platelet inhibitors</strong></th>
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</thead>
</table>
| All platelet inhibitors, e.g., | **Interactions/Adverse Consequences**  
• May cause thrombocytopenia and increase risk of bleeding  
• Common side effects include headache, dizziness, and vomiting  
• See discussion at NSAIDs regarding aspirin  
• Concurrent use with warfarin or NSAIDs may increase risk of bleeding  

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<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Platelet inhibitors (cont.)</strong></td>
<td></td>
</tr>
<tr>
<td>ticlopidine</td>
<td><strong>Indication</strong></td>
</tr>
<tr>
<td></td>
<td>• Use may be appropriate in individuals who have had a previous stroke or have evidence of stroke precursors (i.e., transient ischemic attacks (TIAs)), and who cannot tolerate aspirin or another platelet inhibitor</td>
</tr>
<tr>
<td></td>
<td><strong>Adverse Consequences</strong></td>
</tr>
<tr>
<td></td>
<td>• Associated with more severe side effects and considerably more toxic than other platelet inhibitors; use should be avoided in older individuals</td>
</tr>
<tr>
<td></td>
<td>• Most serious side effects involve the hematologic system, including potentially life-threatening neutropenia</td>
</tr>
<tr>
<td></td>
<td>• May also cause nausea, vomiting, and diarrhea</td>
</tr>
<tr>
<td><strong>Respiratory medications</strong></td>
<td></td>
</tr>
<tr>
<td>theophylline</td>
<td><strong>Interactions</strong></td>
</tr>
<tr>
<td></td>
<td>• Potentially significant interactions with many other medications may occur, especially various antibiotics, seizure medications, and cardiac medications</td>
</tr>
<tr>
<td></td>
<td><strong>Monitoring/Adverse Consequences</strong></td>
</tr>
<tr>
<td></td>
<td>• There should be monitoring for signs and symptoms of toxicity, such as arrhythmia, seizure, GI upset, diarrhea, nausea/vomiting, abdominal pain, nervousness, headache, insomnia, distress, dizziness, muscle cramp, tremor</td>
</tr>
<tr>
<td></td>
<td>• Periodic monitoring of serum concentrations helps identify or verify toxicity</td>
</tr>
</tbody>
</table>
### Medication Issues and Concerns

#### Respiratory medications (cont.)

<table>
<thead>
<tr>
<th>Medication Classes</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inhalant medications classes, e.g.,</strong></td>
<td></td>
</tr>
<tr>
<td>Anticholinergic, e.g.,</td>
<td>- Inhaled anticholinergics can cause xerostomia (dry mouth)</td>
</tr>
<tr>
<td>• ipratropium</td>
<td></td>
</tr>
<tr>
<td>• tiotropium</td>
<td>- Inhaled beta agonists can cause restlessness, increased heart rate, and anxiety</td>
</tr>
<tr>
<td><strong>Beta 2 agonists, e.g.,</strong></td>
<td>- Inhaled steroids can cause throat irritation and oral candidiasis, especially if the mouth is not rinsed after administration</td>
</tr>
<tr>
<td>• albuterol</td>
<td></td>
</tr>
<tr>
<td>• formoterol</td>
<td></td>
</tr>
<tr>
<td>• pirbuterol acetate</td>
<td></td>
</tr>
<tr>
<td>• salmeterol</td>
<td></td>
</tr>
<tr>
<td><strong>Corticosteroids, e.g.,</strong></td>
<td></td>
</tr>
<tr>
<td>• beclomethasone</td>
<td></td>
</tr>
<tr>
<td>• budesonide</td>
<td></td>
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<tr>
<td>• flunisolide</td>
<td></td>
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<tr>
<td>• fluticasone</td>
<td></td>
</tr>
<tr>
<td>• triamcinolone acetone</td>
<td></td>
</tr>
<tr>
<td><strong>Miscellaneous, e.g.,</strong></td>
<td></td>
</tr>
<tr>
<td>• cromolyn</td>
<td></td>
</tr>
<tr>
<td>• nedocromil sodium</td>
<td></td>
</tr>
</tbody>
</table>

#### Adverse Consequences

- Inhaled anticholinergics can cause xerostomia (dry mouth)
- Inhaled beta agonists can cause restlessness, increased heart rate, and anxiety
- Inhaled steroids can cause throat irritation and oral candidiasis, especially if the mouth is not rinsed after administration

### Sedatives/Hypnotics (sleep medications)

<table>
<thead>
<tr>
<th>Medication Classes</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All hypnotics</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Benzodiazepine hypnotics, e.g.,</strong></td>
<td></td>
</tr>
<tr>
<td>• estazolam</td>
<td></td>
</tr>
<tr>
<td>• flurazepam</td>
<td></td>
</tr>
<tr>
<td>• quazepam</td>
<td></td>
</tr>
<tr>
<td>• temazepam</td>
<td></td>
</tr>
<tr>
<td>• triazolam</td>
<td></td>
</tr>
<tr>
<td><strong>Non-benzodiazepine hypnotics, e.g.,</strong></td>
<td></td>
</tr>
<tr>
<td>• eszopiclone</td>
<td></td>
</tr>
<tr>
<td>• zaleplon</td>
<td></td>
</tr>
<tr>
<td>• zolpidem</td>
<td></td>
</tr>
<tr>
<td><strong>Melatonin receptor agonists, e.g.,</strong></td>
<td></td>
</tr>
<tr>
<td>• ramelteon</td>
<td></td>
</tr>
<tr>
<td><strong>Other hypnotics, e.g.,</strong></td>
<td></td>
</tr>
<tr>
<td>• chloral hydrate</td>
<td></td>
</tr>
<tr>
<td><strong>Miscellaneous agents used for sleep, e.g.,</strong></td>
<td></td>
</tr>
<tr>
<td>• sedating antidepressants (e.g., trazodone)</td>
<td></td>
</tr>
<tr>
<td>• sedating antihistamines (e.g., hydroxyzine)</td>
<td></td>
</tr>
</tbody>
</table>

#### Indications

- Most cases of insomnia are associated with underlying conditions (secondary or co-morbid insomnia) such as psychiatric disorders (e.g., depression), cardiopulmonary disorders (e.g., COPD, CHF), urinary frequency, pain, obstructive sleep apnea, and restless leg syndrome. Insomnia may be further described by the duration of symptoms
- Before initiating medications to treat insomnia, other factors potentially causing insomnia should be evaluated, including, for example:
  - environment, such as excessive heat, cold, or noise; lighting
  - inadequate physical activity
  - facility routines that may not accommodate residents’ individual needs (e.g., time for sleep, awakening, toileting, medication treatments)
  - provision of care in a manner that disrupts sleep
  - caffeine or medications known to disrupt sleep
  - pain and discomfort
<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
</table>
| Sedatives/Hypnotics (sleep medications) (cont.) | • underlying conditions (secondary or co-morbid insomnia) such as psychiatric disorders (e.g., depression), cardiopulmonary disorders (e.g., COPD, CHF), urinary frequency, pain, obstructive sleep apnea, and restless leg syndrome  
  • It is expected that interventions (such as sleep hygiene approaches, individualizing the sleep and wake times to accommodate the person’s wishes and prior customary routine, and maximizing treatment of any underlying conditions) are implemented to address the causative factor(s)  
  • These guidelines apply to any medication that is being used to treat insomnia. Initiation of medications to induce or maintain sleep should be preceded or accompanied by other interventions to try to improve sleep. All sleep medications should be used in accordance with approved product labeling; for example, timing and frequency of administration relative to anticipated waking time  
  • The use of sedating medications for individuals with diagnosed sleep apnea requires careful assessment, documented clinical rationale, and close monitoring  
  Exceptions:  
  • Use of a single dose sedative for dental or medical procedures  
  • During initiation of treatment for depression, pain or other comorbid condition(s), short-term use of a sleep medication may be necessary until symptoms improve or the underlying aggravating factor can be identified and/or effectively treated |
### Dosage

**Daily Dose Thresholds For Sedative-Hypnotic Medications**

<table>
<thead>
<tr>
<th>Generic Medication</th>
<th>Oral Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>chloral hydrate*</td>
<td>500 mg</td>
</tr>
<tr>
<td>diphenhydramine*</td>
<td>25 mg</td>
</tr>
<tr>
<td>estazolam</td>
<td>0.5 mg</td>
</tr>
<tr>
<td>eszopiclone</td>
<td>1 mg</td>
</tr>
<tr>
<td>flurazepam*</td>
<td>15 mg</td>
</tr>
<tr>
<td>hydroxyzine*</td>
<td>50 mg</td>
</tr>
<tr>
<td>lorazepam</td>
<td>1 mg</td>
</tr>
<tr>
<td>oxazepam</td>
<td>15 mg</td>
</tr>
<tr>
<td>quazepam*</td>
<td>7.5 mg</td>
</tr>
<tr>
<td>ramelteon</td>
<td>8 mg</td>
</tr>
<tr>
<td>temazepam</td>
<td>15 mg</td>
</tr>
<tr>
<td>triazolam*</td>
<td>0.125 mg</td>
</tr>
<tr>
<td>zaleplon</td>
<td>5 mg</td>
</tr>
<tr>
<td>zolpidem IR</td>
<td>5 mg</td>
</tr>
<tr>
<td>zolpidem CR</td>
<td>6.25 mg</td>
</tr>
</tbody>
</table>

* These medications are not considered medications of choice for the management of insomnia, especially in older individuals.


### Duration

- If used to induce sleep or treat a sleep disorder, refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance.
<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barbiturates, e.g.,</td>
<td><strong>NOTE:</strong> Refers to barbiturates used to induce sleep or treat anxiety disorder</td>
</tr>
<tr>
<td>• amobarbital</td>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>• butabarbital</td>
<td>• Barbiturates should not be initiated in any dose for any individuals to treat anxiety or insomnia; as they are highly addictive and cause numerous adverse effects, especially in older individuals</td>
</tr>
<tr>
<td>• pentobarbital</td>
<td><strong>Exception:</strong> These guidelines do not apply to the use of phenobarbital to treat seizure disorders (see Anticonvulsant section)</td>
</tr>
<tr>
<td>• secobarbital</td>
<td><strong>Interactions/Adverse Consequences</strong></td>
</tr>
<tr>
<td>• phenobarbital</td>
<td>• May increase the metabolism of many medications (e.g., anticonvulants, antipsychotics), which may lead to decreased effectiveness and subsequent worsening of symptoms or decreased control of underlying illness</td>
</tr>
<tr>
<td>• amobarbital-secobarbital</td>
<td>• May cause hypotension, dizziness, lightheadedness, “hangover” effect, drowsiness, confusion, mental depression, unusual excitement, nervousness, headache, insomnia, nightmares, and hallucinations</td>
</tr>
<tr>
<td>• barbiturates with other medications</td>
<td>• May increase the risk for falls</td>
</tr>
<tr>
<td><strong>Thyroid medications</strong></td>
<td></td>
</tr>
<tr>
<td>All thyroid medications, e.g.,</td>
<td><strong>Interactions</strong></td>
</tr>
<tr>
<td>• levothyroxine</td>
<td>• Many clinically significant medication interactions have been identified; therefore, re-evaluation of medication doses is indicated</td>
</tr>
<tr>
<td>• triiodothyronine</td>
<td><strong>Dosage</strong></td>
</tr>
<tr>
<td></td>
<td>• Initiation of thyroid supplementation should occur at low doses and be increased gradually to avoid precipitating cardiac failure or adrenal crisis</td>
</tr>
<tr>
<td></td>
<td><strong>Monitoring</strong></td>
</tr>
<tr>
<td></td>
<td>• Assessment of thyroid function (e.g., TSH, serum T4 or T3) should occur prior to initiation and periodically thereafter, including when new signs and symptoms of hypo- or hyperthyroidism are present</td>
</tr>
</tbody>
</table>
Medication Issues and Concerns

Urinary Incontinence Types and Agents, e.g.,

Urge incontinence:
- Anticholinergics, e.g.,
  - darifenacin
  - oxybutynin
  - tolterodine
  - trospium
- Tricyclic antidepressants, e.g.,
  - desipramine
  - imipramine

Stress incontinence:
- Alpha adrenergic agonists, e.g.,
  - pseudoephedrine

Mixed incontinence, e.g.,
- estrogen replacement agents
- imipramine

Overflow incontinence, e.g.,
- alpha adrenergic antagonists (see antihypertensives)
- bethanechol chloride

Indications
- Before or soon after initiating medication(s) to manage urinary incontinence, assessment of underlying causes and identification of the type/category of urinary incontinence needs to be documented
- These medications have specific, limited indications based on the cause and type/category of incontinence

Monitoring
- Ongoing assessments of the effects of the medication on the individual’s urinary incontinence as well as lower urinary tract symptoms should be done periodically

Adverse Consequences
- Anticholinergics and TCAs may cause anticholinergic effects (see Table II)
- Estrogen Replacement Agents: oral agents may cause systemic side effects and increased risks (e.g., deep venous thrombosis, breast cancer); therefore, topical agents may be preferred
- Bethanechol may cause hypotension, increased sweating and salivation, headache, cramps, diarrhea, nausea and vomiting, and worsening of asthma

TABLE II

Medications with Significant Anticholinergic Properties

Table II lists common medications with significant anticholinergic properties and potential adverse consequences, but is not all-inclusive. Any of the following signs and symptoms may be caused by any of the medications in the lists below, alone or in combination, as well as by other medications not listed here that have anticholinergic properties.

This table is provided because: 1) Medications in many categories have anticholinergic properties; 2) The use of multiple medications with such properties may be particularly problematic because of the cumulative effects; and 3) Anticholinergic side effects are particularly common and problematic, especially in the older individual.\textsuperscript{61, 62}
### Examples of Medications with Anticholinergic Properties

<table>
<thead>
<tr>
<th>Antihistamines (H-1 Blockers)</th>
<th>Cardiovascular Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>chlorpheniramine</td>
<td>furosemide</td>
</tr>
<tr>
<td>diphenhydramine</td>
<td>digoxin</td>
</tr>
<tr>
<td>hydroxyzine</td>
<td>nifedipine</td>
</tr>
<tr>
<td></td>
<td>disopyramide</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Antidepressants</th>
<th>Gastrointestinal Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>amoxapine</td>
<td>diphenoxylate</td>
</tr>
<tr>
<td>clomipramine</td>
<td>atropine</td>
</tr>
<tr>
<td>doxepin</td>
<td>chlorpromazine</td>
</tr>
<tr>
<td>nortriptyline</td>
<td>clozapine</td>
</tr>
<tr>
<td>paroxetine</td>
<td>olanzapine</td>
</tr>
<tr>
<td></td>
<td>thioridazine</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Antiparkinson Medications</th>
<th>Antipsychotic Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>amantadine</td>
<td>chlorpromazine</td>
</tr>
<tr>
<td>biperiden</td>
<td>olanzapine</td>
</tr>
<tr>
<td></td>
<td>thioridazine</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Muscle Relaxants</th>
<th>Urinary Incontinence</th>
</tr>
</thead>
<tbody>
<tr>
<td>cyclobenzaprine</td>
<td>oxybutynin</td>
</tr>
<tr>
<td>orphenadrine</td>
<td>solifenacin</td>
</tr>
<tr>
<td></td>
<td>trolumip</td>
</tr>
</tbody>
</table>

### Potential Adverse Consequences of Medications with Anticholinergic Properties

- Blood pressure, increased
- Clumsiness or unsteadiness
- Digestive system changes, e.g.,
  - Bloating
  - Bowel motility, decreased
  - Constipation
  - Ileus, paralytic/adynamic
  - Nausea or vomiting
  - Swallowing difficulty
  - with dry mouth
- Delirium
- Drowsiness
- Headache
- Lethargy, fatigue
- Muscle weakness, severe
- Skin, changes
  - Dryness
  - Sweating, decreased
  - Flushing Warmth, excessive
- Urinary retention or difficulty
- Breathing difficulty, changes
- Convulsions
- Mental status/behavior changes, e.g.,
  - Distress, excitement, nervousness
  - Attention, impaired
  - Cognitive decline
  - Confusion/disorientation
  - Hallucinations
  - Memory loss
  - Restlessness or irritability
- Dizziness
- Fever
- Heart rate, increased
- Mucous membrane dryness: mouth, nose
- Speech, slurring
- Vision impairment, changes in acuity
  - Blurring
  - Glaucoma, worsening
  - Eye pain
- Light sensitivity
§483.25(m) Medication Errors

The facility must ensure that —

[F332] §483.25(m)(1) It is free of medication error rates of 5% or greater; and

[F333] §483.25(m)(2) Residents are free of any significant medication errors.

Interpretive Guidelines §483.25(m)

Medication Error – The observed preparation or administration of drugs or biologicals which is not in accordance with:

1. Physician’s orders;

2. Manufacturer’s specifications (not recommendations) regarding the preparation and administration of the drug or biological;

5. Accepted professional standards and principles which apply to professionals providing services. Accepted professional standards and principles include the various practice regulations in each state and current commonly accepted health standards established by national organizations, boards, and councils.

“Significant medication error” means one which causes the resident discomfort or jeopardizes his or her health and safety. Criteria for judging significant medication errors as well as examples are provided under significant and non-significant medication errors. Discomfort may be a subjective or relative term used in different ways depending on the individual situation. (Constipation that is unrelieved by an ordered laxative that results in a drug error that is omitted for one day may be slightly uncomfortable or perhaps not uncomfortable at all. When the constipation persists for greater than three days, the constipation may be more significant. Constipation causing obstruction or fecal impaction can jeopardize the resident’s health and safety.)

“Medication error rate” is determined by calculating the percentage of errors. The numerator in the ratio is the total number of errors that the survey team observes, both significant and nonsignificant. The denominator is called “opportunities for errors” and includes all the doses the survey team observed being administered plus the doses ordered but not administered. The equation for calculating a medication error rate is as follows:

\[
\text{Medication Error Rate} = \frac{\text{Number of Errors Observed}}{\text{Opportunities for Errors}} \times 100.
\]

A medication error rate of 5% or greater includes both significant and nonsignificant medication errors. It indicates that the facility may have systemic problems with its drug distribution system and a deficiency should be written.

The error rate must be 5% or greater. Rounding of a lower rate (e.g., 4.6%) to a 5% rate is not permitted.
Significant and Nonsignificant Medication Errors

“Determining Significance” — The relative significance of medication errors is a matter of professional judgment. Follow three general guidelines in determining whether a medication error is significant or not.

“Resident Condition” — The resident’s condition is an important factor to take into consideration. For example, a fluid pill erroneously administered to a dehydrated resident may have serious consequences, but if administered to a resident with a normal fluid balance may not. If the resident’s condition requires rigid control, a single missed or wrong dose can be highly significant.

“Drug Category” — If the drug is from a category that usually requires the resident to be titrated to a specific blood level, a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity. This is especially important with a drug that has a Narrow Therapeutic Index (NTI) (i.e., a drug in which the therapeutic dose is very close to the toxic dose). Examples of drugs with NTI are as follows: Anticonvulsant: phenytoin (Dilantin), carbamazepine (Tegretol), Anticoagulants: warfarin (Coumadin), Antiarrythmic (digoxin) (Lanoxin), Antiasthematics: theophylline (TheoDur), Antimanic Drugs: lithium salts (Eskalith, Lithobid).

“Frequency of Error” — If an error is occurring with any frequency, there is more reason to classify the error as significant. For example, if a resident’s drug was omitted several times, as verified by reconciling the number of tablets delivered with the number administered, classifying that error as significant would be more in order. This conclusion should be considered in concert with the resident’s condition and the drug category.
§483.25(n) Influenza and pneumococcal immunizations---

(1) Influenza. The facility must develop policies and procedures that ensure that--

i. Before offering the influenza immunization, each resident or the resident’s legal representative receives education regarding the benefits and potential side effects of the immunization;

ii. Each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has already been immunized during this time period;

iii. The resident or the resident’s legal representative has the opportunity to refuse immunization; and

iv. The resident’s medical record includes documentation that indicates, at a minimum, the following:

   (A) That the resident or resident’s legal representative was provided education regarding the benefits and potential side effects of influenza immunization; and

   (B) That the resident either received the influenza immunization or did not receive the influenza immunization due to medical contraindications or refusal.

(2) Pneumococcal disease. The facility must develop policies and procedures that ensure that—

i. Before offering the pneumococcal immunization, each resident or the resident’s legal representative receives education regarding the benefits and potential side effects of the immunization;

ii. Each resident is offered an pneumococcal immunization, unless the immunization is medically contraindicate or the resident has already been immunized;

iii. The resident or the resident’s legal representative has the opportunity to refuse immunization; and

iv. The resident’s medical record includes documentation that indicates, at a minimum, the following:

   (A) That the resident or resident’s legal representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and

   (B) That the resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindication or refusal.

v. Exception. As an alternative, based on an assessment and practitioner
recommendation, a second pneumococcal immunization may be given after 5 years following the first pneumococcal immunization, unless medically contraindicated or the resident or the resident’s legal representative refuses the second immunization.

End Notes


§483.40 Physician Services

A physician must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician.

§483.40(a) Physician Supervision

The facility must ensure that —

(1) The medical care of each resident is supervised by a physician; and

(2) Another physician supervises the medical care of residents when their attending physician is unavailable.

Interpretive Guidelines §483.40

A physician’s “personal approval” of an admission recommendation must be in written form. The physician’s admission orders for the resident’s immediate care as required in §483.20(a) will be accepted as “personal approval” of the admission.

“Supervising the medical care of residents” means participating in the resident's assessment and care planning, monitoring changes in resident's medical status, and providing consultation or treatment when called by the facility. It also includes, but is not limited to, prescribing new therapy, ordering a resident’s transfer to the hospital, conducting required routine visits or delegating and supervising follow-up visits to nurse practitioners or physician assistants. Each resident should be allowed to designate a personal physician. (See §485.10(d)(1).) The facility's responsibility in this situation is to simply assist the resident, when necessary, in his or her efforts to obtain those services. For example, the facility could put the resident in touch with the county medical society for the purpose of obtaining referrals to practicing physicians in the area.

Facilities should share MDS and other assessment data with the physician.

§483.40(b) Physician Visits

The physician must —

(1) Review the resident's total program of care, including medications and treatments, at each visit required by paragraph (c) of this section;

(2) Write, sign and date progress notes at each visit; and

(5) Sign and date all orders with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications.

Interpretive Guidelines §483.40(b)
Total program of care includes all care the facility provides residents to maintain or improve their highest practicable mental and physical functional status, as defined by the comprehensive assessment and plan of care. Care includes medical services and medication management, physical, occupational, and speech-language therapy, nursing care, nutritional interventions, social work and activity services that maintain or improve psychosocial functioning.

The physician records residents’ progress and problems in maintaining or improving their mental and physical functional status. The physician need not review the total plan of care at each visit, but must review the total plan of care at visits required by §483.40(c). There is no requirement for physician renewal of orders.

In cases where facilities have created the option for a resident’s record to be maintained by computer, rather than hard copy, electronic signatures are acceptable. See Guidelines for §483.75(l)(1) for information on facility safeguards concerning electronic signatures.

Physician orders may be transmitted by facsimile machine if the following conditions are met:

- The physician should have signed and retained the original copy of the order from which the facsimile was transmitted and be able to provide it upon request. Alternatively, the original may be sent to the facility at a later time and substituted for the facsimile.

- The facility should photocopy the faxed order since some facsimiles fade over time. The facsimile copy can be discarded after facility photocopies it.

- A facility using such a system should establish adequate safeguards to assure that it is not subject to abuse.

It is not necessary for a physician to re-sign the facsimile order when he or she visits the facility.

When rubber stamp signatures are authorized by the facility’s management, the individual whose signature the stamp represents shall place in the administrative offices of the facility a signed statement to the effect that he or she is the only one who has the stamp and uses it. A list of computer codes and written signatures must be readily available and maintained under adequate safeguards.

§483.40(c) Frequency of Physician Visits

(1) The residents must be seen by a physician at least once every 50 days for the first 90 days after admission, and at least once every 60 thereafter.

(2) A physician visit is considered timely if it occurs not later than 10 days after the date the visit was required.

§483.40(c)(5) Except as provided in paragraphs (c)(4) and (f) of this section, all required physician visits must be made by the physician personally.

§483.40(c)(4) At the option of the physician, required visits in SNFs, after the...
initial visit, may alternate between personal visits by the physician and visits by a physician assistant, nurse practitioner or clinical nurse specialist in accordance with paragraph (e) of this section.

Interpretive Guidelines §483.40(c)

“Must be seen” means that the physician must make actual face-to-face contact with the resident. There is no requirement for this type of contact at the time of admission, since the decision to admit an individual to a nursing facility (whether from a hospital or from the individual's own residence) generally involves physician contact during the period immediately preceding the admission.

After the initial physician visit in SNFs, where states allow their use, a qualified nurse practitioner (NP), clinical nurse specialist or physician assistant (PA) may make every other required visit. (See §483.40(e) Physician delegation of tasks in SNFs.)

In a NF, the physician visit requirement, in accordance with the state law, may be satisfied by NP, clinical nurse specialist or PA. (See §483.40(f).)

The timing of physician visits is based on the admission date of the resident. Visits will be made within the first 50 days, and then at 50-day intervals up until 90 days after the admission date. Visits will then be at 60-day intervals. Permitting up to 10-days slippage of a due date will not affect the next due date. However, do not specifically look at the timetables for physician visits unless there is indication of inadequate medical care. The regulation states that the physician (or his or her delegate) must visit the resident at least every 50 or 60 days. There is no provision for physicians to use discretion in visiting at intervals longer than those specified at §483.40(c).

Policy that allows an NP, clinical nurse specialist or PA to make every other required visit, and that allows a 10 day slippage in the time of the visit, does not relieve the physician of the obligation to visit a resident when the resident's medical condition makes that visit necessary.

It is expected that visits will occur at the facility rather than the doctor's office unless office equipment is needed or a resident specifically requests an office visit. If the facility has established policy that residents leave the grounds for medical care, the resident does not object and this policy does not infringe on his or her rights, there is no prohibition to this practice. The facility should inform the resident of this practice, in accordance with §483.10(b).

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§483.40(d) Availability of Physicians for Emergency Care

The facility must provide or arrange for the provision of physician services 24 hours a day, in case of emergency.

Interpretive Guidelines §483.40(d)

If a resident's own physician is unavailable, the facility should attempt to contact that physician's designated referral physician before assuming the responsibility of assigning a physician. Arranging for physician services may include assuring resident transportation to a hospital emergency room/ward or other medical facility if the facility is unable to provide emergency medical care at the facility.
§483.40(e) Physician Delegation of Tasks in SNFs

(1) Except as specified in paragraph (e)(2) of this section, a physician may delegate tasks to a physician assistant, nurse practitioner or clinical nurse specialist who:

   (i) Meets the applicable definition in §491.2 of this chapter or, in the case of a clinical nurse specialist, is licensed as such by the state;

   (ii) Is acting within the scope of practice as defined by state law; and

   (iii) Is under the supervision of the physician.

(2) A physician may not delegate a task when the regulations specify that the physician must perform it personally, or when the delegation is prohibited under state law or by the facility’s own policies.

Interpretive Guidelines §483.40(e)

“Nurse practitioner” is a registered professional nurse now licensed to practice in the state and who meets the state’s requirements governing the qualification of nurse practitioners.

“Clinical nurse specialist” is a registered professional nurse currently in practice in the state and who meets the state’s requirements governing the qualifications of clinical nurse specialists.

“Physician assistant” is a person who meets the applicable state requirements governing the qualifications for assistants to physician.

When personal performance of a particular task by a physician is specified in the regulations, performance of that task cannot be delegated to anyone else. The tasks of examining the resident, reviewing the resident’s total program of care, writing progress notes, and signing orders may be delegated according to state law. The extent to which physician services are delegated to physician extenders in SNFs will continue to be determined by the provisions of §483.40(e), while the extent to which these services are performed by physician extenders in NFs will be determined by the individual states under §483.40(f).

§483.40(f) Performance of Physician Tasks in NFs

At the option of state, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician.

Interpretive Guidelines §483.40(f)

If delegation of physician tasks is permitted in your state and the physician extender does not meet the qualifications listed here, cite F588.
§483.45 Specialized Rehabilitative Services

F406

§483.45(a) Provision of Services

If specialized rehabilitative services such as, but not limited to physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for mental illness and mental retardation, are required in the resident’s comprehensive plan of care, the facility must —

(1) Provide the required services; or

(2) Obtain the required services from an outside resource (in accordance with §483.75(h) of this part) from a provider of specialized rehabilitative services.

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§483.45(b) Qualifications

Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.
§483.60 Pharmacy Services

The facility must provide routine and emergency drugs and biologicals to its residents or obtain them under an agreement described in §483.75(h) of this part. The facility may permit unlicensed personnel to administer drugs if state law permits, but only under the general supervision of a licensed nurse.

(a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(b) Service Consultation. The facility must employ or obtain the services of a licensed pharmacist who—

(1) Provides consultation on all aspects of the provision of pharmacy services in the facility;

INTENT (F425) 42 CFR 483.60, 483.60(a) & (b)(1)

The intent of this requirement is that:

- In order to meet the needs of each resident, the facility accurately and safely provides or obtains pharmaceutical services, including the provision of routine and emergency medications and biologicals, and the services of a licensed pharmacist;

- The licensed pharmacist collaborates with facility leadership and staff to coordinate pharmaceutical services within the facility, and to guide development and evaluation of the implementation of pharmaceutical services procedures;

- The licensed pharmacist helps the facility identify, evaluate, and address/resolve pharmaceutical concerns and issues that affect resident care, medical care or quality of life such as the:
  - Provision of consultative services by a licensed pharmacist between the pharmacist's visits, as necessary; and
  - Coordination of the pharmaceutical services if multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans [PDP]); and

- The facility utilizes only persons authorized under state requirements to administer medications.

NOTE: Although the regulatory language refers to “drugs,” the guidance in this document generally will refer to “medications,” except in those situations where the term “drug” has become part of an established pharmaceutical term (e.g., adverse drug event, adverse drug reaction or consequence).

For purposes of this guidance, references to “the pharmacist” mean the licensed pharmacist, whether employed directly by the facility or through arrangement.
§483.60(c) Drug Regimen Review

(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(2) The pharmacist must report any irregularities to the attending physician, and the director of nursing, and these reports must be acted upon.

INTENT (F428) 42 CFR 483.60(c)(1)(2) Medication Regimen Review

The intent of this requirement is that the facility maintains the resident’s highest practicable level of functioning and prevents or minimizes adverse consequences related to medication therapy to the extent possible, by providing:

- A licensed pharmacist’s review of each resident’s regimen of medications at least monthly; or
- A more frequent review of the regimen depending upon the resident’s condition and the risks or adverse consequences related to current medication(s);
- The identification and reporting of irregularities to the attending physician and the director of nursing; and
- Action taken in response to the irregularities identified.

NOTE: Although the regulatory language refers to “drugs,” the guidance in this document generally will refer to “medications,” except in those situations where the term “drug” has become part of an established pharmaceutical term (e.g., adverse drug event, and adverse drug reaction or consequence).

For purposes of this guidance, references to “the pharmacist” mean the licensed pharmacist, whether employed directly by the facility or through arrangement.

DEFINITIONS

Definitions are provided to clarify terminology related to pharmaceutical services and the management of each resident’s medication regimen for effectiveness and safety.

- “Adverse consequence” refers to an unpleasant symptom or event that is due to or associated with a medication, such as impairment or decline in an individual’s mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease).

NOTE: Adverse drug reaction (ADR) is a form of adverse consequence. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic and helpful effects of the medication or any response to a medication that is noxious and unintended and occurs in doses used for prophylaxis, diagnosis, or therapy. The term “side effect” is often used
interchangeably with ADR; however, side effects are but one of five ADR categories. The others are hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not rise to the level of being an adverse consequence.

• “Clinically significant” means effects, results, or consequences that materially affect or are likely to affect an individual's mental, physical, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.

• “Dose” is the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.

• “Excessive dose” (including duplicate therapy) means the total amount of any medication given at one time or over a period of time that is greater than the amount recommended by the manufacturer's label, package insert, or current standards of practice for a resident's age and condition; without evidence of a review for the continued necessity of the dose or of attempts at, or consideration of the possibility of, tapering a medication; and there is no documented clinical rationale for the benefit of, or necessity for the dose or for the use of multiple medications from the same class.

• “Duration” is the total length of time the medication is being received.

• “Excessive Duration” means the medication is administered beyond the manufacturer's recommended time frames or facility-established stop order policies, beyond the length of time advised by current standards of practice, and/or without either evidence of additional therapeutic benefit for the resident or clear clinical factors that would warrant the continued use of the medication.

• “Irregularity” refers to any event that is inconsistent with usual, proper, accepted, or right approaches to providing pharmaceutical services (see definition in F425), or that impedes or interferes with achieving the intended outcomes of those services.

• “Medication Interaction” is the impact of another substance (such as another medication, herbal product, food or substances used in diagnostic studies) upon a medication. The interactions may alter absorption, distribution, metabolism, or elimination. These interactions may decrease the effectiveness of the medication or increase the potential for adverse consequences.

• “Medication Regimen Review” (MRR) is a thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication. The review includes preventing, identifying, reporting,
and resolving medication-related problems, medication errors, or other irregularities, and collaborating with other members of the interdisciplinary team.55

- “Monitoring” is the ongoing collection and analysis of information (such as observations and diagnostic test results) and comparison to baseline data in order to:
  - Ascertain the individual’s response to treatment and care, including progress or lack of progress toward a therapeutic goal;
  - Detect any complications or adverse consequences of the condition or of the treatments; and
  - Support decisions about modifying, discontinuing, or continuing any interventions.

- “Pharmacy Assistant or Technician” refers to ancillary personnel who work under the supervision and delegation of the pharmacist as consistent with state requirements.

OVERVIEW

Many nursing home residents require multiple medications to address their conditions, leading to complex medication regimens. Medications are used for their therapeutic benefits in diagnosing, managing, and treating acute and/or chronic conditions, for maintaining and/or improving a resident’s functional status, and for improving or sustaining the resident’s quality of life. The nursing home population may be quite diverse and may include geriatric residents as well as individuals of any age with special needs, such as those who are immunocompromised or who have end stage renal disease or spinal cord or closed head injuries. Regardless, this population has been identified as being at high risk for adverse consequences related to medications. Some adverse consequences may mimic symptoms of chronic conditions, the aging process, or a newly emerging condition.

Transitions in care such as a move from home or hospital to the nursing home, or vice versa, increases the risk of medication-related issues. Medications may be added, discontinued, omitted, or changed. It is important, therefore, to review the medications. Currently, safeguards to help identify medication issues include:

- The physician providing and reviewing the orders and total program of care on admission and the prescriber reviewing at each visit;
- The nurse reviewing medications when transmitting the orders to the pharmacy and/or prior to administering medications;
- The interdisciplinary team reviewing the medications as part of the comprehensive assessment for the Resident Assessment Instrument (RAI) and/or care plan;
- The pharmacist reviewing the prescriptions prior to dispensing; and
- The pharmacist performing the medication regimen review at least monthly.

During the MRR, the pharmacist applies his/her understanding of medications and related cautions, actions and interactions as well as current medication advisories and information. The pharmacist provides consultation to the facility and the attending physician(s) regarding the medication regimen and is an important
member of the interdisciplinary team. Regulations prohibit the pharmacist from delegating the medication regimen reviews to ancillary staff.

Some resources are available to facilitate evaluating medication concerns related to the performance of the MRR, such as:

- American Society of Consultant Pharmacists (ASCP) www.ascp.com;
- American Medical Directors Association (AMDA) www.amda.com;
- National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) www.nccmerp.org;
- American Geriatrics Society (AGS) www.americangeriatrics.org;
- U.S. Department of Health and Human Services, Food and Drug Administration (FDA) http://www.fda.gov/medwatch/safety.htm; and

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.

This guidance is not intended to imply that all adverse consequences related to medications are preventable, but rather to specify that a system exists to assure that medication usage is evaluated on an ongoing basis, that risks and problems are identified and acted upon, and that medication-related problems are considered when the resident has a change in condition. This guidance will discuss the following aspects of the facility's MRR component of the pharmaceutical services systems:

- A pharmacist’s review of the resident’s medication regimen to identify and report irregularities; and
- Acting upon identified irregularities in order to minimize or prevent adverse consequences, to the extent possible.

NOTE: The surveyor’s review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents.
MEDICATION REGIMEN REVIEW (MRR)

The MRR is an important component of the overall management and monitoring of a resident’s medication regimen. The pharmacist must review each resident’s medication regimen at least once a month in order to identify irregularities; and to identify clinically significant risks and/or adverse consequences resulting from or associated with medications. It may be necessary for the pharmacist to conduct the MRR more frequently, for example weekly, depending on the resident’s condition and the risks for adverse consequences related to current medications.

Generally, MRRs are conducted in the facility because important information about indications for use, potential medication irregularities or adverse consequences (such as symptoms of tardive dyskinesia, dizziness, anorexia, or falls) may be attainable only by talking to the staff, reviewing the medical record, and observing and speaking with the resident. However, electronic health and medication records and other available technology may permit the pharmacist to conduct some components of the review outside the facility.

Important aspects of the MRR include identification of irregularities, including medication-related errors and adverse consequences, location and notification of MRR findings, and response to identified irregularities. This guidance discusses these aspects and also provides some examples of clinically significant medication interactions.

Identification of Irregularities

An objective of the MRR is to try to minimize or prevent adverse consequences by identifying irregularities including, for example: syndromes potentially related to medication therapy, emerging or existing adverse medication consequences, as well as the potential for adverse drug reactions and medication errors. The resident’s record may contain information regarding possible and/or actual medication irregularities. Possible sources to obtain this information include: the medication administration records (MAR); prescribers’ orders; progress, nursing and consultants’ notes; the Resident Assessment Instrument (RAI); laboratory and diagnostic test results, and other sources of information about behavior monitoring and/or changes in condition. The pharmacist may also obtain information from the Quality Measures/Quality Indicator reports, the attending physician, facility staff, and (as appropriate) from interviewing, assessing, and/or observing the resident.

The pharmacist’s review considers factors such as:

- Whether the physician and staff have documented objective findings, diagnoses and/or symptom(s) to support indications for use;
- Whether the physician and staff have identified and acted upon, or should be notified about, the resident’s allergies and/or potential side effects and significant medication interactions (such as medication-medication, medication-food, medication-disease, medication-herbal interactions);
- Whether the medication dose, frequency, route of administration, and duration are consistent with the resident’s condition, manufacturer’s recommendations, and applicable standards of practice;
- Whether the physician and staff have documented progress towards, or maintenance of, the goal(s) for the medication therapy;
• Whether the physician and staff have obtained and acted upon laboratory results, diagnostic studies, or other measurements (such as bowel function, intake and output) as applicable;

• Whether medication errors exist or circumstances exist that make them likely to occur; and

• Whether the physician and staff have noted and acted upon possible medication-related causes of recent or persistent changes in the resident's condition such as worsening of an existing problem or the emergence of new signs or symptoms. The following are examples of changes potentially related to medication use that could occur at any age, however, some of the changes are more common in the geriatric population and may be unrelated to medications:
  – Anorexia and/or unplanned weight loss, or weight gain;
  – Behavioral changes, unusual behavior patterns (including increased distressed behavior);
  – Bowel function changes including constipation, ileus, impaction;
  – Confusion, cognitive decline, worsening of dementia (including delirium) of recent onset;
  – Dehydration, fluid/electrolyte imbalance;
  – Depression, mood disturbance;
  – Dysphagia, swallowing difficulty;
  – Excessive sedation, insomnia, or sleep disturbance;
  – Falls, dizziness, or evidence of impaired coordination;
  – Gastrointestinal bleeding;
  – Headaches, muscle pain, generalized aching or pain;
  – Rash, pruritus;
  – Seizure activity;
  – Spontaneous or unexplained bleeding, bruising;
  – Unexplained decline in functional status (e.g., ADLs, vision); and
  – Urinary retention or incontinence.

Upon conducting the MRR, the pharmacist may identify and report concerns in one or more of the following categories:66 (See F329 for additional discussion of irregularities relating to dose, duration, indications for use, monitoring, and adverse consequences.)

• The use of a medication without identifiable evidence of adequate indications for use;

• The use of a medication to treat a clinical condition without identifiable evidence that safer alternatives or more clinically appropriate medications have been considered;

• The use of an appropriate medication that is not helping attain the intended treatment goals because of timing of administration, dosing intervals, sufficiency of dose, techniques of administration, or other reasons;

• The use of a medication in an excessive dose (including duplicate therapy) or for excessive duration, thereby placing the resident at greater risk for adverse consequences or causing existing adverse consequences;
• The presence of an adverse consequence associated with the resident’s current medication regimen;

• The use of a medication without evidence of adequate monitoring; i.e., either inadequate monitoring of the response to a medication or an inadequate response to the findings;

• Presence of medication errors or the risk for such errors;

• Presence of a clinical condition that might warrant initiation of medication therapy; and

NOTE: The presence of a diagnosis or symptom does not necessarily warrant medication, but often depends on the consideration of many factors simultaneously.

• A medication interaction associated with the current medication regimen.

The following table provides examples of some problematic medication interactions in the long-term care population. These examples represent common interactions but are not meant to be all inclusive.

NOTE: Concomitant use of these medication combinations is not necessarily inappropriate and these examples are not intended to imply that the medications cannot be used simultaneously. Often, several medications with documented interactions can be given together safely. However, concomitant use of such medications warrants careful consideration of potential alternatives, possible need to modify doses, and diligent monitoring.

(See next page for Common Medication-Medication Interactions in Long Term Care table.)
<table>
<thead>
<tr>
<th>Medication 1</th>
<th>Medication 2</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>warfarin</td>
<td>NSAIDs such as ibuprofen, naproxen, COX-2 inhibitors</td>
<td>Potential for serious gastrointestinal bleeding</td>
</tr>
<tr>
<td>warfarin</td>
<td>sulfonamides such as trimethoprim/ sulfamethoxazole</td>
<td>Increased effects of warfarin, with potential for bleeding</td>
</tr>
<tr>
<td>warfarin</td>
<td>macrolides such as clarithromycin, erythromycin</td>
<td>Increased effects of warfarin, with potential for bleeding</td>
</tr>
<tr>
<td>warfarin</td>
<td>fluoroquinolones such as ciprofloxacin, levofloxacin, ofloxacin</td>
<td>Increased effects of warfarin, with potential for bleeding</td>
</tr>
<tr>
<td>warfarin</td>
<td>phenytoin</td>
<td>Increased effects of warfarin and/or phenytoin</td>
</tr>
<tr>
<td>ACE Inhibitors such as benazepril, captopril, enalapril, and lisinopril</td>
<td>potassium supplements</td>
<td>Elevated serum potassium levels</td>
</tr>
<tr>
<td>ACE Inhibitors such as benazepril, captopril, enalapril, and lisinopril</td>
<td>spironolactone</td>
<td>Elevated serum potassium levels</td>
</tr>
<tr>
<td>digoxin</td>
<td>amiodarone</td>
<td>digoxin toxicity</td>
</tr>
<tr>
<td>digoxin</td>
<td>verapamil</td>
<td>digoxin toxicity</td>
</tr>
<tr>
<td>theophylline</td>
<td>fluoroquinolones such as ciprofloxacin, levofloxacin, ofloxacin</td>
<td>theophylline toxicity</td>
</tr>
</tbody>
</table>
Location and Notification of Medication Regimen Review Findings

The pharmacist is expected to document either that no irregularity was identified or the nature of any identified irregularities. The pharmacist is responsible for reporting any identified irregularities to the attending physician and director of nursing. The timeliness of notification of irregularities depends on factors including the potential for or presence of serious adverse consequences; for example, immediate notification is indicated in cases of bleeding in a resident who is receiving anticoagulants or in cases of possible allergic reactions to antibiotic therapy. If no irregularities were identified during the review, the pharmacist includes a signed and dated statement to that effect. The facility and the pharmacist may collaborate to identify the most effective means for assuring appropriate notification. This notification may be done electronically.

The pharmacist does not need to document a continuing irregularity in the report each month if the pharmacist has deemed the irregularity to be clinically insignificant or evidence of a valid clinical reason for rejecting the pharmacist’s recommendation was provided. In this situation, the pharmacist need only reconsider annually whether to report the irregularity again or make a new recommendation.

The pharmacist’s findings are considered part of each resident’s clinical record. If documentation of the findings is not in the active record, it is maintained within the facility and is readily available for review. The interdisciplinary team is encouraged to review the reports and to get the pharmacist’s input on resident problems and issues. Establishing a consistent location for the pharmacist’s findings and recommendations can facilitate communication with the attending physician, the director of nursing, the remainder of the interdisciplinary team, the medical director, the resident and his or her legal representative (in accord with 42 CFR 483.10(b)(2),(d)(2)), ombudsman (with permission of the resident in accord with 42 CFR 483.10(j)(3)), and surveyors.

Response to Irregularities Identified in the MRR

Throughout this guidance, a response from a physician regarding a medication problem 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 determines that those are medically valid and indicated.

For those issues that require physician intervention, the physician either accepts and acts upon the report and potential recommendations or rejects all or some of the report and provides a brief explanation of why the recommendation is rejected, such as in a dated progress note. It is not acceptable for a physician to document only that he/she disagrees with the report, without providing some basis for disagreeing.

If there is the potential for serious harm and the attending physician does not concur with or take action on the report, the facility and the pharmacist should contact the facility’s medical director for guidance and possible intervention to resolve the issue. The facility should have a procedure to resolve the situation when the attending physician is also the medical director. For those recommendations that do not require a physician intervention, such as one to monitor vital signs or weights, the
§483.65 Infection Control

The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.

§483.65(a) Infection Control Program

The facility must establish an infection control program under which it —

(1) Investigates, controls and prevents infections in the facility;

(2) Decides what procedures, such as isolation, should be applied to an individual resident; and

(3) Maintains a record of incidents and corrective actions related to infections.

§483.65(b) Preventing Spread of Infection

(1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.

§483.65(b)(2) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.

§483.65(b)(5) The facility must require staff to wash their hands after each direct resident contact for which handwashing is indicated by accepted professional practice.

End Notes

65 Adapted from American Society of Consultant Pharmacists (ASCP) Guidelines for Assessing the Quality of Drug Regimen Review in Long-Term Care Facilities.


67 Adapted from Top 10 Dangerous Drug Interactions in Long-Term Care presented by the Multidisciplinary Medication Management Project, a collaborative initiative of the American Society of Consultant Pharmacists (ASCP) and the American Medical Directors Association (AMDA).
§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.

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 healthcare 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.

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 are consistent with current standards of practice and facility policies.

Overview

The Medical Director has an important leadership role in actively helping long-term care facilities provide quality care. The regulation requires each facility to have a Medical Director who is responsible for the implementation of resident care policies and the coordination of medical care. These two roles provide the basis for the functions and tasks discussed in this guidance. The Medical Director’s roles and functions require the physician serving in that capacity to be knowledgeable about current standards of practice in caring for long-term care residents, and about how to coordinate and oversee related practitioners. As a clinician, the Medical Director plays a pivotal role in providing clinical leadership regarding application of current standards of practice for resident care and new or proposed treatments, practices and approaches to care. The Medical Director’s input promotes the attainment of optimal resident outcomes which may also be influenced by many other factors, such as resident characteristics and preferences, individual attending physician actions, and facility support.

The 2001 Institute of Medicine report, “Improving the Quality of Long-Term Care,” urged facilities to give Medical Directors greater authority for medical services and care. The report states, “nursing homes should develop structures and processes that enable and require a more focused and dedicated medical staff responsible for patient care.” The medical director is in a position, because of his or her roles and functions, to provide input to surveyors on physician issues, individual resident’s clinical issues, and the facility’s clinical practices. The text “Medical Direction in Long-Term Care” asserts that:

“The Medical Director has an important role in helping the facility deal with regulatory and survey issues...the Medical Director can help ensure that appropriate systems exist to facilitate good medical care, establish and apply good monitoring systems and effective documentation and follow up of findings, and help improve physician compliance with regulations, including required visits. During and after the survey process, the Medical Director can clarify for the surveyors clinical questions or information about the care of specific residents, request surveyor clarification of citations on clinical care, attend the exit conference to demonstrate physician interest and help in understanding the nature and scope of the facility's deficiencies, and help the facility draft corrective actions.”

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

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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 or 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 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 healthcare professionals such as nurses, therapists, dietitians, pharmacists, social workers, and other healthcare 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 healthcare issues related to the quality of care and quality of life of residents. “A Medical Director should establish a framework for physician participation, and physicians should believe that they are accountable for their actions and their care.” The Medical Director addresses issues related to the coordination of medical care identified through the facility’s quality assessment and assurance committee and quality assurance program, and other activities related to the coordination of care. This includes, but is not limited to, helping the facility:

- Ensure that residents have primary attending and backup physician coverage;
- Ensure that physician and healthcare 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 healthcare practitioner credentials (e.g., licensure and pertinent background);
- Address and resolve concerns and issues between the physicians, healthcare 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 healthcare 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 healthcare practitioner about medical care that is inconsistent with applicable current standards of care;
- Assuring that a system exists to monitor the performance of the healthcare 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


2. Institute of Medicine (2001). Improving the Quality of Long-Term Care (pp. 201). Washington, DC: National Academy Press.


LABORATORY SERVICES

F502

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

F504

§483.75(j)(2) The facility must--

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

Intent §483.75(j)(2)(i)

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

F505

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

Intent §483.75(j)(2)(ii)

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

F507

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

Intent §483.75(j)(2)(iv)

The intent of this regulation is to assure that the laboratory performing the tests is Medicare approved, and that test results are accurate and are available for clinical management.
F508

§483.75(k) Radiology and Other Diagnostic Services

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

Intent §483.75(k)(1)

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

F510

§483.75(k)(2) The Facility must---

(i) Provide or obtain radiology and other diagnostic services only when ordered by the attending physician;

F511

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

F512

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

F513

§483.75(k)(2)(iv) File in the resident’s clinical record signed and dated reports of x-ray and other diagnostic services.
§483.75(1) Clinical Records

(1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are--

   (i) Complete;

   (ii) Accurately documented;

   (iii) Readily accessible; and

   (iv) Systematically organized.

Intent §483.75(1)(1)

To assure that the facility maintains accurate, complete and organized clinical information about each resident that is readily accessible for resident care.

Reference:

QUALITY ASSESSMENT AND ASSURANCE

F520

§485.75(o) Quality Assessment and Assurance

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

   (i) The director of nursing services;

   (ii) A physician designated by the facility; and

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

F521

(2) The quality assessment and assurance committee —

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

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

(5) A state or the secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this section.

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