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Department of Health &
Human Services (DHHS)
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Transmittal 130

Date: December 12, 2014

SUBJECT: Revisions to State Operations Manual (SOM), Appendix PP – “Guidance to Surveyors for Long Term Care Facilities”

I. SUMMARY OF CHANGES: This instruction revises the Interpretive Guideline for F309–Quality of Care and F329-Unnecessary Drugs.

NEW/REVISED MATERIAL - EFFECTIVE DATE: December 12, 2014

IMPLEMENTATION DATE: December 12, 2014

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

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix PP/F309/§483.25 Quality of Care
R	Appendix PP/F329/§483.25(l) Unnecessary Drugs

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	One-Time Notification –Confidential
	Recurring Update Notification

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

F309

(Rev. 130; Issued: 12-12-14, Effective: 12-12-14, Implementation: 12-12-14)

§483.25 Quality of Care

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

Intent: §483.25

The facility must ensure that the resident obtains optimal improvement or does not deteriorate within the limits of a resident's right to refuse treatment, and within the limits of recognized pathology and the normal aging process.

NOTE: Use guidance at F309 for review of quality of care not specifically covered by 42 CFR 483.25 (a)-(m). Tag F309 includes, but is not limited to, care such as *care of a resident with dementia*, end-of-life, diabetes, renal disease, fractures, congestive heart failure, non-pressure related skin ulcers, pain, and fecal impaction.

Definitions: §483.25

“Highest practicable physical, mental, and psychosocial well-being” is defined as the highest possible level of functioning and well-being, limited by the individual's recognized pathology and normal aging process. Highest practicable is determined through the comprehensive resident assessment and by recognizing and competently and thoroughly addressing the physical, mental or psychosocial needs of the individual.

Interpretive Guidelines §483.25

In any instance in which there has been a lack of improvement or a decline, the survey team must determine if the occurrence was unavoidable or avoidable. A determination of unavoidable decline or failure to reach highest practicable well-being may be made only if all of the following are present:

- An accurate and complete assessment (see §483.20);
- A care plan that is implemented consistently and based on information from the assessment; and
- Evaluation of the results of the interventions and revising the interventions as necessary.

Determine if the facility is providing the necessary care and services based on the findings of the comprehensive assessment and plan of care. If services and care are being provided, determine if the facility is evaluating the resident's outcome and changing the interventions if needed. This should be done in accordance with the resident's customary daily routine.

Procedures §483.25

Assess a facility's compliance with these requirements by determining if the services noted in the plan of care are: based on a comprehensive and accurate functional assessment of the resident's strengths, weaknesses, risk factors for deterioration and potential for improvement; continually and aggressively implemented; and updated by the facility staff. In looking at assessments, use both the MDS and CAAs information, any other pertinent assessments, and resulting care plans.

If the resident has been in the facility for less than 14 days (before completion of all the RAI is required), determine if the facility is conducting ongoing assessment and care planning, and, if appropriate care and services are being provided.

General Investigative Protocol for F309, Quality of Care

Use:

Use this General Investigative Protocol to investigate Quality of Care concerns that are not otherwise covered in the remaining tags at §483.25, Quality of Care or for which specific investigative protocols have not been established. For investigating concerns regarding management of pain, use the pain management investigative protocol below. Surveyors should consider any quality of care issue that is not covered in a specific Quality of Care tag to be covered under this tag, F309.

Procedure:

Briefly review the assessment, care plan and orders to identify whether the facility has recognized and addressed the concerns or resident care needs being investigated. Also use this review to identify facility interventions and to guide observations to be made. Corroborate observations by interview and record review.

Observations:

Observe whether staff consistently implement the care plan over time and across various shifts. During observations of the interventions, note and/or follow up on deviations from the care plan, deviations from current standards of practice, and potential negative outcomes.

Resident/Representative Interview

Interview the resident or representative to the degree possible to determine the resident's or representative's:

- Awareness of the current condition(s) or history of the condition(s) or diagnosis/diagnoses;
- Involvement in the development of the care plan, goals, and if interventions reflect choices and preferences; and
- How effective the interventions have been and if not effective, whether alternate approaches have been tried by the facility.

Nursing Staff Interview

Interview nursing staff on various shifts to determine:

- Their knowledge of the specific interventions for the resident, including facility-specific guidelines/protocols;
- Whether nursing assistants know how, what, when, and to whom to report changes in condition; and
- How the charge nurse monitors for the implementation of the care plan, and changes in condition.

Assessment

Review information such as orders, medication administration records, multi-disciplinary progress notes, the RAI/MDS, and any specific assessments that may have been completed. Determine if the information accurately and comprehensively reflects the resident's condition. In considering the appropriateness of a facility's response to the presence or progression of a condition/diagnosis, take into account the time needed to determine the effectiveness of treatment, and the facility's efforts, where possible, to remove, modify, or stabilize the risk factors and underlying causal factors.

NOTE: Although Federal requirements dictate the completion of RAI assessments according to certain time frames, standards of good clinical practice dictate that the assessment process is more fluid and should be ongoing. (Federal Register Vol. 62, No. 246, 12/23/97, page 67193)

Care Planning

Determine whether the facility developed a care plan that was consistent with the resident's specific conditions, risks, needs, behaviors, preferences and with current standards of practice

and included measurable objectives and timetables with specific interventions. If the care plan refers to a specific facility treatment protocol that contains details of the treatment regimen, the care plan should refer to that protocol and should clarify any major deviations from or revisions to the protocol for this resident. The treatment protocol must be available to the caregivers and staff should be familiar with the protocol requirements.

NOTE: A specific care plan intervention is not needed if other components of the care plan address related risks adequately. For example, the risk of nutritional compromise for a resident with diabetes mellitus might be addressed in that part of the care plan that deals with nutritional management.

Care Plan Revision

Determine whether staff have monitored the resident's condition and effectiveness of the care plan interventions and revised the care plan with input by the resident and/or the representative, to the extent possible, (or justified the continuation of the existing plan) based upon the following:

- Achieving the desired outcome;
- Resident failure or inability to comply with or participate in a program to attain or maintain the highest practicable level of well-being; and/or
- Change in resident condition, ability to make decisions, cognition, medications, behavioral symptoms or visual problems.

Interview with Health Care Practitioners and Professionals

If the care provided has not been consistent with the care plan or the interventions defined or care provided appear not to be consistent with recognized standards of practice, interview one or more health care practitioners and professionals as necessary (e.g., physician, charge nurse, director of nursing, therapist) who, by virtue of training and knowledge of the resident, should be able to provide information about the causes, treatment and evaluation of the resident's condition or problem. If there is a medical question, contact the physician if he/she is the most appropriate person to interview. If the attending physician is unavailable, interview the medical director, as appropriate. Depending on the issue, ask about:

- How it was determined that chosen interventions were appropriate;
- Risks identified for which there were no interventions;
- Changes in condition that may justify additional or different interventions; or
- How staff validated the effectiveness of current interventions.

DETERMINATION OF COMPLIANCE WITH F309 (Task 6, Appendix P) THAT IS NOT RELATED TO PAIN OR PAIN MANAGEMENT

Synopsis of Regulation (Tag F309)

The resident must receive and the facility must provide the necessary care and services to attain or maintain his/her highest practicable level of physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

Criteria for Compliance:

Compliance with F309, Quality of Care - The facility is in compliance with this requirement if staff:

- Recognized and assessed factors placing the resident at risk for specific conditions, causes, and/or problems;
- Defined and implemented interventions in accordance with resident needs, goals, and recognized standards of practice;
- Monitored and evaluated the resident's response to preventive efforts and treatment; and
- Revised the approaches as appropriate.

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements.

During the investigation, the surveyor may have identified concerns with related structure, process, and/or outcome requirements. If an additional concern has been identified, the surveyor must investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirement. Some examples include, but are not limited to, the following:

- **42 CFR 483.10(b)(11), F157, Notification of Changes**

Determine whether staff notified the resident and consulted the physician regarding significant changes in the resident's condition or a need to alter treatment significantly or notified the representative of a significant condition change.

- **42 CFR 483.(20)(b), F272, Comprehensive Assessments**

Determine whether the facility assessed the resident's condition, including existing status, and resident-specific risk factors (including potential causative factors) in relation to the identified concern under review.

- **42 CFR 483.20(k), F279, Comprehensive Care Plan**

Determine whether the facility established a care plan with timetables and resident specific goals and interventions to address the care needs and treatment related to the clinical diagnosis and/or the identified concern.

- **42 CFR 483.20(k)(2)(iii), 483.10(d)(3), F280, Care Plan Revision**

Determine whether the staff reviewed and revised the care plan as indicated based upon the resident's response to the care plan interventions, and obtained input from the resident or representative to the extent possible.

- **42 CFR 483.20(k)(3)(i), F281, Services Provided Meets Professional Standards of Quality**

Determine whether the facility, beginning from the time of admission, provided care and services related to the identified concern that meet professional standards of quality.

- **42 CFR 483.20(k)(3)(ii), F282, Care Provided by Qualified Persons in Accordance with Plan of Care**

Determine whether care was provided by qualified staff and whether staff implemented the care plan correctly and adequately.

- **42 CFR 483.30(a), F353, Sufficient Staff**

Determine whether the facility had qualified nursing staff in sufficient numbers to assure the resident was provided necessary care and services 24 hours a day, based upon the comprehensive assessment and care plan.

- **42 CFR 483.40(a)(1)&(2), F385, Physician Supervision**

- Determine whether the physician has assessed and developed a relevant treatment regimen and responded appropriately to the notice of changes in condition.

- **42 CFR 483.75(f), F498, Proficiency of Nurse Aides**

- Determine whether nurse aides demonstrate competency in the delivery of care and services related to the concern being investigated.

- **42 CFR 483.75(i)(2), F501, Medical Director**

Determine whether the medical director:

- Assisted the facility in the development and implementation of policies and procedures and that these are based on current standards of practice; and
 - Interacts with the physician supervising the care of the resident if requested by the facility to intervene on behalf of the residents.
- **42 CFR 483.75(I), F514, Clinical Records**

Determine whether the clinical records:

- Accurately and completely document the resident's status, the care and services provided in accordance with current professional standards and practices; and
- Provide a basis for determining and managing the resident's progress including response to treatment, change in condition, and changes in treatment.

DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the harm or potential for harm to the resident. The key elements for severity determination for F309 Quality of Care requirements are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care, such as decline in function or failure to achieve the highest possible level of well-being.
2. Degree of harm (actual or potential) related to the non-compliance. Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:
 - If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort to the resident(s); and
 - If harm has not yet occurred, determine the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident(s).
3. The immediacy of correction required. Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm for F309 based upon the four levels of severity. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. Follow the guidance in Appendix Q, Determining Immediate Jeopardy.

If specific guidance and examples have not been established elsewhere for the concern having been reviewed, follow the general guidance in Appendix P regarding Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide.

Interpretive Guidelines for Selected Specific Quality of Care Issues at §483.25.

The following sections describe some specific issues or care needs that are not otherwise covered in the remaining tags of §483.25, Quality of Care. These are only some of the issues that may arise with a resident's quality of care. Surveyors should consider any quality of care issue that is not covered in a specific Quality of Care tag to be covered under this tag, F309.

Review of Care and Services for a Resident with Dementia

Use this guidance for a resident with dementia. If the resident is receiving one or more psychopharmacological agents, also review the guidance at F329, Unnecessary Drugs.

There is no specific investigative protocol for care of a resident with dementia. For the traditional survey, the surveyor may use the surveyor checklist titled, “Review of Care and Services for a Resident with Dementia” to assist in investigating the care and services provided to a resident with a diagnosis of dementia. For the QIS survey, the surveyor will use the general CE pathway and may use the checklist as a guide to completing that pathway.

Definitions Related to Recognition and Management of Dementia

- *Behavioral interventions are individualized approaches (including direct care and activities) that are provided as part of a supportive physical and psychosocial environment, and are directed toward understanding, preventing, relieving, and/or accommodating a resident's distress or loss of abilities.*
- *Person-Centered or Person-Appropriate Care is care that is individualized by being tailored to all relevant considerations for that individual, including physical, functional, and psychosocial aspects. For example, activities should be relevant to the specific needs, interests, culture, background, etc. of the individual for whom they are developed and medical treatment should be tailored to an individual's risk factors, current conditions, past history, and details of any present symptoms.*
- *Behavioral or Psychological Symptoms of Dementia (BPSD) is a term used to describe behavior or other symptoms in individuals with dementia that cannot be attributed to a specific medical or psychiatric cause. The term “behaviors” is more general and may encompass BPSD or responses by individuals to a situation, the environment or efforts to communicate an unmet need.*

Overview of Dementia and Behavioral Health

What is Behavior?

Human behavior is the response of an individual to a wide variety of factors. Behavior is generated through brain function, which is in turn influenced by input from the rest of the body. Specific behavioral responses depends on many factors, including personal experience and past learning, inborn tendencies and genetic traits, the environment and response to the actions and reactions of other people. A condition (such as dementia) that affects the brain and the body may affect behavior.

What is Dementia?

Dementia is not a specific disease. It is a descriptive term for a collection of symptoms that can be caused by a number of disorders that affect the brain. People with dementia have significantly impaired intellectual functioning that interferes with normal activities and relationships. They also lose their ability to solve problems and maintain emotional control, and they may experience personality changes and behavioral problems, such as agitation, delusions, and hallucinations. While memory loss is a common symptom of dementia, memory loss by itself does not mean that a person has dementia. Doctors diagnose dementia only if two or more brain functions - such as memory and language skills -- are significantly impaired without loss of consciousness.

Some of the diseases that can cause symptoms of dementia are Alzheimer's disease, vascular dementia, Lewy body dementia, fronto-temporal dementia, Huntington's disease, and Creutzfeldt-Jakob disease. Doctors have identified other conditions that can cause dementia or dementia-like symptoms including reactions to medications, metabolic problems and endocrine abnormalities, nutritional deficiencies, infections, poisoning, brain tumors, anoxia or hypoxia (conditions in which the brain's oxygen supply is either reduced or cut off entirely), and heart and lung problems. Although it is common in very elderly individuals, dementia is not a normal part of the aging process.

Some individuals with dementia may have coexisting symptoms or psychiatric conditions such as depression or bipolar affective disorder, paranoia, delusions or hallucinations. Progressive dementia may exacerbate these and other symptoms.

Behavioral or psychological symptoms are often related to the brain disease in dementia; however behavior and other symptoms may also be caused or exacerbated by environmental triggers. Behavior often represents a person's attempt to communicate an unmet need, discomfort or thoughts that they can no longer articulate. Knowing detailed cultural, medical and psychosocial information about a person can help caregivers identify potential environmental or other triggers in order to prevent or reduce, to the extent possible, behavior or other expressions of distress.² Because behavioral symptoms may be caused by medical conditions such as delirium, medication side effects, and psychiatric symptoms such as delusions or hallucinations, these should be considered as possible causes in addition to environmental triggers.

What is Delirium?

A resident may have undiagnosed delirium, which is an acute confusional state that includes symptoms very similar to those of dementia and psychiatric disorders. The diagnostic criteria for delirium include a fluctuating course throughout the day, inattention as evidenced by being easily distracted, cognitive changes, and perceptual disturbances³.

Delirium develops rapidly over a short time period, such as hours or days, and is associated with an altered level of consciousness. Delirium has an underlying physiologic cause that can generally be identified through a diagnostic evaluation. Potential causes include, but are not limited to, infection, fluid/electrolyte imbalance, medication, or multiple factors. Specific diagnostic criteria are outlined in the DSM IV-TR or the Confusion Assessment Method^{3,4}.

Classic delirium is often characterized as hyperactive (e.g., extreme restlessness, climbing out of bed); but more commonly delirium is hypoactive often leading to the misdiagnosis of dementia or a psychiatric disorder. Delirium is particularly common post-hospitalization; signs and symptoms may be subtle and therefore are often missed. Although generally thought to be short lived, delirium can persist for months.

Delirium and dementia are now recognized as being related. Individuals with dementia are at higher risk for developing delirium and it now appears that delirium increases the risk of developing dementia over time⁵. Recognizing delirium is critical, as failure to act quickly to identify and treat the underlying causes may result in poor health outcomes, hospitalization or even death⁶.

Therapeutic Interventions or Approaches

The use of any approach must be based on a careful, detailed assessment of physical, psychological and behavioral symptoms and underlying causes as well as potential situational or environmental reasons for the behaviors. Caregivers and practitioners are expected to understand or explain the rationale for interventions/approaches, to monitor the effectiveness of those interventions/approaches, and to provide ongoing assessment as to whether they are improving or stabilizing the resident's status or causing adverse consequences. Describing the details and possible consequences of resident behaviors helps to distinguish expressions such as restlessness or continual verbalization from potentially harmful actions such as kicking, biting or striking out at others. This description alone does not suggest that a specific intervention is or is not indicated; however, it is important information that may assist the care team (including the resident and/or family or representative) in decision-making and in matching selected interventions to the individual needs of each resident.

Identifying the frequency, intensity, duration and impact of behaviors, as well as the location, surroundings or situation in which they occur may help staff and practitioners identify individualized interventions or approaches to prevent or address the behaviors. Individualized, person-centered interventions must be implemented to address behavioral expressions of distress in persons with dementia. In many situations, medications may not be necessary; staff/practitioners should not automatically assume that medications are an appropriate treatment without a systematic evaluation of the resident. Examples of techniques or

environmental modifications that may prevent certain behavior related to dementia may include (but are not limited to):

- *Arranging staffing to optimize familiarity with the resident (e.g., consistent caregiver assignment);*
- *Identifying, to the extent possible, factors that may underlie the resident's expressions of distress, as well as applying knowledge of lifelong patterns, preferences, and interests for daily activities to enhance quality of life and individualize routine care.*
- *Understanding that the resident with dementia may be responding predictably given the situation or surroundings. For example, being awakened at night in his/her bedroom by staff and not recognizing the staff could elicit an aggressive response; and*
- *Matching activities for a resident with dementia to his/her individual cognitive and other abilities and the specific behaviors in that individual based on the assessment.*

Medication Use in Dementia (see also F329)

It has been a common practice to use various types of psychopharmacological medications in nursing homes to try to address behavioral or psychological symptoms of dementia (BPSD)^{7,8} without first determining whether there is an underlying medical, physical, functional, psychosocial, emotional, psychiatric, or environmental cause of the behaviors. Medications may be effective when they are used appropriately to address significant, specific underlying medical and psychiatric causes or new or worsening behavioral symptoms. However, medications may be ineffective and are likely to cause harm when given without a clinical indication, at too high a dose or for too long after symptoms have resolved and if the medications are not monitored. All interventions including medications need to be monitored for efficacy, risks, benefits and harm.

These agents must only be used if the steps in the care process below and as outlined in F329 have been followed.

When antipsychotic medications are used without an adequate rationale, or for the sole purpose of limiting or controlling behavior of an unidentified cause, there is little chance that they will be effective, and they commonly cause complications such as movement disorders, falls, hip fractures, cerebrovascular adverse events (cerebrovascular accidents and transient ischemic events) and increased risk of death.^{9,10,11,12} The FDA Black Box Warning Regarding Atypical Antipsychotics in Dementia states, "Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo." The FDA issued a similar Black Box Warning for conventional antipsychotic drugs. (Additional information on the FDA black box warning is available at <http://www.fda.gov/Drugs/default.htm>.)

Recent studies suggest that certain antipsychotic medications may have greater risks than others in that same class of medications.^{13,14} Other classes of psychopharmacological agents may carry significant risks as well.

NOTE: *If a concern is identified during a survey that an antipsychotic medication may potentially be administered for discipline, convenience and/or is not being used to treat a medical symptom, consider reviewing F222 - 483.3(a) Restraints, for the right to be free from any chemical restraints.*

Resident and/or Family/Representative Involvement:

CMS expects that the resident and family/representatives, to the extent possible, are involved in helping staff to understand the potential underlying causes of behavioral distress and to participate in the development and implementation of the resident's care plan. Residents have the right to be informed about their medical condition, care and treatment; they have the right to refuse treatment and the right to participate in the care plan process. (See F154, F155, F242, F279, F280)

Facilities should be able to identify how they have involved residents/families/representatives in discussions about potential approaches to address behaviors and about the potential risks and benefits of a psychopharmacological medication (e.g., FDA black box warnings), the proposed course of treatment, expected duration of use of the medication, use of individualized approaches, plans to evaluate the effects of the treatment, and pertinent alternatives. The discussion should be documented in the resident's record. (See F154)

NOTE: *some states have specific laws/licensing rules regarding the provision of informed consent. The State Agency determines and directs the surveyors regarding the review for those provisions under their State licensing authority. If non-compliance with the State regulation is identified, the surveyors may only cite this non-compliance at F492 when the Federal, State or local authority having jurisdiction has both made a determination of non-compliance AND has taken a final adverse action.*

The facility should document attempts to include the family/representative, to the extent possible, in the decision-making process. If the family/representative is unable to participate in person, were further attempts made to include the family/representative in the discussions/development of the care planning through alternative methods, such as by phone or electronic methods?

If the resident lacks decision-making capacity and lacks an effective family/representative support, contact the facility social worker to determine what type of social services or referrals have been attempted to assist the resident. (See F250)

During interviews with the family/representative, surveyors should ask if families have observed staff implementing the individualized care plan interventions that were developed. (See F282)

Care Process for a Resident with Dementia

Fundamental principles of care for persons with dementia include an interdisciplinary team approach that focuses holistically on the needs of the resident as well as the needs of the other residents in the nursing home. It is important for the facility to have systems and procedures in place to assure that assessments are timely and accurate; interventions are described, consistently implemented, monitored, and revised as appropriate in accordance with current standards of practice.

It is expected that a facility's approach to care for a resident with dementia follows a systematic care process in order to gather and analyze information necessary to provide appropriate care and services, and that the resident and/or family or representative is engaged throughout the process. It is expected that the resident's record reflects the implementation of the following care processes:

- A. Recognition and Assessment;*
- B. Cause Identification and Diagnosis;*
- C. Development of Care Plan;*
- D. Individualized Approaches and Treatment;*
- E. Monitoring, Follow-up and Oversight; and*
- F. Quality Assessment and Assurance (QAA).*

See Additional Resources section below for some suggested resources that facilities may consult in developing their dementia care policies.

The following guidance aggregates requirements in a number of other F-tags such as comprehensive assessment, activities, resident rights, unnecessary medications and others, bringing that guidance together into a framework for evaluating care of individuals with dementia.

A. Recognition and Assessment:

This step includes collecting detailed information about a resident. The resident's record should reflect comprehensive information about the person including, but not limited to: past life experiences, description of behaviors, preferences such as those for daily routines, food, music, exercise and others; oral health, presence of pain, medical conditions; cognitive status and related abilities and medications. When reviewing the comprehensive assessment (see F272), the Care Area Assessment (CAA) Resources, particularly those related to Activities and Behavioral Symptoms, found in the Long-Term Care Facility Resident Assessment Instrument User's Manual, Version 3.0 may be helpful.

It is important to determine whether the record reflects the evaluation of, but is not limited to:

- *How the resident typically communicates physical needs such as pain, discomfort, hunger or thirst, as well as emotional and psychological needs such as frustration or boredom; or a desire to do or express something that he/she cannot articulate;*
- *The resident's usual and current cognitive patterns, mood and behavior, and whether these present a risk to the resident or others;*
- *How the resident typically displays personal distress such as anxiety or fatigue.*

This and other information enables an understanding of the individual and provides a basis for cause identification (based on knowing the whole person and how the situation and environment may trigger behaviors) and individualized interventions. If the resident expresses distress, staff should specifically describe the behavior (including potential underlying causes, onset, duration, intensity, precipitating events or environmental triggers, etc.) and related factors (such as appearance and alertness) in the medical record with enough detail of the actual situation to permit cause identification and individualized interventions. (See F154) For example, noting that the resident is generally "violent," "agitated" or "aggressive" does not identify the specific behavior exhibited by the resident. Noting instead that the resident responds in crowded, busy group activities by yelling or throwing furniture reflects not only a potential safety issue but should result in the resident being provided alternative activities to meet his/her needs.

B. Cause Identification and Diagnosis:

This step uses the information collected about an individual to help identify the physical, functional, psychosocial, environmental, and other potential causes of behavior and related symptoms, including how they interact with each other. Staff, in collaboration with the practitioner, should identify possible risk and causal/contributing factors for behaviors, such as:

- *Presence of co-existing medical or psychiatric conditions, including acute/chronic pain, constipation, delirium and others, or worsening of mental function; and/or*
- *Adverse consequences related to the resident's current medications. (See F329)*

Staff must make an ongoing effort to identify and document the new onset or worsening behavioral symptoms, including whether or not the behavior presents a significant risk for adverse consequences to the resident and/or others.

The attending physician is responsible for supervising each resident's medical care. In addition, the facility must immediately consult with the resident's physician when there is a significant change in the resident's physical, mental, or psychosocial status. (See F157) If the behaviors observed represent a change or worsening from the baseline, the attending physician/practitioner and staff are expected to consider potential underlying medical, physical, psychosocial, or environmental causes of the behaviors (See F385). If the resident has

experienced two or more areas of decline or improvement, including a change related to behavior, a Significant Change in Clinical Status Assessment (SCSA) should be considered (see F274).

If medical causes are ruled out, the facility should attempt to establish other root causes of behavior using individualized, holistic knowledge about the person and when possible, information from the resident, family or previous caregivers, and direct care staff. This includes conducting a systematic analysis and consideration of possible causes, including but not limited to:

- *Boredom; lack of meaningful activity or stimulation during customary routines and activities;*
- *Anxiety related to changes in routines such as shift changes, unfamiliar or different caregivers, change of (or relationship with) roommate, inability to communicate;*
- *Care routines (such as bathing) that are inconsistent with a person's preferences;*
- *Personal needs not being met appropriately or sufficiently, such as hunger, thirst, constipation;*
- *Fatigue, lack of sleep or change in sleep patterns which may make the person more likely to misinterpret environmental cues resulting in anxiety, aggression or confusion.*
- *Environmental factors, for example noise levels that could be causing or contributing to discomfort or misinterpretation of noises such as over-head pages, alarms, etc. causing delusions and/or hallucinations.*
- *Mismatch between the activities or routines selected and the resident's cognitive and other abilities to participate in those activities/routines. For example, a resident who has progressed from mid to later stages of dementia may become frustrated and upset if he/she is trying but unable to do things that she previously enjoyed, or unable to perform tasks such as dressing or grooming.*

C. Development of Care Plan:

This step identifies the approaches, interventions, therapies, medications, etc. for a specific resident. The care plan should include a well-defined problem-statement and should outline the goals of care. It should include measurable objectives and timetables for individualized interventions. It should also identify the responsibilities of various staff to implement the approaches effectively. The care plan should reflect:

- *Baseline and ongoing details (e.g., frequency, intensity, and duration) of common behavioral expressions and expected response to interventions (See F279);*

- *Specific goals for and monitoring of all interventions for effectiveness in responding to target behaviors/expressions of distress (See F279); and*
- *For any medications, indication/rationale for use, specific target behaviors and expected outcomes, dosage, duration, monitoring for efficacy and/or adverse consequences and (when applicable) plans for gradual dose reduction (GDR) if an antipsychotic medication is used (See F329).*

In developing the plan of care, the interdisciplinary team, in collaboration with the resident or family/representative, reviews the results of the assessment and cause identification above in order to develop individualized, person-centered interventions. Staff should determine, in collaboration with the practitioner, resident, and family/resident representative if and why behaviors should be addressed (e.g., severely distressing to resident and unrelieved by other approaches or interventions). Individualized, person-centered approaches should be implemented to address expressions of distress. These may include:

- *Non-pharmacological approaches. Section 483.25 (l)(2)(ii) - F329, requires that “Residents who use antipsychotic drugs receive gradual dose reductions and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.”*

The guidance at F248, §483.15(f)(1), Activities, provides examples of non-pharmacological approaches for several types of distressed behavior such as constant walking, yelling, going through others’ belongings, etc. Certain behavior may be anticipated and sometimes may be preventable based on understanding the underlying causes and possible triggers for each individual.

Current published clinical guidelines^{5,6,7,8,9} recommend use of non-pharmacological interventions for BPSD.

Utilizing a consistent process to address behaviors that focuses on the resident’s individual needs and tries to understand their behaviors as a form of communication may help to reduce behavioral expressions of distress in those residents.

Several techniques are also outlined in the CMS DVD series for nursing assistant training, “Hand in Hand,” distributed to all U.S. nursing homes in 2012, and other materials available on the Advancing Excellence website: <http://www.nhqualitycampaign.org>.

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

- *Pharmacological interventions: In certain cases, residents may benefit from the use of medications. For example, a person who has a persistent, frightening delusion that she has left her children unattended and that they are in danger is inconsolable most of the day or night despite a number of staff and family approaches to address this fear. If other potential causes are ruled out, the team may determine that a trial of a low dose antipsychotic medication is warranted.*

If a psychopharmacologic medication is initiated or continued, review the guidance at F329, and interview staff about:

- *What was the person trying to communicate through their behavior;*
- *What were the possible reasons for the person's behavior that led to the initiation of the medication;*
- *What other approaches and interventions were attempted prior to the use of the antipsychotic medication;*
- *Was the family or representative contacted prior to initiating the medication;*
- *Was the medication clinically indicated and/or necessary to treat a specific condition and target symptoms as diagnosed and documented in the record;*
- *Was the medication adjusted to the lowest possible dosage to achieve the desired therapeutic effects;*
- *Were gradual dose reductions planned and behavioral interventions, unless clinically contraindicated, provided in an effort to discontinue the medication;*
- *Was the interdisciplinary team, including the primary care practitioner, involved in the care planning process; and*
- *How does the staff monitor for the effectiveness and possible adverse consequences of the medication.*

If the resident experienced a decline in function, an increased or worsening behavior, or less than anticipated level of improvement in response to interventions, or refused or resisted the interventions, the care plan approaches should be reviewed and revised/updated as appropriate. (See F280)

D. Individualized Approaches and Treatment:

This step implements the care plan interventions to address the needs of a resident with dementia. It includes addressing the causes and consequences of the resident's behavior and staff communication and interactions with residents and families to try to prevent potentially

distressing behaviors or symptoms. It is important to conduct sufficient observations in order to determine if the care plan is being implemented as written. Observations should focus on whether staff:

- *Identify and document specific target behaviors, expressions of distress and desired outcomes (See F279 and F514); and*
- *Implement appropriate, individualized, person-centered interventions and document the results (See F240, F309, F329 and F514);*
- *Communicate and consistently implement the care plan, over time and across various shifts (See F282 and F498).*

Staffing and Staff Training

During observations, determine whether there are sufficient numbers of staff to consistently implement the care plan. (See F353) The nursing home must provide staff, both in terms of quantity (direct care as well as supervisory staff) and quality to meet the needs of the residents as determined by resident assessments and individual plans of care. The facility must strive to staff in a way that optimizes familiarity with residents. The principles for quality include, but are not limited to, the facility ensuring that nursing assistants are able to demonstrate competency in skills and techniques necessary to care for residents' needs as identified through resident assessments, and as described in the plan of care. (See F498) Surveyors should focus on observations of staff interactions with residents who have dementia to determine whether staff consistently applies basic principles for quality in the provision of care.

Nursing assistants must receive a performance review at least once every 12 months and receive regular in-service education based on the outcome of the reviews. (See F497) In addition, the facility must provide training in care of individuals with dementia and related behaviors to nursing assistants when initially hired and annually thereafter.

Research on caregivers of people with dementia suggests that caregiver stress can have a significant impact on outcomes and behavioral expressions of distress in the individual with dementia. This may be true for family, community or institutional caregivers. Some facilities may have systems in place to assist their staff in identifying, addressing and supporting staff who may exhibit "caregiver stress." See the Additional Resources section here for an example of tools to assess caregiver stress.

Involvement of the Medical Team

During observations and record review, if potential medical causes of behavior or other symptoms (such as those indicating possible delirium or infection) were identified, determine whether the attending physician was contacted promptly and a workup and/or treatment were initiated. (See F157 and F385) Residents who exhibit new or worsening BPSD should have an evaluation by the interdisciplinary team, including the physician and knowledgeable staff, in order to identify and address, to the extent possible, treatable medical, physical, emotional, psychiatric, psychological, functional, social, and environmental factors that may be contributing to behaviors, in order to develop a comprehensive plan of care to address expressions of distress. If a medication(s) was ordered, determine if the staff and practitioner

identified and the medical record reflected documentation of the appropriate indication(s) for use. (See F329, Table 1 and F428) For a resident who is receiving any type of psychopharmacologic medication, staff must attempt non-pharmacological interventions, unless clinically contraindicated. (See F329 and F428)

None of the guidance to surveyors should be construed as evaluating the practice of medicine. Surveyors are instructed to evaluate the process of care, including the communication among the prescriber/practitioner, pharmacist, interdisciplinary team, resident or family/representative, and the review of the nursing home practice to prevent unnecessary use of psychopharmacological medications and to closely monitor those medications when they are used. Interviews with the attending physician or other primary care provider (e.g., NP, PA, CNS), medical director, behavioral health specialist and other team members help clarify the reasons for using a psychopharmacological medication or any other interventions for a specific resident. In addition, interviewing the medical director with regard to policies and procedures for behavioral health and psychopharmacological medication use is strongly encouraged.

F. Monitoring and Follow-up:

It is important that surveyors evaluate whether or not a facility used the steps identified above to develop the plan of care. To meet requirements related to monitoring and follow-up of care plan implementation, surveyors evaluate whether or not the interdisciplinary team reviewed a resident's progress towards defined goals, adjusted interventions as needed, and identified when care objectives were met. Monitoring and follow-up of care plan implementation includes, but is not limited to, the following:

- Staff monitors and documents (See F514) the implementation of the care plan, identifies effectiveness of interventions relative to target behaviors and/or psychological symptoms and changes in a resident's level of distress or emergence of adverse consequences.*
- In collaboration with the practitioner, staff adjusts the interventions based on the effectiveness and/or adverse consequences related to treatment. (See F280, F329, F428)*
- If concerns are identified related to the effectiveness or potential or actual adverse consequences of a resident's medication regimen, staff must notify the physician and the physician must respond and, as necessary, initiate a change to the resident's care. (F157, F385, F428)*
- If the physician does not provide a timely and appropriate response to the notification, staff must contact the medical director for further review, and if the medical director was contacted, he/she must respond and intervene as needed. (See F501)*

G. Quality Assessment and Assurance (QAA):

NOTE: *Refer to F520 Quality Assessment and Assurance for guidance regarding information that is obtainable from the QAA committee.*

This guidance addresses the evaluation of a facility's systemic approaches to deliver care and services for a resident with dementia. The medical director and the quality assessment and assurance committee can help the facility evaluate existing strategies for coordinating the care of a resident with dementia and ensure that facility policies and procedures are consistent with current standards of practice.

During interviews with the staff responsible for the QAA functions, determine whether the QAA committee has identified and corrected, as indicated, any quality deficiencies related to the care of residents with dementia. In addition, determine whether the QAA committee has monitored and overseen the following areas related to dementia care:

- Whether resident care policies reflect the facility's overall approach to the care of residents with dementia including a clearly outlined process for their care (see also F501);*
- How the facility monitors whether staff follow related policies and procedures in choosing and implementing individualized interventions for the care of each resident with dementia;*
- Whether the facility has trained staff (such as nursing, dietary, therapy or rehabilitation staff, social workers) in how to communicate with and address behaviors in residents with dementia and were the trainings evaluated for effectiveness, including initial and annual dementia care training for CNAs (See F495 and F497);*
- Whether there is sufficient staff to implement the care plan for residents with dementia, so that medication is not used instead of pertinent non-pharmacological interventions, unless clinically contraindicated (See F353 and F222);*
- Whether staff collect and analyze data to monitor the pharmacological and non-pharmacological interventions used to care for residents with dementia; and*
- How the committee helps the facility monitor responses to the issues and concerns identified through the consultant pharmacist medication regimen review. (See F329 and F428)*

Criteria for Compliance (F309)

Compliance at F309, care for persons with dementia, is based upon a set of key principles. For a resident with dementia, the facility is in compliance with F309, care for persons with dementia, if they:

- 1. Obtained details about the person's behaviors (nature, frequency, severity, and duration) and risks of those behaviors, and discussed potential underlying causes with the care team and (to the extent possible) resident, family or representative;*

- 2. Excluded potentially remediable (medical, medication-related, psychiatric, physical, functional, psychosocial, emotional, environmental) causes of behaviors and determined if symptoms were severe, distressing or risky enough to adversely affect the safety of residents;*
- 3. Implemented environmental and other approaches in an attempt to understand and address behavior as a form of communication and modified the environment and daily routines to meet the person's needs;*
- 4. Implemented the care plan consistently and communicated across shifts and among caregivers and with the resident or family/representative (to the extent possible); and*
- 5. Assessed the effects of the approaches, identified benefits and complications in a timely fashion, involved the attending physician and medical director as appropriate, and adjusted treatment accordingly.*

If not, cite F309.

(For residents with dementia for whom antipsychotic or other medications were prescribed, surveyors must also assess for compliance using guidance at F329, Unnecessary Medications).

Review of a Resident with Non Pressure-Related Skin Ulcer/Wound.

Residents may develop various types of skin ulceration. At the time of the assessment and diagnosis of a skin ulcer/wound, the clinician is expected to document the clinical basis (e.g., underlying condition contributing to the ulceration, ulcer edges and wound bed, location, shape, condition of surrounding tissues) which permit differentiating the ulcer type, especially if the ulcer has characteristics consistent with a pressure ulcer, but is determined not to be one. This section differentiates some of the different types of skin ulcers/wounds.

NOTE: Guidance regarding pressure ulcers is found at 42 CFR 483.25 (c), F314 Pressure Sore. Use F309 for issues of quality of care regarding non-pressure related ulcers.

An arterial ulcer is ulceration that occurs as the result of arterial occlusive disease when non-pressure related disruption or blockage of the arterial blood flow to an area causes tissue necrosis. Inadequate blood supply to the extremity may initially present as intermittent claudication. Arterial/Ischemic ulcers may be present in individuals with moderate to severe peripheral vascular disease, generalized arteriosclerosis, inflammatory or autoimmune disorders (such as arteritis), or significant vascular disease elsewhere (e.g., stroke or heart attack). The arterial ulcer is characteristically painful, usually occurs in the distal portion of the lower extremity and may be over the ankle or bony areas of the foot (e.g., top of the foot or toe, outside edge of the foot). The wound bed is frequently dry and pale with minimal or no exudate. The affected foot may exhibit: diminished or absent pedal pulse, coolness to touch, decreased pain

when hanging down (dependent) or increased pain when elevated, blanching upon elevation, delayed capillary fill time, hair loss on top of the foot and toes, toenail thickening.

A venous ulcer (previously known as a stasis ulcer) is an open lesion of the skin and subcutaneous tissue of the lower leg, often occurring in the lower leg around the medial ankle. Venous ulcers are reported to be the most common vascular ulceration and may be difficult to heal, may occur off and on for several years, and may occur after relatively minor trauma. The ulcer may have a moist, granulating wound bed, may be superficial, and may have minimal to copious serous drainage unless the wound is infected. The resident may experience pain that may increase when the foot is in a dependent position, such as when a resident is seated with her or his feet on the floor.

Recent literature implicates venous hypertension as a causative factor. Venous hypertension may be caused by one (or a combination of) factor(s) including: loss of (or compromised) valve function in the vein, partial or complete obstruction of the vein (e.g., deep vein thrombosis, obesity, malignancy), and/or failure of the calf muscle to pump the blood (e.g., paralysis, decreased activity). Venous insufficiency may result in edema and induration, dilated superficial veins, dry scaly crusts, dark pigmented skin in the lower third of the leg, or dermatitis. The pigmentation may appear as darkening skin, tan or purple areas in light skinned residents and dark purple, black or dark brown in dark skinned residents. Cellulitis may be present if the tissue is infected.

A diabetic neuropathic ulcer requires that the resident be diagnosed with diabetes mellitus and have peripheral neuropathy. The diabetic ulcer characteristically occurs on the foot, e.g., at mid-foot, at the ball of the foot over the metatarsal heads, or on the top of toes with Charcot deformity.

Review of a Resident Receiving Hospice Services.

When a facility resident has also elected the Medicare hospice benefit, the hospice and the nursing home must communicate, establish, and agree upon a coordinated plan of care for both providers which reflects the hospice philosophy, and is based on an assessment of the individual's needs and unique living situation in the facility. The plan of care must include directives for managing pain and other uncomfortable symptoms and be revised and updated as necessary to reflect the individual's current status. This coordinated plan of care must identify the care and services which the SNF/NF and hospice will provide in order to be responsive to the unique needs of the patient/resident and his/her expressed desire for hospice care.

The SNF/NF and the hospice are responsible for performing each of their respective functions that have been agreed upon and included in the plan of care. The hospice retains overall professional management responsibility for directing the implementation of the plan of care related to the terminal illness and related conditions.

For a resident receiving hospice benefit care, evaluate if:

- The facility completed a MDS Significant Change in Status Assessment (SCSA) when the resident elected the hospice benefit;
- The facility completed a MDS Significant Change in Status Assessment (SCSA) when the resident revoked the hospice benefit;
- The plan of care reflects the participation of the hospice, the facility, and the resident or representative to the extent possible;
- The plan of care includes directives for managing pain and other uncomfortable symptoms and is revised and updated as necessary to reflect the resident's current status;
- Medications and medical supplies are provided by the hospice as needed for the palliation and management of the terminal illness and related conditions;
- The hospice and the facility communicate with each other when any changes are indicated to the plan of care;
- The hospice and the facility are aware of the other's responsibilities in implementing the plan of care;
- The facility's services are consistent with the plan of care developed in coordination with the hospice, (the hospice patient residing in a SNF/NF should not experience any lack of SNF/NF services or personal care because of his/her status as a hospice patient); and
- The SNF/NF offers the same services to its residents who have elected the hospice benefit as it furnishes to its residents who have not elected the hospice benefit. The resident has the right to refuse services in conjunction with the provisions of 42 CFR 483.10(b)(4), Tag F155.

NOTE: If a resident is receiving services from a Medicare certified hospice and the hospice was advised of concerns by the facility and failed to address and/or resolve issues related to coordination of care or implementation of appropriate services, refer the concerns as a complaint to the State Agency responsible for oversight of this hospice, identifying the specific resident(s) involved and the concerns identified.

Review of a Resident Receiving Dialysis Services.

When dialysis is provided in the facility by an outside entity, or the resident leaves the facility to obtain dialysis, the nursing home should have an agreement or arrangement with the entity. This agreement/arrangement should include all aspects of how the resident's care is to be managed, including:

- Medical and non-medical emergencies;
- Development and implementation of the resident's care plan;
- Interchange of information useful/necessary for the care of the resident; and
- Responsibility for waste handling, sterilization, and disinfection of equipment.

If there is a sampled resident who is receiving dialysis care, evaluate the following, in addition to the standard Resident Review protocol:

- Review to assure that medications are administered before and after dialysis as ordered by the physician. This should account for the optimal timing to maximize effectiveness and avoid adverse effects of the medications;
- Whether staff know how to manage emergencies and complications, including equipment failure and alarm systems (if any), bleeding/hemorrhaging, and infection/bacteremia/septic shock;
- Whether facility staff are aware of the care of shunts/fistulas, infection control, waste handling, nature and management of end stage renal disease (including nutritional needs, emotional and social well-being, and aspects to monitor); and
- Whether the treatment for this (these) resident(s), affects the quality of life, rights or quality of care for other residents, e.g., restricting access to their own space, risk of infections.

NOTE: If a resident is receiving services from a dialysis provider, and the survey team has concerns about the quality of care and services provided to the resident by that provider, refer the concerns as a complaint to the State Agency responsible for oversight of the dialysis provider, identifying the specific resident(s) involved and the concerns identified.

Review of a Resident Who has Pain Symptoms, is being Treated for Pain, or Who has the Potential for Pain Symptoms Related to Conditions or Treatments.

Recognition and Management of Pain - In order to help a resident attain or maintain his or her highest practicable level of well-being and to prevent or manage pain, the facility, to the extent possible:

- Recognizes when the resident is experiencing pain and identifies circumstances when pain can be anticipated;

- Evaluates the existing pain and the cause(s), and
- Manages or prevents pain, consistent with the comprehensive assessment and plan of care, current clinical standards of practice, and the resident’s goals and preferences.

Definitions Related to Recognition and Management of Pain

- **“Addiction”** is a primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by an overwhelming craving for medication or behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.¹
- **"Adjuvant Analgesics"** describes any medication with a primary indication other than pain management but with analgesic properties in some painful conditions.²
- **“Adverse Consequence”** is an unpleasant symptom or event that is due to or associated with a medication, such as impairment or decline in a resident’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.

- **“Complementary and Alternative Medicine”** (CAM) is a group of diverse medical and health care systems, practices, and products that are not presently considered to be a part of conventional medicine.³
- **“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.
- **“Pain”** is an unpleasant sensory and emotional experience that can be acute, recurrent or persistent.⁴ Following are descriptions of several different types of pain:
 - **“Acute Pain”** is generally pain of abrupt onset and limited duration, often

associated with an adverse chemical, thermal or mechanical stimulus such as surgery, trauma and acute illness;

- “Breakthrough Pain” refers to an episodic increase in (flare-up) pain in someone whose pain is generally being managed by his/her current medication regimen;
 - “Incident Pain” refers to pain that is typically predictable and is related to a precipitating event such as movement (e.g., walking, transferring, or dressing) or certain actions (e.g., disimpaction or wound care); and
 - “Persistent Pain” or “Chronic Pain” refers to a pain state that continues for a prolonged period of time or recurs more than intermittently for months or years.
- **“Physical Dependence”** is a physiologic state of neuroadaptation that is characterized by a withdrawal syndrome if a medication or drug is stopped or decreased abruptly, or if an antagonist is administered.
 - **“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.
 - **“Tolerance”** is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose.⁵

Overview of Pain Recognition and Management

Effective pain recognition and management requires an ongoing facility-wide commitment to resident comfort, to identifying and addressing barriers to managing pain, and to addressing any misconceptions that residents, families, and staff may have about managing pain. Nursing home residents are at high risk for having pain that may affect function, impair mobility, impair mood, or disturb sleep, and diminish quality of life.⁶ The onset of acute pain may indicate a new injury or a potentially life-threatening condition or illness. It is important, therefore, that a resident’s reports of pain, or nonverbal signs suggesting pain, be evaluated.

The resident’s needs and goals as well as the etiology, type, and severity of pain are relevant to developing a plan for pain management. It should be noted that while analgesics can reduce pain and enhance the quality of life, they do not necessarily address the underlying cause of pain. It is important to consider treating the underlying cause, where possible. Addressing underlying causes may permit pain management with fewer analgesics, lower doses, or medications with a lower risk of serious adverse consequences.

Certain factors may affect the recognition, assessment, and management of pain. For example, residents, staff, or practitioners may misunderstand the indications for, and benefits and risks of,

opioids and other analgesics; or they may mistakenly believe that older individuals have a higher tolerance for pain than younger individuals, or that pain is an inevitable part of aging, a sign of weakness, or a way just to get attention. Other challenges to successfully evaluating and managing pain may include communication difficulties due to illness or language and cultural barriers, stoicism about pain, and cognitive impairment.^{7,8,9}

It is a challenge to assess and manage pain in individuals who have cognitive impairment or communications difficulties.^{10,11} Some individuals with advanced cognitive impairment can accurately report pain and/or respond to questions regarding pain.^{12,13} One study noted that 83 percent of nursing home residents could respond to questions about pain intensity.¹⁴

Those who cannot report pain may present with nonspecific signs such as grimacing, increases in confusion or restlessness or other distressed behavior. Effective pain management may decrease distressed behaviors that are related to pain.¹⁵ However, these nonspecific signs and symptoms may reflect other clinically significant conditions (e.g., delirium, depression, or medication-related adverse consequences) instead of, or in addition to, pain. To distinguish these various causes of similar signs and symptoms, and in order to manage pain effectively, it is important to evaluate (e.g., touch, look at, move) the resident in detail, to confirm that the signs and symptoms are due to pain.

Resources Related to Pain Management

Examples of clinical resources available for guidance regarding the assessment and management of pain include:

- American Geriatrics Society Clinical Practice Guideline at: http://www.americangeriatrics.org/education/cp_index.shtml;
- American Medical Directors Association (AMDA) Clinical Practice Guideline “Pain Management in the Long-Term Care Setting” (2003) at: www.amda.com/tools/guidelines.cfm;
- American Academy of Hospice and Palliative Medicine at www.aahpm.org;
- American Academy of Pain Medicine at <http://www.painmed.org>;
- American Pain Society at www.ampainsoc.org;
- Brown University’s Pain and Physical Symptoms Toolkit at <http://www.chcr.brown.edu/pcoc/physical.htm>;
- Hospice and Palliative Nurses Association at <http://www.hpna.org>;
- John A Hartford Institute for Geriatric Nursing "Try This" series at http://www.hartfordign.org/Resources/Try_This_Series;

- National Initiative on Pain Control at www.painedu.org;
- Partners Against Pain[®] at <http://www.partnersagainstpain.com>;
- Quality Improvement Organizations at www.medqic.org; and
- Resource Center for Pain Medicine and Palliative Care at Beth Israel Medical Center (2000) at http://www.stoppain.org/education_research/index.html.

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Care Process for Pain Management

Processes for the prevention and management of pain include:

- Assessing the potential for pain, recognizing the onset or presence of pain, and assessing the pain;
- Addressing/treating the underlying causes of the pain, to the extent possible;
- Developing and implementing interventions/approaches to pain management, depending on factors such as whether the pain is episodic, continuous, or both;
- Identifying and using specific strategies for different levels or sources of pain or pain-related symptoms, including:
 - Identifying interventions to address the pain based on the resident-specific assessment, a pertinent clinical rationale, and the resident’s goals;
 - Trying to prevent or minimize anticipated pain;¹⁶
 - Considering non-pharmacological and CAM interventions;
 - Using pain medications judiciously to balance the resident’s desired level of pain relief with the avoidance of unacceptable adverse consequences;
- Monitoring appropriately for effectiveness and/or adverse consequences (e.g., constipation, sedation) including defining how and when to monitor the resident’s

symptoms and degree of pain relief; and

- Modifying the approaches, as necessary.

Pain Recognition

Because pain can significantly affect a person's well-being, it is important that the facility recognize and address pain promptly. The facility's evaluation of the resident at admission and during ongoing assessments helps identify the resident who is experiencing pain or for whom pain may be anticipated during specific procedures, care, or treatment. In addition, it is important that a resident be monitored for the presence of pain and be evaluated when there is a change in condition and whenever new pain or an exacerbation of pain is suspected. As with many symptoms, pain in a resident with moderate to severe cognitive impairment may be more difficult to recognize and assess.^{17,18,19}

Expressions of pain may be verbal or nonverbal. A resident may avoid the use of the term "pain." Other words used to report or describe pain may differ by culture, language and/or region of the country. Examples of descriptions may include heaviness or pressure, stabbing, throbbing, hurting, aching, gnawing, cramping, burning, numbness, tingling, shooting or radiating, spasms, soreness, tenderness, discomfort, pins and needles, feeling "rough," tearing or ripping. Verbal descriptions of pain can help a practitioner identify the source, nature, and other characteristics of the pain. Nonverbal indicators which may represent pain need to be viewed in the entire clinical context with consideration given to pain as well as other clinically pertinent explanations. Examples of possible indicators of pain include, but are not limited to the following:

- Negative verbalizations and vocalizations (e.g., groaning, crying/whimpering, or screaming);
- Facial expressions (e.g., grimacing, frowning, fright, or clenching of the jaw);
- Changes in gait (e.g., limping), skin color, vital signs (e.g., increased heart rate, respirations and/or blood pressure), perspiration;
- Behavior such as resisting care, distressed pacing, irritability, depressed mood, or decreased participation in usual physical and/or social activities;
- Loss of function or inability to perform Activities of Daily Living (ADLs), rubbing a specific location of the body, or guarding a limb or other body parts;
- Difficulty eating or loss of appetite; and
- Difficulty sleeping (insomnia).

In addition to the pain item sections of the MDS, many sections such as sleep cycle, change in mood, decline in function, instability of condition, weight loss, and skin conditions can be

potential indicators of pain. Any of these findings may indicate the need for additional and more thorough evaluation.

Many residents have more than one active medical condition and may experience pain from several different causes simultaneously. Many medical conditions may be painful such as pressure ulcers, diabetes with neuropathic pain, immobility, amputation, post- CVA, venous and arterial ulcers, multiple sclerosis, oral health conditions, and infections. In addition, common procedures, such as moving a resident or performing physical or occupational therapies or changing a wound dressing may be painful. Understanding the underlying causes of pain is an important step in determining optimal approaches to prevent, minimize, or manage pain.

Observations at rest and during movement, particularly during activities that may increase pain (such as dressing changes, exercises, turning and positioning, bathing, rising from a chair, walking) can help to identify whether the resident is having pain. Observations during eating or during the provision of oral hygiene may also indicate dental, mouth and/or facial pain.

Recognizing the presence of pain and identifying those situations where pain may be anticipated involves the participation of health care professionals and direct care and ancillary staff who have contact with the resident. Information may be obtained by talking with the resident, directly examining the resident, and observing the resident's behavior.²⁰ Staffing consistency and the nursing staff's level of familiarity with the residents was reported in one study to have a significant effect on the staff member's ability to identify and differentiate pain-related behavior from other behavior of cognitively impaired residents.²¹

Nursing assistants may be the first to notice a resident's symptoms; therefore, it is important that they are able to recognize a change in the resident and the resident's functioning and to report the changes to a nurse for follow-up. Family members or friends may also recognize and report when the resident experiences pain and may provide information about the resident's pain symptoms, pain history and previously attempted interventions. Other staff, e.g., dietary, activities, therapy, housekeeping, who have direct contact with the resident may also report changes in resident behavior or resident complaints of pain.

Assessment

Observing the resident during care, activities, and treatments helps not only to detect whether pain is present, but also to potentially identify its location and the limitations it places on the resident. The facility must complete the Resident Assessment Instrument (RAI) (See 42 CFR 483.20 F272). According to the CMS Long-Term Care Facility Resident Assessment Instrument User's Manual, Version 3.0, Chapter 1, "Good clinical practice is an expectation of CMS. As such, it is important to note that completion of the MDS does not remove a nursing home's responsibility to document a more detailed assessment of particular issues relevant for a resident....documentation that contributes to identification and communication of residents' problems, needs and strengths, that monitors their condition on an on-going basis, and that records treatment and response to treatment is a matter of good clinical practice and is an expectation of trained and licensed health care professionals." An assessment or an evaluation of

pain based on clinical standards of practice may necessitate gathering the following information, as applicable to the resident:

- History of pain and its treatment (including non-pharmacological and pharmacological treatment);
- Characteristics of pain, such as:
 - Intensity of pain (e.g., as measured on a standardized pain scale);
 - Descriptors of pain (e.g., burning, stabbing, tingling, aching);
 - Pattern of pain (e.g., constant or intermittent);
 - Location and radiation of pain;
 - Frequency, timing and duration of pain;
- Impact of pain on quality of life (e.g., sleeping, functioning, appetite, and mood);
- Factors such as activities, care, or treatment that precipitate or exacerbate pain;
- Strategies and factors that reduce pain;
- Additional symptoms associated with pain (e.g., nausea, anxiety);
- Physical examination (may include the pain site, the nervous system, mobility and function, and physical, psychological and cognitive status);
- Current medical conditions and medications; or
- The resident's goals for pain management and his or her satisfaction with the current level of pain control.

Management of Pain

Based on the evaluation, the facility, in collaboration with the attending physician/prescriber, other health care professionals, and the resident and/or his/her representative, develops, implements, monitors and revises as necessary interventions to prevent or manage each individual resident's pain, beginning at admission. These interventions may be integrated into components of the comprehensive care plan, addressing conditions or situations that may be associated with pain, or may be included as a specific pain management need or goal.

The interdisciplinary team and the resident collaborate to arrive at pertinent, realistic and measurable goals for treatment, such as reducing pain sufficiently to allow the resident to ambulate comfortably to the dining room for each meal or to participate in 30 minutes of physical therapy. Depending on the situation and the resident's wishes, the target may be to reduce the pain level, but not necessarily to become pain-free. To the extent possible, the interdisciplinary team educates the resident and/or representative about the need to report pain when it occurs and about the various approaches to pain management and the need to monitor the effectiveness of the interventions used.

The basis for effective interventions includes several considerations, such as the resident's needs and goals; the source(s), type and severity of pain (recognizing that the resident may experience pain from one or more sources either simultaneously or at different times) and awareness of the available treatment options. Often, sequential trials of various treatment options are needed to develop the most effective approach.

It is important for pain management approaches to follow pertinent clinical standards of practice and to identify who is to be involved in managing the pain and implementing the care or supplying the services (e.g., facility staff, such as RN, LPN, CNA; attending physician or other practitioner; certified hospice; or other contractors such as therapists). Pertinent current standards of practice may provide recommended approaches to pain management even when the cause cannot be or has not been determined.

If a resident or the resident's representative elects the Medicare hospice benefit for end-of-life care, the facility remains the resident's primary care giver and the SNF/NF requirements for participation in Medicare or Medicaid still apply for that resident. According to the Medicare Hospice Conditions of Participation at 42 CFR 418.112(b) Standard: Professional Management, "The hospice must assume responsibility for professional management of the resident's hospice services provided, in accordance with the hospice plan of care and the hospice conditions of participation, and make any arrangements necessary for hospice-related inpatient care in a participating Medicare/Medicaid facility according to §418.100 and §418.112(b)." The care of the resident, including pain management, must be appropriately coordinated among all providers.

In order to provide effective pain management, it is important that staff be educated and guided regarding the proper evaluation and management of pain as reflected in or consistent with the protocols, policies, and procedures employed by the facility.

Non-pharmacological interventions

Non-pharmacologic interventions may help manage pain effectively when used either independently or in conjunction with pharmacologic agents.²² Examples of non-pharmacologic approaches may include, but are not limited to:

- Altering the environment for comfort (such as adjusting room temperature, tightening and smoothing linens, using pressure redistributing mattress and positioning, comfortable seating, and assistive devices);

- Physical modalities, such as ice packs or cold compresses (to reduce swelling and lessen sensation), mild heat (to decrease joint stiffness and increase blood flow to an area), neutral body alignment and repositioning, baths, transcutaneous electrical nerve stimulation (TENS), massage, acupuncture/acupressure, chiropractic, or rehabilitation therapy;
- Exercises to address stiffness and prevent contractures; and
- Cognitive/Behavioral interventions (e.g., relaxation techniques, reminiscing, diversions, activities, music therapy, coping techniques and education about pain).

The list of Complementary and Alternative Medicine (CAM) options is evolving, as those therapies that are proven safe and effective are used more widely.

NOTE: Information on CAM may be found on the following sites:

- National Center for Complementary and Alternative Medicine at www.nccam.nih.gov; and
- Food and Drug Administration (FDA) at www.fda.gov.

Because CAM can include herbal supplements, some of which potentially can interact with prescribed medications, it is important that any such agents are recorded in the resident's chart for evaluation by the physician and consultant pharmacist.

Pharmacological interventions

The interdisciplinary team (nurses, practitioner, pharmacists, etc.) is responsible for developing a pain management regimen that is specific to each resident who has pain or who has the potential for pain, such as during a treatment. The regimen considers factors such as the causes, location, and severity of the pain, the potential benefits, risks and adverse consequences of medications; and the resident's desired level of relief and tolerance for adverse consequences. The resident may accept partial pain relief in order to experience fewer significant adverse consequences (e.g., desire to stay alert instead of experiencing drowsiness/confusion). The interdisciplinary team works with the resident to identify the most effective and acceptable route for the administration of analgesics, such as orally, topically, by injection, by infusion pump, and/or transdermally.

It is important to follow a systematic approach for selecting medications and doses to treat pain. Developing an effective pain management regimen may require repeated attempts to identify the right interventions. General guidelines for choosing appropriate categories of medications in various situations are widely available.^{23,24}

Factors influencing the selection and doses of medications include the resident's medical condition, current medication regimen, nature, severity, and cause of the pain and the course of

the illness. Analgesics may help manage pain; however, they often do not address the underlying cause of pain. Examples of different approaches may include, but are not limited to: administering lower doses of medication initially and titrating the dose slowly upward, administering medications “around the clock” rather than “on demand” (PRN); or combining longer acting medications with PRN medications for breakthrough pain. Recurrent use of or repeated requests for PRN medications may indicate the need to reevaluate the situation, including the current medication regimen. Some clinical conditions or situations may require using several analgesics and/or adjuvant medications (e.g., antidepressants or anticonvulsants) together. Documentation helps to clarify the rationale for a treatment regimen and to acknowledge associated risks.

Opioids or other potent analgesics have been used for residents who are actively dying, those with complex pain syndromes, and those with more severe acute or chronic pain that has not responded to non-opioid analgesics or other measures. Opioids should be selected and dosed in accordance with current standards of practice and manufacturers’ guidelines in order to optimize their effectiveness and minimize their adverse consequences. Adverse consequences may be especially problematic when the resident is receiving other medications with significant effects on the cardiovascular and central nervous systems. Therefore, careful titration of dosages based on monitoring/evaluating the effectiveness of the medication and the occurrence of adverse consequences is necessary. The clinical record should reflect the ongoing communication between the prescriber and the staff is necessary for the optimal and judicious use of pain medications.

Other interventions have been used for some residents with more advanced, complex, or poorly controlled pain. Examples include, but are not limited to: radiation therapy, neurostimulation, spinal delivery of analgesics (implanted catheters and pump systems), and neurolytic procedures (chemical or surgical) ²⁵ that are administered under the close supervision of expert practitioners.

Monitoring, Reassessment, and Care Plan Revision

Monitoring the resident over time helps identify the extent to which pain is controlled, relative to the individual’s goals and the availability of effective treatment. The ongoing evaluation of the status (presence, increase or reduction) of a resident’s pain is vital, including the status of underlying causes, the response to interventions to prevent or manage pain, and the possible presence of adverse consequences of treatment. Adverse consequences related to analgesics can often be anticipated and to some extent prevented or reduced. For example, opioids routinely cause constipation, which may be minimized by an appropriate bowel regimen.

Identifying target signs and symptoms (including verbal reports and non-verbal indicators from the resident) and using standardized assessment tools can help the interdisciplinary team evaluate the resident’s pain and responses to interventions and determine whether the care plan should be revised, for example:

- If pain has not been adequately controlled, it may be necessary to reconsider the current approaches and revise or supplement them as indicated; or

- If pain has resolved or there is no longer an indication or need for pain medication, the facility works with the practitioner to discontinue or taper (as needed to prevent withdrawal symptoms) analgesics.

Endnotes for Pain Management

- ¹Definitions Related to the Use of Opioids for the Treatment of Pain: Consensus document from the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine, 2001. Document available at www.painmed.org, www.ampainsoc.org and www.asam.org.
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www.who.int/cancer/palliative/painladder/en

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www.amda.com/tools/guidelines.cfm

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Investigative Protocol for Pain Management

Quality of Care Related to the Recognition and Management of Pain

Objective

The objective of this protocol is to determine whether the facility has provided and the resident has received care and services to address and manage the resident’s pain in order to support his or her highest practicable level of physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

Use

Use this protocol for a resident who has pain symptoms or who has the potential for pain symptoms related to conditions or treatments. This includes a resident:

- Who states he/she has pain or discomfort;
- Who displays possible indicators of pain that cannot be readily attributed to another cause;
- Who has a disease or condition or who receives treatments that cause or can reasonably be anticipated to cause pain;
- Whose assessment indicates that he/she experiences pain;
- Who receives or has orders for treatment for pain; and/or
- Who has elected a hospice benefit for pain management.

Procedures

Briefly review the care plan and orders to identify any current pain management interventions and to focus observations. Corroborate observations by interview and record review.

NOTE: Determine who is involved in the pain management process (for example, the staff and practitioner, and/or another entity such as a licensed/certified hospice).

1. Observation

Observe the resident during various activities, shifts, and interactions with staff. Use the observations to determine:

- If the resident exhibits signs or symptoms of pain, verbalizes the presence of pain, or requests interventions for pain, or whether the pain appears to affect the resident's function or ability to participate in routine care or activities;
- If there is evidence of pain, whether staff have assessed the situation, identified, and implemented interventions to try to prevent or address the pain and have evaluated the status of the resident's pain after interventions;
- If care and services are being provided that reasonably could be anticipated to cause pain, whether staff have identified and addressed these issues, to the extent possible;
- Staff response, if there is a report from the resident, family, or staff that the resident is experiencing pain;
- If there are pain management interventions for the resident, whether the staff implements them. Follow up on:
 - Deviations from the care plan;
 - Whether pain management interventions have a documented rationale and if it is consistent with current standards of practice; and
 - Potential adverse consequence(s) associated with treatment for pain (e.g., medications); and
- How staff responded, if the interventions implemented did not reduce the pain consistent with the goals for pain management.

2. Resident/Representative Interviews

Interview the resident, or representative to the degree possible in order to determine the resident's/representative's involvement in the development of the care plan, defining the approaches and goals, and if interventions reflect choices and preferences, and how they are involved in developing and revising pain management strategies; revisions to the care plan, if the interventions do not work. If the resident is presently or periodically experiencing pain, determine:

- Characteristics of the pain, including the intensity, type (e.g., burning, stabbing, tingling, aching), pattern of pain (e.g., constant or intermittent), location and radiation of pain and frequency, timing and duration of pain;
- Factors that may precipitate or alleviate the pain;
- How the resident typically has expressed pain and responded to various interventions in the past;
- Who the resident and/or representative has told about the pain/discomfort, and how the staff responded;
- What treatment options (e.g., pharmacological and/or non-pharmacological) were discussed;
- How effective the interventions have been; and
- If interventions have been refused, whether there was a discussion of the potential impact on the resident, and whether alternatives or other approaches were offered.

3. Nurse Aide(s) Interview. Interview staff who provide direct care on various shifts to determine:

- If they are aware of a resident's pain complaints or of signs and symptoms that could indicate the presence of pain;
- To whom they report the resident's complaints and signs, or symptoms; and
- If they are aware of, and implement, interventions for pain/discomfort management for the resident consistent with the resident's plan of care, (for example, allowing a period of time for a pain medication to take effect before bathing and/or dressing).

4. Record review

Assessment. Review information such as orders, medication administration records, multidisciplinary progress notes, The RAI/MDS, and any specific assessments regarding pain that may have been completed. Determine if the information accurately and comprehensively reflects the resident's condition, such as:

- Identifies the pain indicators and the characteristics, causes, and contributing factors related to pain;
- Identifies a history of pain and related interventions, including the effectiveness and any adverse consequences of such interventions;

- Identifies the impact of pain on the resident's function and quality of life;
- Identifies the resident's response to interventions including efficacy and adverse consequences, and any modification of interventions as indicated; and
- Identifies if the resident triggers the CAA for pain.

NOTE: Although Federal requirements dictate the completion of RAI assessments according to certain time frames, standards of good clinical practice dictate that the assessment process is more fluid and should be ongoing. (Federal Register, Vol. 62, No. 246, 12/23/97, Page 67193)

Care Plan. Review the care plan. Determine if pain management interventions include as appropriate:

- Measurable pain management goals, reflecting resident needs and preferences;
- Pertinent non-pharmacological and/or pharmacological interventions;
- Time frames and approaches for monitoring the status of the resident's pain, including the effectiveness of the interventions; and
- Identification of clinically significant medication-related adverse consequences such as falling, constipation, anorexia, or drowsiness, and a plan to try to minimize those adverse consequences.

If the care plan refers to a specific facility pain management protocol, determine whether interventions are consistent with that protocol. If a resident's care plan deviates from the protocol, determine through staff interview or record review the reason for the deviation.

If the resident has elected a hospice benefit, all providers must coordinate their care of the resident. This care includes aspects of pain management, such as choice of palliative interventions, responsibility for assessing pain and providing interventions, and responsibility for monitoring symptoms and adverse consequences of interventions and for modifying interventions as needed.

NOTE: If a resident is receiving services from a Medicare certified hospice and the hospice was advised of concerns by the facility and failed to address and/or resolve issues related to coordination of care or implementation of appropriate services, file a complaint with the State Agency responsible for oversight of this hospice, identifying the specific resident(s) involved and the concerns identified.

Care Plan Revisions

Determine whether the pain has been reassessed and the care plan has been revised as necessary (with input from the resident or representative, to the extent possible). For example, if the current interventions are not effective, if the pain has resolved, or the resident has experienced a change of condition or status.

5. Interviews with health care practitioners and professionals:

Nurse Interview. Interview a nurse who is knowledgeable about the needs and care of the resident to determine:

- How and when staff try to identify whether a resident is experiencing pain and/or circumstances in which pain can be anticipated;
- How the resident is assessed for pain;
- How the interventions for pain management have been developed and the basis for selecting them;
- If the resident receives pain medication (including PRN and adjuvant medications), how, when, and by whom the results of medications are evaluated (including the dose, frequency of PRN use, schedule of routine medications, and effectiveness);
- How staff monitor for the emergence or presence of adverse consequences of interventions;
- What is done if pain persists or recurs despite treatment, and the basis for decisions to maintain or modify approaches;
- How staff communicate with the prescriber/practitioner about the resident's pain status, current measures to manage pain, and the possible need to modify the current pain management interventions; and
- For a resident who is receiving care under a hospice benefit, how the hospice and the facility coordinate their approaches and communicate about the resident's needs and monitor the outcomes (both effectiveness and adverse consequences).

Interviews with Other Health Care Professionals. If the interventions or care provided do not appear to be consistent with current standards of practice and/or the resident's pain appears to persist or recur, interview one or more health care professionals as necessary (e.g., attending physician, medical director, consultant pharmacist, director of nursing or hospice nurse) who, by virtue of training and knowledge of the resident, should be able to provide information about the evaluation and management of the resident's pain/symptoms. Depending on the issue, ask about:

- How chosen interventions were determined to be appropriate;

- How they guide and oversee the selection of pain management interventions;
- The rationale for not intervening, if pain was identified and no intervention was selected and implemented;
- Changes in pain characteristics that may warrant review or revision of interventions; or
- When and with whom the professional discussed the effectiveness, ineffectiveness and possible adverse consequences of pain management interventions.

If during the course of this review, the surveyor needs to contact the attending physician regarding questions related to the treatment regimen, it is recommended that the facility's staff have the opportunity to provide the necessary information about the resident and the concerns to the physician for his/her review prior to responding to the surveyor's inquiries. If the attending physician is unavailable, interview the medical director as appropriate.

DETERMINATION OF COMPLIANCE WITH F309 FOR PAIN MANAGEMENT (Task 6, Appendix P)

Synopsis of Regulation (Tag F309)

The resident must receive and the facility must provide the necessary care and services to attain or maintain his/her highest practicable level of physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

Criteria for Compliance with F309 for a Resident with Pain or the Potential for Pain

For a resident with pain or the potential for pain (such as pain related to treatments), the facility is in compliance with F309 Quality of Care as it relates to the recognition and management of pain, if each resident has received and the facility has provided the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care i.e., the facility:

- Recognized and evaluated the resident who experienced pain to determine (to the extent possible) causes and characteristics of the pain, as well as factors influencing the pain;
- Developed and implemented interventions for pain management for a resident experiencing pain, consistent with the resident's goals, risks, and current standards of practice; or has provided a clinically pertinent rationale why they did not do so;
- Recognized and provided measures to minimize or prevent pain for situations where pain could be anticipated;

- Monitored the effects of interventions and modified the approaches as indicated; and
- Communicated with the health care practitioner when a resident was having pain that was not adequately managed or was having a suspected or confirmed adverse consequence related to the treatment.

If not, cite at F309.

Noncompliance with F309 for a Resident with Pain or the Potential for Pain

After completing the Investigative Protocol, analyze the data in order to determine whether or not noncompliance with the regulation exists. Noncompliance for F309, with regard to pain management, may include, for example, failure to:

- Recognize and evaluate the resident who is experiencing pain in enough detail to permit pertinent individualized pain management;
- Provide interventions for pain management in situations where pain can be anticipated;
- Develop interventions for a resident who is experiencing pain (either specific to an overall pain management goal or as part of another aspect of the care plan);
- Implement interventions to address pain to the greatest extent possible consistent with the resident's goals and current standards of practice and have not provided a clinically pertinent rationale why this was not done;
- Monitor the effectiveness of intervention to manage pain; or
- Coordinate pain management as needed with an involved hospice to meet the resident's needs.

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements for a Resident with Pain or the Potential for Pain

During the investigation of care and services provided regarding pain management, the surveyor may have identified concerns with related structure, process, and/or outcome requirements. If an additional concern has been identified, the surveyor must investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirement. Some examples include, but are not limited to, the following:

- 42 CFR 483.10(b)(4) F155, The Right to Refuse Treatment

If a resident has refused treatment or services, determine whether the facility has assessed the reason for this resident's refusal, clarified and educated the resident as to the

consequences of refusal, offered alternative treatments, and continued to provide all other services.

- 42 CFR 483.10(b)(11), F157, Notification of Changes

Determine if staff notified:

- The physician when pain persisted or recurred despite treatment or when they suspected or identified adverse consequences related to treatments for pain; and
- The resident's representative (if known) of significant changes in the resident's condition in relation to pain management and/or the plan of care for pain.

- 42 CFR 483.15(b), F242, Self-determination and Participation.

Determine if the facility has provided the resident with relevant choices about aspects of pain management.

- 42 CFR 483.15(e)(1), F246, Accommodation of Needs

Determine whether the facility has adapted the resident's physical environment (room, bathroom, furniture) to reasonably accommodate the resident's individual needs, related to pain management.

- 42 CFR 483.20, F272, Comprehensive Assessments

Determine if the facility comprehensively assessed the resident's physical, mental, and psychosocial needs to identify characteristics and determine underlying causes (to the extent possible) of the resident's pain and the impact of the pain upon the resident's function, mood, and cognition.

- 42 CFR 483.20(g) F278, Accuracy of Assessments

Determine whether the assessment accurately reflects the resident's status.

- 42 CFR 483.20(k), F279, Comprehensive Care Plans

Determine if the facility's comprehensive care plan for the resident included measurable objectives, time frames, and specific interventions/services to meet the resident's pain management needs, consistent with the resident's specific conditions, risks, needs, goals, and preferences and current standards of practice.

- 42 CFR 483.20(k)(2)(iii), 483.10(d)(3), F280, Comprehensive Care Plan Revision

Determine if the care plan was periodically reviewed and revised by a team of qualified

persons with input from the resident or representative to try to reduce pain or discomfort.

- 42 CFR 483.20(k)(3)(i), F281, Services provided meet professional standards of quality

Determine if care was provided in accordance with accepted professional standards of quality for pain management.

- 42 CFR 483.20(k)(3)(ii), F282, Care provided by qualified persons in accordance with the plan of care

Determine whether care is being provided by qualified staff, and/or whether the care plan is adequately and/or correctly implemented.

- 42 CFR 483.25(l), F329, Unnecessary Drugs

Determine whether medications ordered to treat pain are being monitored for effectiveness and for adverse consequences, including whether any symptoms could be related to the medications.

- 42 CFR 483.40(a), F385, Physician Supervision

Determine if pain management is being supervised by a physician, including participation in the comprehensive assessment process, development of a treatment regimen consistent with current standards of practice, monitoring, and response to notification of change in the resident's medical status related to pain.

- 42 CFR 483.60, F425, Pharmacy Services

Determine if the medications required to manage a resident's pain were available and administered as indicated and ordered at admission and throughout the stay.

- 42 CFR 483.75(i)(2), F501, Medical Director

Determine whether the medical director helped the facility develop and implement policies and procedures related to preventing, identifying and managing pain, consistent with current standards of practice; and whether the medical director interacted with the physician supervising the care of the resident if requested by the facility to intervene on behalf of a resident with pain or one who may have been experiencing adverse consequences related to interventions to treat pain.

- 42 CFR 483.75(l) F514, Clinical Records

Determine whether the clinical record:

- Accurately and completely documents the resident's status, the care and services provided, (e.g., to prevent to the extent possible, or manage the resident's pain) in

accordance with current professional standards and practices and the resident's goals; and

- Provide a basis for determining and managing the resident's progress including response to treatment, change in condition, and changes in treatment.

DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and *identified any deficient practice(s)* that *demonstrate* that noncompliance *with the regulation at F309* exists, the team must determine the severity of each deficiency, based on the *resultant* harm or potential for harm to the resident. *(Note: some of the examples here involving residents with dementia who receive an antipsychotic medication may also be cited at F329. Surveyors should evaluate compliance at each tag separately).*

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

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed, caused, or resulted in, or is likely to allow, cause, or result in serious injury, harm, impairment, or death to a resident; and
- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

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

Severity Level 3 Considerations: Actual Harm that is **Not Immediate Jeopardy**

Level 3 indicates noncompliance that resulted in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being.

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

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

Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his

or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided.

The following examples illustrate the differences among compliance and non-compliance at levels 4, 3 and 2 for F309 Review of a Resident with Dementia. This is only one example; surveyors must investigate each case as the specific situation will vary and may lead to different conclusions based on the evidence.

F309 – Review of a Resident with Dementia – Compliance Example

A resident with dementia was admitted after hospitalization for a hip fracture she sustained while showering at home. The social worker’s note, the nurses’ notes and the care plan all included information from the family: they had reported on admission that the resident was now very fearful of showers. The RAI indicated choosing the method she was bathed was “very important” and the resident’s daughter stated she preferred sponge baths due to her fear of showers. The interventions in the care plan were implemented consistently across all shifts and levels of staff. The nurses and social workers documented ongoing discussions with family and reassessments to ensure the resident’s needs were being met and that no new issues had been identified. The criteria for compliance were met.

F309 – Review of a Resident with Dementia - Level 4 Severity Non-compliance Example

A resident with dementia was admitted after hospitalization for a hip fracture she sustained while showering at home. The social worker’s note, the nurses’ notes and the care plan all included information from the family: they had reported on admission that the resident was now very fearful of showers. The RAI indicated choosing the method the resident was bathed was “very important” and her daughter stated she preferred sponge baths due to her fear of showers.

In addition to the basic facts noted above in the level 4 severity non-compliance example:

- The surveyor observed an occurrence of bathing for the resident described above during the survey. The resident displayed substantial distress and fearfulness, calling out “help me,” crying, striking out and grabbing at the staff, and made repeated attempts to get out of the shower chair.*
- The staff member present called for a second staff member to help her complete the shower. Despite the resident’s cries for help, no other staff members intervened or attempted to determine whether or not her distress warranted a different approach to the bathing routine/schedule.*
- Significant psychological distress was noted during the bathing and for the remainder of the day and was documented in the nurse’s notes.*
- The surveyor observed that no other staff members intervened to assess the resident’s situation or consult the care plan during or after the bathing.*

- *The surveyor interviewed direct care staff and nurses on the unit. One licensed nurse stated, “That resident always yells out during her shower” and attributed this to her dementia. Neither CNA interviewed was aware that the resident had sustained a hip fracture during a shower prior to admission.*
- *The resident’s fear of bathing was noted in the care plan; however during interviews/observations, direct care staff could not articulate this information about the resident.*
- *The staff admitted they had not considered alternative routines/approaches for bathing this resident, despite the fact that the family had reported the resident’s fear of showers and despite repeated episodes of distress.*
- *In addition to the staff being unaware of the resident’s fear of showers, they also failed to investigate for other causes of the behavior.*
- *Upon further investigation related to quality assurance, there was no evidence that a physician attends QA&A meetings regularly.*
- *In reviewing staff training records, it appears that nursing assistants have not received training on how to care for residents with dementia.*

What is the evidence for non-compliance?

- *Resident exhibits adverse reaction to showers with verbal distress, combative behavior, and continuous struggling to get out of the chair.*
- *Facility failed to consider and rule out possible causes such as pain related to hip fracture while sitting in a shower chair or possible discomfort with the approach being used to bathe. Facility also failed to recognize the risk of a fall or injury due to combative behavior that required two staff members.*
- *Facility failed to develop and attempt alternate interventions.*
- *No staff member intervened despite the staff member present calling for help and hearing resident’s cries for help and her obvious distress.*
- *Facility failed to develop a care plan intervention related to trying to reduce or eliminate extreme reactions to showers;*
- *Staff had appropriate care plan but failed to communicate across shifts and caregivers; and/or*
- *Facility failed to assess the effects of the interventions and try to modify interventions based on those assessments.*

Why is this Immediate Jeopardy?

See Decision-Making Grid with Components of Immediate Jeopardy below. Based on the severity of the resident’s reaction, there was evidence that the resident experienced actual psychological harm. In addition, there was immediacy since the repeated attempts at showering

the resident resulted in resident-to-staff altercations and placed her at risk for serious physical harm.

Furthermore, there was no evidence of physician participation in the QA&A committee and no evidence that nurse aides received required training in caring for and communicating with residents with dementia. This suggests a lack of effective systems and processes for the assessment and treatment of a resident with dementia. If so, these systems failures place this and potentially other residents with dementia at risk for serious harm. The facility is culpable for a deficient practice that must be addressed immediately in order to prevent further harm to this and other residents (surveyors may wish to consider whether or not there is a need to expand the sample).

Components of Immediate Jeopardy

Harm	
a. Actual - Was there an outcome of harm? Does the harm meet the definition of Immediate Jeopardy, e.g., has the provider's noncompliance caused serious injury, harm, impairment, or death to an individual?	Yes. Repeated, extreme reaction to attempts to bathe with visible anguish, crying and yelling out reflects actual psychological harm with no attempts to alter the care plan.
b. Potential – Is there a likelihood of potential harm? Does the potential harm meet the definition of Immediate Jeopardy; e.g., is the provider's noncompliance likely to cause serious injury, harm, impairment, or death to an individual?	Yes. Repeated risk of a serious fall on an already injured or vulnerable area due to the struggle related to attempted showering.
Immediacy	
Is the harm or potential harm likely to occur in the very near future to this individual or others in the entity, if immediate action is not taken?	Yes. Potential for subsequent harm (a fall or other injury, psychological harm) exists as the facility did not attempt to identify causes or modify alternate interventions related to showers. Other residents with dementia may also be at risk, as staff had not received training in caring for individuals with dementia including how to understand the communication efforts of residents with dementia. There was no evidence of physician participation with the QA&A committee.
Culpability	
Did the facility know about the situation? If so when did the facility first become aware?	Yes, it had happened repeatedly and the social worker and nurses had been informed on admission of the resident's fear and preferences. While the information was in the care plan, the team had not passed the information along to the direct care staff and staff did not review the care plan. Staff did not intervene during these episodes despite the resident's cries for help. These behaviors were attributed to her dementia and were not considered remediable.
Should the facility have known about the situation?	Yes. There were recurrent episodes and the family had reported similar behavior at home related to showers.

*F309 – Review of a Resident with Dementia - Level 3 Severity Non-compliance Example
A resident with dementia was admitted after hospitalization for a hip fracture she sustained while showering at home. The social services note, the nurses' notes and the care plan all*

included information from the family: they had reported on admission that the resident was now very fearful of showers. The RAI indicated choosing the method she was bathed was “very important” and her daughter stated she preferred sponge baths due to her fear of showers.

In addition to the basic facts noted above in the level 3 severity non-compliance example:

- The information about the resident’s fear of bathing was in the care plan; however during interviews/observations, direct care staff could not articulate this information.*
- The surveyor determined that the resident was taken to the shower room three times in the three weeks since admission. Staff interviews revealed that each time the staff attempted to provide her with a shower, the resident immediately started to call out, “help me, help me.” With each of the three attempts, the shower was stopped, the staff member documented “shower was refused” and the resident was given a sponge bath instead. On those days, the resident was noted to be anxious and fretful, wringing her hands and crying on and off for the rest of the day. These behaviors are not noted on other days.*
- No further investigation occurred after each incident. Neither the physician nor the family was involved in discussions regarding the resident’s response to the shower and no change in the plan of care was evident after the attempts to shower the resident.*

Why is this Level 3 Severity?

There is evidence of actual psychosocial harm to this resident, with no attempts by the facility to identify the underlying cause of her expressions of distress. However this case does not meet the criteria for immediacy, since the staff did not attempt to actually place the resident into the shower once she started to resist. While staff failed to rule out underlying causes of the resident’s behavior, they did provide an alternative when the resident resisted.

F309 – Review of a Resident with Dementia - Level 2 Severity Non-compliance Example

A resident with dementia was admitted after hospitalization for a hip fracture she sustained while showering at home. It was documented in the social service and nurses’ notes that the family had reported on admission that the resident was now very fearful of showers and preferred sponge baths. However, this information was not communicated to other staff nor was it incorporated into the care plan. The care plan stated that the resident would receive weekly showers.

In addition to the basic facts noted above in the level 2 severity example:

- The resident’s daughter insisted on bathing her mother herself for a period of time after admission, and provided sponge baths to the resident several times a week. The staff did not attempt to provide showers to the resident for several weeks after admission.*

- *At the next care plan meeting, the daughter discovered that her mother’s care plan included “provide weekly showers,” and was upset that the information about her mother’s fear of showers had not been identified and addressed in the care plan.*

Why is this Level 2 Severity?

There is potential for more than minimal harm since significant psychological distress was reported by the family to occur consistently with attempts to shower the resident. In addition, the potential for serious physical harm exists if showers are attempted and the resident resists by trying to get up out of the shower chair or becoming combative with staff. This is Level 2 because actual harm did not occur.

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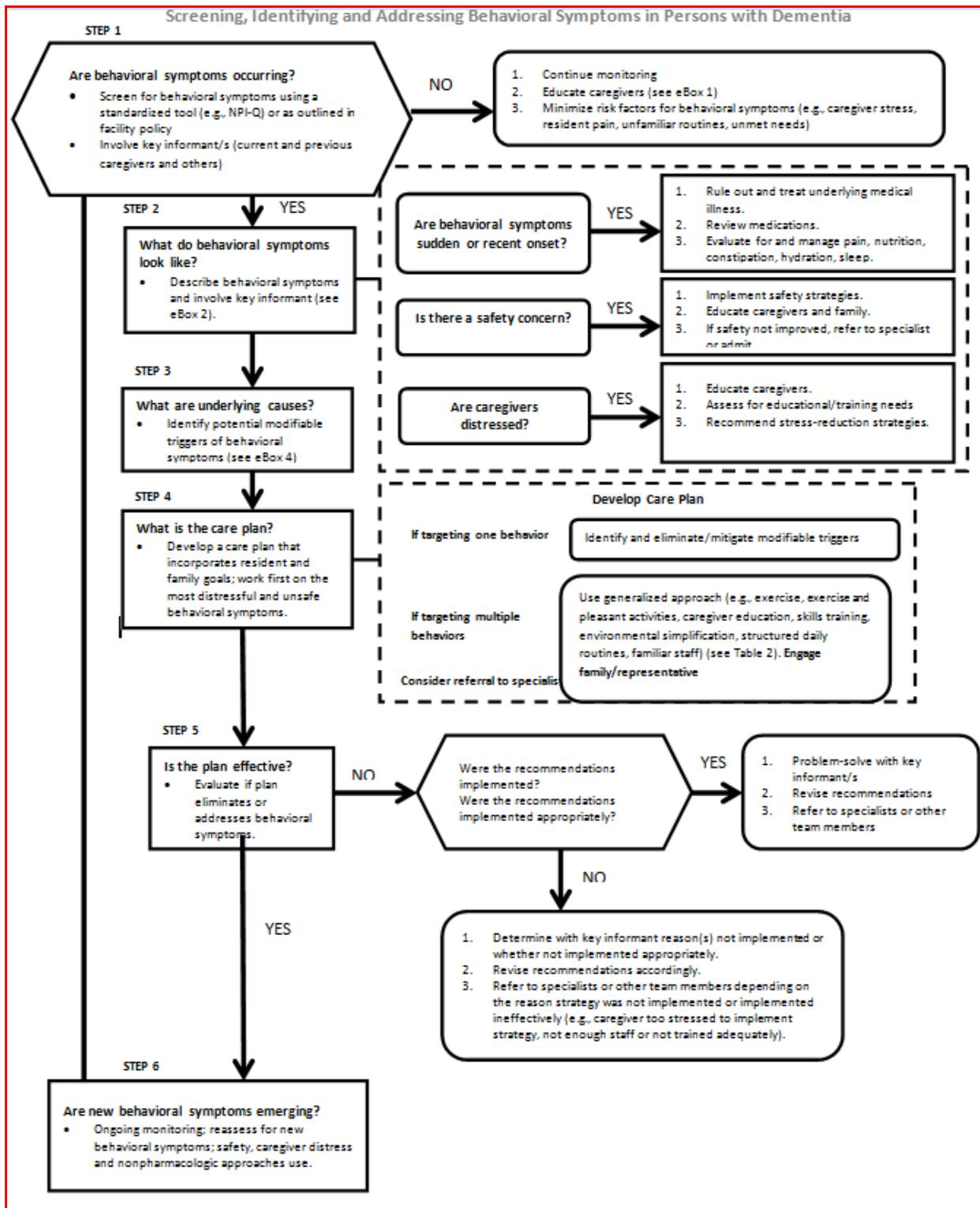
Additional Resources

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.

Some clinical resources that identify the challenges and basic principles of dementia care include, but are not limited to:

- *Advancing Excellence in America's Nursing Homes.* <http://www.nhqualitycampaign.org>
- *Diagnostic and Statistical Manual of Mental Disorders DSM IV-TR Fourth edition.* 2000 American Psychiatric Association.
- *Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia.* *JAMA* 202; 308(9): 2020-2029.

- *Hand in Hand. For information, to download the training modules or inquire about receiving a copy or replacement copies of the Hand in Hand Toolkit please visit <http://www.cms-handinhandtoolkit.info/Index.aspx>*
- *Lyketsos, C., Lipsey, J., Rabins, P., and Slavney, P. Psychiatric Aspects of Neurological Diseases. New York: Oxford University Press, 2008. Print*
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- *Excerpt adapted from: Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. JAMA, November 2, 202; 308(9): 2020-2029. © 202 American Medical Association. All rights reserved.*



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List of Boxes

Box – Key Considerations Caregivers Need to Know to Help Prevent Behavioral

Symptoms

Box 2 – Informal Assessment: Brief Questions to Guide Describing Behavioral Symptoms

Box 3 – Checklist of Factors to Consider to Identify Potential Causes of Behavioral

Symptoms

Box – Key Considerations Caregivers Need to Know to Help Prevent Behavioral Symptoms

- Effectively communicate:*
 - *Use calm voice*
 - *Offer no more than two choices*
 - *Do not use open-ended questions*
 - *Keep it simple – do not over explain or discuss events happening in the future*
- Attend to resident's nonverbal communications:*
 - *Grimacing may be a sign of pain*
 - *Ringing hands may be a sign of anxiety, feelings of insecurity*
- Relax the rules - there is no right or wrong way to perform an activity if resident is safe*
- Establish a structured daily routine for resident that is predictable*
- Keep resident engaged in activities of interest and that match capabilities*
- Use cueing strategies (e.g., touch, verbal directions) to help people with executive dysfunction initiate, sequence, and execute daily activities*

- Understand behaviors are not intentional or done “in spite” but are a consequence of erosion in person’s ability to initiate or comprehend steps of a task or its purpose*
- Inform physician immediately of changes in behavior as they occur (e.g., sleep disruptions, withdrawal, increased confusion)*
- Take care of self as a caregiver/team member:*
 - *Exercise regularly*
 - *Involve other staff and family/representative in care responsibilities as appropriate*
 - *Discuss stressful situations with colleagues and supervisors and brainstorm about potential solutions*
 - *Use stress reduction techniques (see Hand in Hand, CMS video series available in nursing home, or other resources for suggestions)*

Box 2 - Informal Assessment: Brief Questions to Guide Describing Behavioral

Symptoms

- What is the behavior? Can you describe the behavior?*
 - *What did he/she do?*
 - *What did he/she say?*
 - *What did you do and say?*
- Why is this behavior a problem? What about it really gets to you or makes you upset?*
- When does the behavior occur?*
 - *What time of day?*
 - *What day(s) of the week?*
- How often did the behavior happen in the past week? Past month?*
- Where does the behavior occur?*

- *Is there a particular room/setting within the facility where the behavior occurs (e.g., during activities, in dining room, in person's own room with daily care routines)?*
- Can you recognize any patterns?*
 - *Does the behavior happen at the same time every day?*
- What happens right before the behavior occurs?*
- Who is around when the behavior occurs and how do they react?*
- What is the environment like where the behavior occurs?*
 - *Is there a lot of stimulation (television, noise, people)?*
- How would you like this behavior to change? When would you consider the problem "solved"?*

Note: Adapted from randomized trials and the NIH Resources for Enhancing Alzheimer's Caregiver Health (REACH I and II).

Box 3 – Checklist of Factors to Consider to Identify Potential Causes of Behavioral Symptoms

1. Resident-based Factors

- Altered emotional status (feelings of insecurity, sadness, anxiety, or loneliness)*
- Lack of daily routines*
- Sensory deficits (hearing, sight)*
- Basic physical needs (hydration, constipation, body temperature)*
- Interests and preferences not being met*
- Level of stimulation (under or over) not appropriate*
- Health issues (underlying infection)*
- Impact of other illness or conditions*
- Pain*

- Medications (changes in, dosage, polypharmacy, failure to take, inappropriate medication administration)*
- Ambulation and/or difficulty finding one's way (getting lost)*
- Challenges performing daily activities of living (bathing, dressing, using the toilet, grooming, eating)*
- Sleep cycle disruptions*

2. Caregiver-based Factors

- Communications too complex*
- Emotional tone is harsh*
- High level of distress*
- Lack of availability (staffing issues)*
- Poor health status*
- Expectations are too high or too low*
- Cultural expectations and care values and beliefs that are not good fit with dementia care needs*
- Style of caregiving not good fit*
- Poor relationship with resident*
- Lack of education about disease and behaviors*
- Lack of supportive network or system within facility for dementia care*
- Limited opportunities for respite*
- Strained financial situation influencing work performance*
- Employment and other family care responsibilities*

3. Environmental-based factors

- Level of physical and/or social stimulation (too much or too little)*
- Room arrangements*
 - *Amount of clutter*
 - *Needed items are out-of-sight or not in where person can see them*
- Lack of appropriate visual cues*
- Safety risk*
- Too hot or too cold*
- Lack of needed adaptive equipment (grab bars in bathroom)*
- Poor lighting*

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F329

(Rev. 130; Issued: 12-12-14, Effective: 12-12-14, Implementation: 12-12-14)

§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.¹
- “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.² 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.³

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.⁴

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 and www.geriatricsatyourfingertips.org;
- American Medical Directors Association www.amda.com;
- American Psychiatric Association www.psych.org;
- American Society of Consultant Pharmacists www.ASCP.com;
- Agency for Healthcare Research and Quality (AHRQ) www.ahrq.gov;
- American Association for Geriatric Psychiatry www.aagp.org;
- Association for Practitioners in Infection Control and Epidemiology www.apic.org;
- CMS Sharing Innovations in Quality Web site maintained at: <http://siq.air.org>;
- National Guideline Clearinghouse www.guideline.gov;
- Quality Improvement Organizations, Medicare Quality Improvement Community Initiatives www.medqic.org;
- U.S. Department of Health and Human Services, Food and Drug Administration Web site 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;
- Mace N, Rabins P. The 36-Hour Day: A Family Guide to Caring for Persons with Alzheimer Disease, Related Dementing Illnesses, and Memory Loss in Later Life; and
- “Bathing without a battle” 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 CAAs, 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 MDS and CAAs.

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;
 - Environmental stressors (e.g., excessive heat, noise, overcrowding);
 - 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
 - Medical illnesses such as Alzheimer's disease, Lewy body disease, vascular dementia, or frontotemporal dementia.

See Table I below 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 338 (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.⁵

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:

Common Conditions/ Symptoms	Examples of Tools	Potential Applications	Source/Reference
Diabetes	Blood glucose, Hemoglobin A1C	Diagnose diabetes and determine diabetic control	www.endocrineweb.com/diabetes/diagnosis.html www.diabetes.org/home.jsp www.diabetes.niddk.nih.gov/ www.diabetestoolbox.com/HbA1c.asp
Alzheimer’s Disease / Dementia	Mini Mental Status Exam (MMSE)	Determine degree of cognitive impairment	www.emedicine.com/med/topic3358.htm www.fpnotebook.com/NEU75.htm
Functional Decline	Instrumental Activities of Daily Living (IADL) Resident Assessment Instrument (RAI) Functional Alzheimer’s Screening Test (FAST)	Assess functional capabilities Assess aspects of nursing home resident’s behavior and function Assess level of function in individuals with dementia	www.cdc.gov/nchs/dataawh/nchsdefs/iadl.htm www.fpnotebook.com/GER3.htm www.apadiv20.phhp.ufl.edu/fries.htm www.careplans.com/pages/library/RAI_user_guide.pdf http://geriatrics.uthscsa.edu/educational/med_students/fastscale_admin.htm

Common Conditions/Symptoms	Examples of Tools	Potential Applications	Source/Reference
Delirium	Confusion Assessment Method (CAM)	Screen for cognitive impairment and delirium	www.hartfordign.org/publications/trythis/issue13.pdf http://elderlife.med.yale.edu/pdf/The%20Confusion%20Assessment%20Method.pdf
Bipolar Disorder	Mania Rating Scale	Assess severity of mania	www.psychiatryinpractice.com/AssessmentTools/default.aspx?11=3&12=3&13=&13= www.brainexplorer.org/factsheets/Psychiatry%20Rating%20Scales.pdf
Pain	List of pain scales	Assess pain characteristics (e.g., intensity, impact, timing)	www.chcr.brown.edu/pcoc/Physical.htm
Depression	Geriatric Depression Scale Cornell Depression in Dementia Scale	Screen or monitor individuals at risk for depression Screen or monitor for depression in individuals with cognitive impairment	www.assessmentpsychology.com/geriatricscales.htm www.hartfordign.org/publications/trythis/issue04.pdf www.merck.com/mrkshared/mmg/tables/33t4.jsp www.emoryhealthcare.org/departments/fuqua/CornellScale.pdf
Abnormal Movements	Abnormal Involuntary Movement Scales (AIMS)	Assess presence and severity of involuntary movements that may be due to disease or medications	www.carepaths.com/pages/Instruments_AIMS.asp www.mhsip.org/library/pdfFiles/abnormalinvoluntarymovementscale.pdf

Common Conditions/ Symptoms	Examples of Tools	Potential Applications	Source/Reference
Behavioral Symptoms associated with Dementia	Neuro-psychiatric Inventory-Nursing Home Version (NPI-NH)	Screen or monitor for behavior associated with dementia (e.g., hallucinations, agitation or anxiety)	www.alzheimer-insights.com/insights/vol2no3/vol2no3.htm
	Behavioral Pathology in Alzheimer's Disease Rating Scale (Behave AD)	Provide a global rating of non-cognitive symptoms.	www.alzforum.org/dis/dia/tes/neuropsychological.asp
	Cohen-Mansfield Agitation Inventory (CMAI)	Assess/rate distressed behavior in older individuals	www.researchinstituteonaging.org/assessment.html www.geriatrictimes.com/g010533.html

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.⁶ 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.⁷

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.^{8,9} 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.¹⁰ 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.

ENDNOTES

- ¹ Adapted from American Society of Consultant Pharmacists (ASCP) Guidelines for Assessing the Quality of Drug Regimen Review in Long-Term Care Facilities.
- ² Tobias, DE & Sey, M. (2001). General and psychotherapeutic medication use in 328 nursing facilities: A year 2000 national survey. *The Consultant Pharmacist*, 15, pp. 34-42.
- ³ Briesacher, B.A., Limcangco, M.R., Simoni-Wastila, L., Doshi, J.A., Levens, S.R., Shea, D.G., & Stuart, B. (2005). The quality of antipsychotic drug prescribing in nursing homes. *Archives of Internal Medicine*, 165, pp. 1280-1285.
- ⁴ Ray, W.A., Taylor, J.A., Meador, K.G., Lichtenstein, M.J., Griffin, M.R., Fought, R., Adams, M.L., & Blazer, D.G. (1993). Reducing antipsychotic drug use in nursing homes. A controlled trial of provider education. *Archives of Internal Medicine*, 153(6), pp. 713-21.
- ⁵ Gurwitz, J.H., Field, T.S., Judge, J., Rochon, P., Harrold, L.R., Cadoret, C., Lee, M., White, K., LaPrino, J., Erramuspe-Mainard, J., DeFlorio, M., Gavendo, L., Auger, J., & Bates, D.W. (2005). Incidence of adverse drug consequences in two large academic long-term care facilities. *American Journal of Medicine*, 118, pp. 251-258.
- ⁶ Gurwitz, J.H., Field, T.S., Avorn, J., McCormick, D., Jain, S., Eckler, M., Benser, M., Edmondson, A.C., & Bates, D.W. (2000). Incidence and preventability of adverse drug events in nursing homes. *American Journal of Medicine*, 109, pp. 87-94.
- ⁷ Gurwitz, J.H., Field, T.S., Avorn, J., McCormick, D., Jain, S., Eckler, M., Benser, M.,

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- Edmondson, A.C., & Bates, D.W. (2000). Incidence and preventability of adverse drug events in nursing homes. *American Journal of Medicine*, 109, pp. 87-94.
- ⁸ Field T.S., Gurwitz J.H., Avorn J., McCormick, D., Shailavi, J., Eckler, M., Benser, M., & Bates, D.W. (2001). Risk factors for adverse drug events among nursing home residents. *Archives of Internal Medicine*, 161, pp. 1629-34.
- ⁹ Denham, M.J. (1990). Adverse drug reactions. *British Medical Bulletin*, 46, pp. 53-62.
- ¹⁰ Rosen's Emergency Medicine: Concepts and Clinical Practice, 5th ed., (2002). Marx, J.A., Hockberger, R.S., Walls, R.M., Adams, J., Barkin, R.M., Danzl, D.F., Gausche-Hill, M., Hamilton, G.C., Ling, L.J., & Newton, E. (Eds.). St Louis: Mosby, Inc., p. 1469.

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.

Medication	Issues and Concerns
Analgesics	
acetaminophen	Dosage / Adverse Consequences <ul style="list-style-type: none">• Daily doses greater than 4 grams/day from all sources (alone or as part of combination products) may increase risk of liver toxicity Monitoring <ul style="list-style-type: none">• For doses greater than the maximum recommended daily dose, documented assessment should reflect periodic monitoring of liver function and indicate that benefits outweigh risks

Medication	Issues and Concerns
<p data-bbox="250 226 513 331">Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)</p> <p data-bbox="250 428 617 462">Non-selective NSAIDs, e.g.,</p> <ul data-bbox="302 483 545 903" style="list-style-type: none"> • aspirin • diclofenac • diflunisal • ibuprofen • indomethacin • ketorolac • meclofenamate • naproxen • piroxicam • salicylates • tolmetin <p data-bbox="250 987 613 1058">Cyclooxygenase-II (COX-2) inhibitors, e.g.,</p> <ul data-bbox="302 1079 470 1108" style="list-style-type: none"> • celecoxib 	<p data-bbox="659 218 812 252">Indications</p> <ul data-bbox="669 277 1325 457" style="list-style-type: none"> • 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 <p data-bbox="760 491 1341 638">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</p> <p data-bbox="659 667 824 701">Interactions</p> <ul data-bbox="669 730 1364 903" style="list-style-type: none"> • 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 <p data-bbox="659 932 818 966">Monitoring</p> <ul data-bbox="669 995 1351 1247" style="list-style-type: none"> • 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 See 42 CFR 483.60(c) F428 for Table of Common Medication-Medication Interactions in Long Term Care) <p data-bbox="659 1268 971 1302">Adverse Consequences</p> <ul data-bbox="669 1331 1364 1885" style="list-style-type: none"> • 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 platelets 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

Medication	Issues and Concerns
	because of central nervous system side effects, e.g., headache, dizziness, somnolence, confusion
<p>Opioid analgesics</p> <p>Short-acting, e.g.,</p> <ul style="list-style-type: none"> • codeine • fentanyl • hydrocodone • hydromorphone • meperidine • morphine • oxycodone <p>Long-acting, e.g.,</p> <ul style="list-style-type: none"> • fentanyl, transdermal • methadone • morphine sustained release • oxycodone, sustained release 	<p>Indications</p> <ul style="list-style-type: none"> • 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 • Meperidine is not an effective oral analgesic in doses commonly used in older individuals <p>Adverse Consequences</p> <ul style="list-style-type: none"> • 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 • Meperidine use (oral or injectable) may cause confusion, respiratory depression even with therapeutic analgesic doses • Active metabolite of meperidine (normeperidine) accumulates with repeated use and has been associated with seizures
pentazocine	<p>Indications</p> <ul style="list-style-type: none"> • Limited effectiveness because it is a partial opiate agonist-antagonist; is not recommended for use in older individuals <p>Adverse Consequences</p> <ul style="list-style-type: none"> • This opioid analgesic causes central nervous system side effects (including confusion and hallucinations) more commonly than other opioid analgesics • May cause dizziness, lightheadedness, euphoria, sedation, hypotension, tachycardia, syncope

Medication	Issues and Concerns
propoxyphene and combination products with aspirin or acetaminophen	<p>Indications</p> <ul style="list-style-type: none"> • 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 <p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause hypotension and central nervous system effects (e.g., confusion, drowsiness, dizziness) that can lead to other adverse consequences such as falls
Antibiotics	
All antibiotics	<p>Indications</p> <ul style="list-style-type: none"> • Use of antibiotics should be limited to confirmed or suspected bacterial infection <p>Adverse Consequences</p> <ul style="list-style-type: none"> • Any antibiotic may cause diarrhea, nausea, vomiting, anorexia, and hypersensitivity/allergic reactions • 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
Parenteral vancomycin and aminoglycosides, e.g., <ul style="list-style-type: none"> • amikacin • gentamycin/gentamicin • tobramycin 	<p>Monitoring</p> <ul style="list-style-type: none"> • Use must be accompanied by monitoring of renal function tests (which should be compared with the baseline) and by serum medication concentrations • Serious adverse consequences may occur insidiously if adequate monitoring does not occur <p>Exception: Single dose administration prophylaxis</p> <p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause or worsen hearing loss and renal

Medication	Issues and Concerns
	failure
nitrofurantoin	<p>Indications</p> <ul style="list-style-type: none"> • 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 <60 ml/min) because of ineffectiveness and the high risk of serious adverse consequences <p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause pulmonary fibrosis (e.g., symptoms including dyspnea, cough) and peripheral neuropathy
<p>Fluoroquinolones, e.g.,</p> <ul style="list-style-type: none"> • ciprofloxacin • levofloxacin • moxifloxacin • ofloxacin 	<p>Indications</p> <ul style="list-style-type: none"> • Use should be avoided in individuals with prolonged QTc intervals or who are receiving antiarrhythmic agents in class Ia (e.g., procainamide), class Ic (e.g., flecainide) or class III (e.g., amiodarone) <p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause prolonged QTc interval • May increase risk of hypo- or hyperglycemia in individuals age 65 or older, and in individuals with diabetes mellitus, renal insufficiency (CrCl < 60 ml/min), or those receiving other glucose-altering medications • May increase risk of acute tendonitis
Anticoagulants	
warfarin	<p>Monitoring</p> <ul style="list-style-type: none"> • 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 <p>Adverse Consequences</p> <ul style="list-style-type: none"> • Multiple medication interactions exist (See 42 CFR

Medication	Issues and Concerns
	<p>483.60(c) F428 for Table of Common Medication-Medication Interactions in Long Term Care), which may:</p> <ul style="list-style-type: none"> ○ Significantly increase PT/INR results to levels associated with life-threatening bleeding, or ○ Decrease PT/INR results to ineffective levels, or ○ Increase or decrease the serum concentration of the interacting medication
Anticonvulsants	
<p>All anticonvulsants, e.g.,</p> <ul style="list-style-type: none"> • carbamazepine • gabapentin • lamotrigine • levetiracetam • oxcarbazepine • phenobarbital • phenytoin • primidone • valproic acid 	<p>Indications</p> <ul style="list-style-type: none"> • 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 • 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.) <p>Duration</p> <ul style="list-style-type: none"> • 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 <p>Monitoring</p> <ul style="list-style-type: none"> • 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 • Serum medication concentrations may help identify toxicity, but significant signs and symptoms of toxicity can occur even at normal or

Medication	Issues and Concerns
	<p>low serum concentrations.</p> <ul style="list-style-type: none"> • 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 • Symptom control for seizures or behavior can occur with subtherapeutic serum medication concentrations <p>Adverse Consequences</p> <ul style="list-style-type: none"> • 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	
<p>All antidepressants classes, e.g.,</p> <p>Alpha-adrenoceptor antagonist, e.g.,</p> <ul style="list-style-type: none"> • mirtazapine <p>Dopamine-reuptake blocking compounds, e.g.,</p> <ul style="list-style-type: none"> • bupropion <p>Monoamine oxidase inhibitors (MAOIs)</p> <p>Serotonin (5-HT₂) antagonists, e.g.,</p> <ul style="list-style-type: none"> • nefazodone • trazodone <p>Selective serotonin-norepinephrine reuptake</p>	<p>Indications</p> <ul style="list-style-type: none"> • 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 <p>Dosage</p> <ul style="list-style-type: none"> • 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

Medication	Issues and Concerns
<p>inhibitors (SNRIs), e.g.,</p> <ul style="list-style-type: none"> • duloxetine, • venlafaxine <p>Selective serotonin reuptake inhibitors (SSRIs), e.g.,</p> <ul style="list-style-type: none"> • citalopram • escitalopram • fluoxetine • fluvoxamine • paroxetine • sertraline <p>Tricyclic (TCA) and related compounds</p>	<p>Duration</p> <ul style="list-style-type: none"> • Duration should be in accordance with pertinent literature, including clinical practice guidelines • Prior to discontinuation, many antidepressants may need a gradual dose reduction or tapering to avoid a withdrawal syndrome (e.g., SSRIs, TCAs) • 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 <p>Monitoring</p> <ul style="list-style-type: none"> • 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 <p>Interactions/Adverse Consequences</p> <ul style="list-style-type: none"> • 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 • Bupropion may increase seizure risk and be associated with seizures in susceptible individuals • 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
<p>Monoamine oxidase inhibitors (MAOIs), e.g.,</p> <ul style="list-style-type: none"> • isocarboxazid • phenelzine • tranylcypromine 	<p>Indications/Contraindications</p> <ul style="list-style-type: none"> • Should not be administered to anyone with a confirmed or suspected cerebrovascular defect or to anyone with confirmed cardiovascular disease or hypertension • Should not be used in the presence of pheochromocytoma • MAO Inhibitors are rarely utilized due to their

Medication	Issues and Concerns
	<p>potential interactions with tyramine or tryptophan-containing foods, other medications, and their profound effect on blood pressure</p> <p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause hypertensive crisis if combined with certain foods, cheese, wine <p>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</p> <p>Interactions</p> <ul style="list-style-type: none"> • 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
<p>Tricyclic antidepressants (TCAs), e.g.,</p> <ul style="list-style-type: none"> • amitriptyline • amoxapine • doxepin • combination products, e.g., <ul style="list-style-type: none"> ○ amitriptyline and chlordiazepoxide ○ amitriptyline and perphenazine 	<p>Indications</p> <ul style="list-style-type: none"> • Because of strong anticholinergic and sedating properties, TCAs and combination products are rarely the medication of choice in older individuals <p>Exception: Use of TCAs may be appropriate if:</p> <ul style="list-style-type: none"> ○ 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 non-pharmacological interventions or alternative therapies are not indicated or have been considered, attempted, and failed <p>Adverse Consequences</p> <ul style="list-style-type: none"> • Compared to other categories of antidepressants, TCAs cause significant anticholinergic side effects

Medication	Issues and Concerns
	and sedation (nortriptyline and desipramine are less problematic)
Antidiabetic medications	
<p>Insulin and oral hypoglycemics, e.g.,</p> <ul style="list-style-type: none"> • acarbose • acetohexamide • chlorpropamide • glimepiride • glipizide • glyburide • metformin • repaglinide • rosiglitazone • tolazamide • tolbutamide <p>Including combination products, e.g.,</p> <ul style="list-style-type: none"> • rosiglitazone/metformin • glyburide/metformin • glipizide/metformin • pioglitazone/metformin 	<p>Monitoring</p> <ul style="list-style-type: none"> • 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 <p>NOTE: Continued or long-term need for sliding scale insulin for non-emergency coverage may indicate inadequate blood sugar control</p> <ul style="list-style-type: none"> • Residents on rosiglitazone should be monitored for visual deterioration due to new onset and/or worsening of macular edema in diabetic patients <p>Adverse Consequences</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ 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

Medication	Issues and Concerns
	<p>ketoacidosis)</p> <ul style="list-style-type: none"> 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
<p>chlorpropamide glyburide</p>	<p>Indications</p> <ul style="list-style-type: none"> 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 <p>Adverse Consequences</p> <ul style="list-style-type: none"> May cause prolonged and serious hypoglycemia (with symptoms including tachycardia, palpitations, irritability, headache, hypothermia, visual disturbances, lethargy, confusion, seizures, and/or coma)
Antifungals	
<p>Imidazoles for systemic use, e.g.,</p> <ul style="list-style-type: none"> fluconazole itraconazole ketoconazole 	<p>Indications</p> <ul style="list-style-type: none"> Should be used in lowest possible dose for shortest possible duration, especially in anyone receiving other medications known to interact with these medications <p>Interactions/Adverse Consequences</p> <ul style="list-style-type: none"> Interaction with warfarin can cause markedly elevated PT/INR, increasing bleeding risk Multiple potentially significant medication interactions may occur, for example: <ul style="list-style-type: none"> These medications when administered concurrently may increase the effect or toxicity of phenytoin, theophylline, sulfonylureas (hypoglycemics) Other medications such as rifampin and

Medication	Issues and Concerns
	<p>cimetidine may decrease the effect of these antifungals</p> <ul style="list-style-type: none"> • May cause hepatotoxicity, headaches, GI distress <p>Monitoring</p> <ul style="list-style-type: none"> • Enhanced monitoring may be required to identify and minimize adverse consequences when these antifungals are given with the following: <ul style="list-style-type: none"> ○ warfarin (PT/INR) ○ phenytoin (serum phenytoin levels) ○ theophylline (serum theophylline levels) ○ sulfonylureas (fasting blood glucose)
Antimanic medications	
Lithium	<p>Indications</p> <ul style="list-style-type: none"> • Should generally not be given to individuals with significant renal or cardiovascular disease, severe debilitation, dehydration, or sodium depletion <p>Monitoring</p> <ul style="list-style-type: none"> • Toxic levels are very close to therapeutic levels. Serum lithium concentration should be monitored periodically, and dosage adjusted accordingly <p>Interactions/Adverse Consequences</p> <ul style="list-style-type: none"> • 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	<p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause significant confusion, restlessness,

Medication	Issues and Concerns
<p>Transferase (COMT) Inhibitors, e.g.,</p> <ul style="list-style-type: none"> • entacapone <p>Dopamine agonists, e.g.,</p> <ul style="list-style-type: none"> • bromocriptine • ropinirole • pramipexole <p>MAO inhibitors, e.g.,</p> <ul style="list-style-type: none"> • selegiline <p>Others, e.g.,</p> <ul style="list-style-type: none"> • amantadine <p>Various dopaminergic combinations, e.g.,</p> <ul style="list-style-type: none"> • carbidopa/levodopa • carbidopa/levodopa/entacapone 	<p>delirium, dyskinesia, nausea, dizziness, hallucinations, agitation</p> <ul style="list-style-type: none"> • Increased risk of postural hypotension and falls, especially when given in conjunction with antihypertensive medications
<p>Antipsychotic medications</p>	
<p>All classes, e.g.,</p> <p>First generation (conventional) agents, e.g.</p> <ul style="list-style-type: none"> • chlorpromazine • fluphenazine • haloperidol • loxapine • mesoridazine • molindone • perphenazine • promazine • thioridazine • thiothixene • trifluoperazine • triflupromazine <p>Second generation (atypical) agents, e.g.</p> <ul style="list-style-type: none"> • <i>asenapine</i> • aripiprazole • clozapine • <i>iloperidone</i> 	<p>Indications <i>for Use:</i></p> <p>A. <i>Conditions Other than Dementia</i></p> <p>An antipsychotic medication should <i>generally</i> 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):</p> <ul style="list-style-type: none"> ○ Schizophrenia ○ Schizo-affective disorder ○ <i>Schizophreniform disorder</i> ○ <i>Delusional disorder</i> ○ <i>Mood disorders (e.g. bipolar disorder, severe depression refractory to other therapies and/or with psychotic features)</i>

Medication	Issues and Concerns
<ul style="list-style-type: none"> • <i>lurasidone</i> • <i>olanzapine</i> • <i>paliperidone</i> • <i>quetiapine</i> • <i>risperidone</i> • <i>ziprasidone</i> 	<ul style="list-style-type: none"> ○ <i>Psychosis in the absence of dementia</i> ○ <i>Medical illnesses with psychotic symptoms (e.g., neoplastic disease or delirium) and/or treatment related psychosis or mania (e.g., high-dose steroids)</i> ○ <i>Tourette’s Disorder</i> ○ <i>Huntington disease</i> ○ <i>Hiccups (not induced by other medications)</i> ○ <i>Nausea and vomiting associated with cancer or chemotherapy</i> <p><i>B. Behavioral or Psychological Symptoms of Dementia (BPSD)</i></p> <p><i>(Use this guidance in conjunction with guidance at §483.25 F309 Quality of Care, Review of Care and Services for a Resident with Dementia. Also consider §483.10(d)(2) F154, Right to be informed in advance about care and treatment; F155, Right to refuse treatment; and §483.10(d)(3) F280, Right to participate in planning care and treatment.) Antipsychotic medications are only appropriate for elderly residents in a small minority of circumstances (unless the antipsychotic is prescribed to treat previously diagnosed mental illness such as schizophrenia or possibly other conditions listed above). All antipsychotic medications carry a Food and Drug Administration (FDA) Black Box Warning. Since June 16, 2008, FDA warned healthcare professionals that both conventional and atypical antipsychotics are associated with an increased risk of death in elderly patients treated for dementia-related psychosis. Addition information is available at: http://www.fda.gov/Drugs/default.htm.</i></p> <p><i>(A black box warning means that medical studies indicate that the drug carries a significant risk of serious or even life-threatening adverse effects. It is</i></p>

Medication	Issues and Concerns
	<p><i>the strongest warning that the U.S. Food and Drug Administration can require a pharmaceutical company to place on the labeling of a prescription drug, or in the product literature describing it. The intent of §483.25(l) is that each resident's entire medication regimen be managed and monitored to promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being.)</i></p> <p><i>Antipsychotic medications may be considered for elderly residents with dementia but only after medical, physical, functional, psychological, emotional psychiatric, social and environmental causes have been identified and addressed. Antipsychotic medications must be prescribed at the lowest possible dosage for the shortest period of time and are subject to gradual dose reduction and re-review.</i></p> <p><i>Inadequate Indications:</i></p> <p><i>Antipsychotic medications in persons with dementia should not be used if the only indication is one or more of the following:</i></p> <ul style="list-style-type: none"> <i>• wandering</i> <i>• poor self-care</i> <i>• restlessness</i> <i>• impaired memory</i> <i>• mild anxiety</i> <i>• insomnia</i> <i>• inattention or indifference to surroundings</i> <i>• sadness or crying alone that is not related to depression or other psychiatric disorders</i> <i>• fidgeting</i>

Medication	Issues and Concerns
	<ul style="list-style-type: none"> • <i>nervousness</i> • <i>uncooperativeness (e.g. refusal of or difficulty receiving care).</i> <p>Criteria:</p> <p><i>All of the above highlight conditions/diagnoses where antipsychotic medications may possibly be appropriate, but diagnoses alone do not warrant the use of an antipsychotic unless the following criteria are also met:</i></p> <ul style="list-style-type: none"> ○ <i>The behavioral symptoms present a danger to the resident or others</i> <p><i>AND one or both of the following:</i></p> <ul style="list-style-type: none"> ○ <i>The symptoms are identified as being due to mania or psychosis (such as: auditory, visual, or other hallucinations; delusions, paranoia or grandiosity);</i> <p>OR</p> <ul style="list-style-type: none"> ○ <i>Behavioral interventions have been attempted and included in the plan of care, except in an emergency.</i> <p>Additional Criteria:</p> <p><i>Acute Situations/Emergency</i></p> <p>When an antipsychotic medication is being initiated or used to treat an <i>emergency situation (i.e., acute onset or exacerbation of symptoms or immediate threat to health or safety of resident or others)</i> related to one or more of the aforementioned conditions/diagnoses, <i>the use must meet the above criteria</i> and all of the following additional requirements:</p> <ol style="list-style-type: none"> 1. The acute treatment period is limited to seven days or less; AND 2. <i>A clinician in conjunction with the interdisciplinary team must evaluate</i>

Medication	Issues and Concerns
	<p data-bbox="846 216 1341 432"><i>and document the situation within 7 days to identify and address any contributing and underlying causes of the acute condition and verify the continuing need for an antipsychotic medication.</i></p> <p data-bbox="761 468 1333 722">3. <i>If the behaviors persist beyond the emergency situation, pertinent non-pharmacological interventions must be attempted, unless clinically contraindicated, and documented following the resolution of the acute psychiatric event.</i></p> <p data-bbox="656 753 919 785"><i>Additional Criteria:</i></p> <p data-bbox="704 821 987 852"><i>Enduring Conditions</i></p> <p data-bbox="761 884 1369 1062">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 Section B above.</p> <p data-bbox="761 1098 1346 1314"><i>In addition, before initiating or increasing an antipsychotic medication for enduring conditions, the target behavior/s must be clearly and specifically identified and documented. Monitoring must ensure that the behavioral symptoms are:</i></p> <p data-bbox="761 1350 1365 1644">1. Not due to a medical condition or problem (e.g., pain, fluid or electrolyte imbalance, infection, obstipation, medication side effect or polypharmacy) that can be expected to improve or resolve as the underlying condition is treated <i>or the offending medication(s) are discontinued;</i></p> <p data-bbox="829 1675 899 1707"><i>AND</i></p> <p data-bbox="761 1743 1325 1883">2. <i>Not due to environmental stressors alone (e.g., alteration in the resident's customary location or daily routine, unfamiliar care provider, hunger or</i></p>

Medication	Issues and Concerns
	<p><i>thirst, excessive noise for that individual, inadequate or inappropriate staff response), that can be addressed to improve the symptoms or maintain safety;</i></p> <p><i>AND</i></p> <p><i>3. Not due to psychological stressors alone (e.g., loneliness, taunting, abuse), 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, unaddressed sensory deficits) that can be expected to improve or resolve as the situation is addressed;</i></p> <p><i>AND</i></p> <p><i>4. Persistent. In this case, there must be clear documented evidence in the medical record that the situation or condition continues or recurs over time (persists) and that other approaches that have been attempted have failed to adequately address the behavioral/psychological symptoms and that the resident's quality of life is negatively affected by the behaviors/symptoms as described above.</i></p> <p><i>New Admissions:</i></p> <p><i>Many residents are admitted to a SNF/NF already on an antipsychotic medication. The medication may have been started in the hospital or the community, which can make it challenging for the facility and clinical team to identify the indication for use. However, the facility is responsible for:</i></p> <ul style="list-style-type: none"> <i>• Preadmission screening for mentally ill and intellectually disabled individuals, and;</i> <i>• Obtaining physician's orders for</i>

Medication	Issues and Concerns
	<p style="text-align: center;"><i>the resident's immediate care.</i></p> <p><i>This PASRR screening (F285) should provide pertinent information including appropriate clinical indications for the use of an antipsychotic.</i></p> <p><i>For residents who do not require PASRR screening and are admitted on an antipsychotic medication, the facility must re-evaluate the use of the antipsychotic medication at the time of admission and/or within two weeks of admission (at the time of the initial MDS assessment) and consider whether or not the medication can be reduced (tapered) or discontinued).</i></p>
	<p><i>Dosage:</i></p> <p><i>When dosing an antipsychotic, the treatment should be at the lowest possible dose to improve the target symptoms being monitored. It is important to note that doses for acute indications (e.g. delirium or acute psychosis) may differ from those used for long-term treatment of various conditions.</i></p> <p><i>The table below is provided only as a general guide for residents with dementia who have met all of the criteria outlined above. Orders for doses greater than those that appear in the table warrant closer review for adverse effects and risk/benefit evaluation. However, also note that in some cases, residents may require lower doses than those listed on the table. This is an individual, clinical decision based on a number of complex factors. Surveyors are strongly advised to speak with the practitioner/prescriber and/or consultant pharmacist in cases where an antipsychotic medication is prescribed for an elderly resident with dementia.</i></p>

Medication	Issues and Concerns																																												
	<p style="text-align: center;">Daily Dose Thresholds for Antipsychotic Medications Used <i>to Treat Residents with BPSD</i></p> <table border="1" data-bbox="659 432 1364 1325"> <thead> <tr> <th data-bbox="659 432 1003 506"><i>Generic Name</i></th> <th data-bbox="1003 432 1364 506"><i>Maximum Total Dosage (mg) per day</i></th> </tr> </thead> <tbody> <tr> <td colspan="2" data-bbox="659 506 1364 548" style="text-align: center;"><i>First Generation or Typical Agents</i></td> </tr> <tr> <td data-bbox="659 548 1003 583">chlorpromazine</td> <td data-bbox="1003 548 1364 583">75</td> </tr> <tr> <td data-bbox="659 583 1003 619">fluphenazine</td> <td data-bbox="1003 583 1364 619">4</td> </tr> <tr> <td data-bbox="659 619 1003 655">haloperidol</td> <td data-bbox="1003 619 1364 655">2</td> </tr> <tr> <td data-bbox="659 655 1003 690">loxapine</td> <td data-bbox="1003 655 1364 690">10</td> </tr> <tr> <td data-bbox="659 690 1003 726">molindone</td> <td data-bbox="1003 690 1364 726">10</td> </tr> <tr> <td data-bbox="659 726 1003 762">perphenazine</td> <td data-bbox="1003 726 1364 762">8</td> </tr> <tr> <td data-bbox="659 762 1003 798">thioridazine</td> <td data-bbox="1003 762 1364 798">75 *</td> </tr> <tr> <td data-bbox="659 798 1003 833">thiothixene</td> <td data-bbox="1003 798 1364 833">7</td> </tr> <tr> <td data-bbox="659 833 1003 869">trifluoperazine</td> <td data-bbox="1003 833 1364 869">8</td> </tr> <tr> <td colspan="2" data-bbox="659 869 1364 911" style="text-align: center;"><i>Second Generation or Atypical</i></td> </tr> <tr> <td data-bbox="659 911 1003 947">aripiprazole</td> <td data-bbox="1003 911 1364 947">10</td> </tr> <tr> <td data-bbox="659 947 1003 982">clozapine</td> <td data-bbox="1003 947 1364 982">50</td> </tr> <tr> <td data-bbox="659 982 1003 1018">olanzapine</td> <td data-bbox="1003 982 1364 1018">5</td> </tr> <tr> <td data-bbox="659 1018 1003 1054">quetiapine</td> <td data-bbox="1003 1018 1364 1054">150</td> </tr> <tr> <td data-bbox="659 1054 1003 1089">risperidone</td> <td data-bbox="1003 1054 1364 1089">2</td> </tr> <tr> <td data-bbox="659 1089 1003 1125">ziprasidone</td> <td data-bbox="1003 1089 1364 1125">**</td> </tr> <tr> <td data-bbox="659 1125 1003 1161"><i>paliperidone</i></td> <td data-bbox="1003 1125 1364 1161">**</td> </tr> <tr> <td data-bbox="659 1161 1003 1197"><i>asenapine</i></td> <td data-bbox="1003 1161 1364 1197">**</td> </tr> <tr> <td data-bbox="659 1197 1003 1232"><i>iloperidone</i></td> <td data-bbox="1003 1197 1364 1232">**</td> </tr> <tr> <td data-bbox="659 1232 1003 1268"><i>lurasidone</i></td> <td data-bbox="1003 1232 1364 1268">**</td> </tr> </tbody> </table> <p data-bbox="659 1367 1271 1436">* <i>Due to additional black box warnings of QTC prolongation, its use should be avoided.</i></p> <p data-bbox="659 1482 1305 1587">** <i>No studies have been conducted or have results available to assess the drug's safety or efficacy in older adults with dementia.</i></p>	<i>Generic Name</i>	<i>Maximum Total Dosage (mg) per day</i>	<i>First Generation or Typical Agents</i>		chlorpromazine	75	fluphenazine	4	haloperidol	2	loxapine	10	molindone	10	perphenazine	8	thioridazine	75 *	thiothixene	7	trifluoperazine	8	<i>Second Generation or Atypical</i>		aripiprazole	10	clozapine	50	olanzapine	5	quetiapine	150	risperidone	2	ziprasidone	**	<i>paliperidone</i>	**	<i>asenapine</i>	**	<i>iloperidone</i>	**	<i>lurasidone</i>	**
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	<p>Duration:</p> <p><i>Refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance.</i></p>																																												
	<p>Monitoring:</p> <p><i>When monitoring antipsychotics, it is important to not</i></p>																																												

Medication	Issues and Concerns
	<p><i>only evaluate ongoing effectiveness and potential adverse consequences, as discussed below, but also to evaluate the use of any other psychopharmacological medications (e.g. mood stabilizers, benzodiazepines) being given to the resident. Specifically, surveyors should review the record to determine whether the facility can explain the rationale for adding, or switching from an antipsychotic to another category (or categories) of psychopharmacological agents; otherwise, both may potentially be unnecessary medications. Surveyors should investigate further in cases where more than one antipsychotic agent has been prescribed. Surveyors should investigate further in cases where more than one antipsychotic agent has been prescribed, or where an antipsychotic has been discontinued and a medication such as a mood stabilizer has been added.</i></p> <p><i>Effectiveness:</i></p> <p><i>After initiating or increasing the dose of an antipsychotic medication, the behavioral symptoms must be reevaluated periodically (at least during quarterly care plan review, but often more frequently, depending on the resident’s response to the medication) to determine the effectiveness of the antipsychotic and the potential for reducing or discontinuing the dose based on target symptoms and any adverse effects or functional impairment.</i></p> <p><i>Potential Adverse Consequences:</i></p> <p><i>The facility assures that residents are being adequately monitored for adverse consequences such as:</i></p> <ul style="list-style-type: none"> <i>• General: anticholinergic effects (see Table II), falls, excessive sedation</i> <i>• Cardiovascular: cardiac arrhythmias, orthostatic hypotension</i> <i>• Metabolic: increase in total cholesterol and triglycerides, unstable or poorly controlled blood sugar, weight gain</i>

Medication	Issues and Concerns
	<ul style="list-style-type: none"> • <i>Neurologic: akathisia, neuroleptic malignant syndrome (NMS), parkinsonism, tardive dyskinesia, cerebrovascular event (e.g., stroke, transient ischemic attack (TIA)) in individuals with dementia</i> <p><i>If the antipsychotic medication is identified as probably causing or contributing to adverse consequences as identified above, the facility must act upon this. In some cases, the benefits of treatment will still be considered to outweigh the risks or burdens of treatment, so the medication may be continued; however, the facility and prescriber must document the rationale for the decision and also that the resident, family member or legal representative is aware of and involved in the decision to continue the medication.</i></p>
Anxiolytics	
<p>All Anxiolytics</p> <p>Benzodiazepines, Short-acting, e.g.,</p> <ul style="list-style-type: none"> • alprazolam • estazolam • lorazepam • oxazepam • temazepam <p>Benzodiazepines, Long acting, e.g.,</p> <ul style="list-style-type: none"> • chlordiazepoxide • clonazepam • clorazepate • diazepam • flurazepam • quazepam <p>bupirone</p> <p>Other antidepressants except bupropion</p>	<p>Indications</p> <ul style="list-style-type: none"> • Anxiolytic medications should only be used when: <ul style="list-style-type: none"> ○ 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: <ol style="list-style-type: none"> a. Generalized anxiety disorder b. Panic disorder c. Symptomatic anxiety that occurs in residents with another diagnosed psychiatric disorder d. Sleep disorders (See Sedatives/Hypnotics) e. Acute alcohol or benzodiazepine withdrawal f. Significant anxiety in response to a situational trigger

Medication	Issues and Concerns
	<p data-bbox="834 226 1333 331">g. Delirium, dementia, and other cognitive disorders with associated behaviors that:</p> <ul style="list-style-type: none"> <li data-bbox="906 365 1268 436">– Are quantitatively and objectively documented; <li data-bbox="906 470 1141 499">– Are persistent; <li data-bbox="906 533 1328 604">– Are not due to preventable or correctable reasons; and <li data-bbox="906 638 1360 772">– Constitute clinically significant distress or dysfunction to the resident or represent a danger to the resident or others <ul style="list-style-type: none"> <li data-bbox="662 806 1344 877">• Evidence exists that other possible reasons for the individual’s distress have been considered; and <li data-bbox="662 911 1354 1052">• 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 <li data-bbox="662 1085 1354 1157">• There are clinical situations that warrant the use of these medications such as: <ul style="list-style-type: none"> <li data-bbox="786 1190 1360 1295">– a long-acting benzodiazepine is being used to withdraw a resident from a short-acting benzodiazepine <li data-bbox="786 1329 1365 1434">– used for neuromuscular syndromes (e.g., cerebral palsy, tardive dyskinesia, restless leg syndrome or seizure disorders) <li data-bbox="786 1467 1328 1497">– symptom relief in end of life situations <p data-bbox="662 1530 760 1560">Dosage</p> <ul style="list-style-type: none"> <li data-bbox="662 1593 1317 1774">• 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 <p data-bbox="724 1829 1307 1900" style="text-align: center;">Total Daily Dose Thresholds for Anxiolytic Medications</p>

Medication	Issues and Concerns																						
	<table border="1" data-bbox="667 247 1338 701"> <thead> <tr> <th data-bbox="667 247 1002 310">Generic Medication</th> <th data-bbox="1002 247 1338 310">Dosage</th> </tr> </thead> <tbody> <tr> <td data-bbox="667 310 1002 352">flurazepam</td> <td data-bbox="1002 310 1338 352">15 mg</td> </tr> <tr> <td data-bbox="667 352 1002 394">chlordiazepoxide</td> <td data-bbox="1002 352 1338 394">20 mg</td> </tr> <tr> <td data-bbox="667 394 1002 436">clorazepate</td> <td data-bbox="1002 394 1338 436">15 mg</td> </tr> <tr> <td data-bbox="667 436 1002 478">diazepam</td> <td data-bbox="1002 436 1338 478">5 mg</td> </tr> <tr> <td data-bbox="667 478 1002 520">clonazepam</td> <td data-bbox="1002 478 1338 520">1.5 mg</td> </tr> <tr> <td data-bbox="667 520 1002 562">quazepam</td> <td data-bbox="1002 520 1338 562">7.5 mg</td> </tr> <tr> <td data-bbox="667 562 1002 604">estazolam</td> <td data-bbox="1002 562 1338 604">0.5 mg</td> </tr> <tr> <td data-bbox="667 604 1002 646">alprazolam</td> <td data-bbox="1002 604 1338 646">0.75 mg</td> </tr> <tr> <td data-bbox="667 646 1002 688">oxazepam</td> <td data-bbox="1002 646 1338 688">30 mg</td> </tr> <tr> <td data-bbox="667 688 1002 701">lorazepam</td> <td data-bbox="1002 688 1338 701">2 mg</td> </tr> </tbody> </table> <p data-bbox="659 783 784 814">Duration</p> <ul data-bbox="659 846 1328 993" style="list-style-type: none"> • 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 <p data-bbox="659 1024 979 1056">Adverse Consequences</p> <ul data-bbox="659 1087 1357 1119" style="list-style-type: none"> • May increase risk of confusion, sedation, and falls 	Generic Medication	Dosage	flurazepam	15 mg	chlordiazepoxide	20 mg	clorazepate	15 mg	diazepam	5 mg	clonazepam	1.5 mg	quazepam	7.5 mg	estazolam	0.5 mg	alprazolam	0.75 mg	oxazepam	30 mg	lorazepam	2 mg
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lorazepam	2 mg																						
diphenhydramine and hydroxyzine	<p data-bbox="659 1150 813 1182">Indications</p> <ul data-bbox="659 1213 1219 1245" style="list-style-type: none"> • Not appropriate for use as an anxiolytic 																						
meprobamate	<p data-bbox="659 1287 813 1318">Indications</p> <ul data-bbox="659 1350 1304 1413" style="list-style-type: none"> • Highly addictive and sedating medication; not indicated for use in older individuals <p data-bbox="659 1444 889 1476">Dosage/Duration</p> <ul data-bbox="659 1507 1357 1612" style="list-style-type: none"> • Those who have used meprobamate for prolonged periods may be physically and/or psychologically dependent and may need to be withdrawn slowly 																						
Cardiovascular medications (including antihypertensives)																							
All antiarrhythmics	<p data-bbox="659 1791 971 1822">Adverse Consequences</p> <ul data-bbox="659 1854 1344 1885" style="list-style-type: none"> • Cardiac antiarrhythmics can have serious adverse 																						

Medication	Issues and Concerns
	effects in older individuals, including impaired mental function, falls, appetite, behavior, and heart function
amiodarone	<p>Indications</p> <ul style="list-style-type: none"> • 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 • 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* <p>* Goldschlager, N., Epstein, A.E., Naccarelli, G., Olshansky, B., & Singh, B. (2000). Practical guidelines for clinicians who treat patients with amiodarone. <i>Archives of Internal Medicine</i>, 160, pp. 1741-1748.</p> <p>* Denus, S., Sanoski, C.A., Carlson, J., Opolski, G., & Spinler, S.A. (2005). Rate vs rhythm control in patients with atrial fibrillation: A meta-analysis. <i>Archives of Internal Medicine</i>, 165, pp. 258-262.</p> <p>Dosage/Monitoring</p> <ul style="list-style-type: none"> • 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 <p>Interactions/Adverse Consequences</p> <ul style="list-style-type: none"> • 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 • May cause clinically significant medication

Medication	Issues and Concerns
	<p>interactions; for example, with digoxin and warfarin</p> <ul style="list-style-type: none"> • Toxicity increases with higher doses and longer duration of use
disopyramide	<p>Adverse Consequences</p> <ul style="list-style-type: none"> • Disopyramide has potent negative inotropic effects (decreased force of heart contraction), which may induce heart failure in older individuals, and is also strongly anticholinergic
All antihypertensives	<p>Dosage/Monitoring</p> <ul style="list-style-type: none"> • Doses of individual antihypertensives may require modification in order to achieve desired effects while minimizing adverse consequences, especially when multiple antihypertensives are prescribed simultaneously • When discontinuing some antihypertensives (e.g., clonidine, beta blockers), gradual tapering may be required to avoid adverse consequences caused by abrupt cessation <p>Interactions/Adverse Consequences</p> <ul style="list-style-type: none"> • May cause dizziness, postural hypotension, fatigue, and an increased risk for falls • Many other medications may interact with antihypertensives to potentiate their effect (e.g., levodopa, nitrates)
<p>Alpha blockers, e.g.,</p> <ul style="list-style-type: none"> • alfuzosin • doxazosin • prazosin • tamsulosin • terazosin 	<p>Adverse Consequences</p> <ul style="list-style-type: none"> • 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 • Prazosin can cause more CNS side effects and generally should be avoided in older individuals
Angiotensin converting enzyme (ACE) inhibitors,	Monitoring

Medication	Issues and Concerns
<p>e.g.,</p> <ul style="list-style-type: none"> • benazepril • captopril • enalapril • fosinopril • lisinopril • ramipril <p>Angiotensin II receptor blockers, e.g.,</p> <ul style="list-style-type: none"> • candesartan • eprosartan • irbesartan • losartan • olmesartan • valsartan 	<ul style="list-style-type: none"> • Monitoring of serum potassium is necessary especially in individuals receiving ACE inhibitors with potassium, or potassium sparing diuretics <p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause angioedema (signs and symptoms of immediate hypersensitivity), chronic persistent nonproductive cough, or may worsen renal failure • Potential for life-threatening elevation of serum potassium concentrations when used in combination with potassium supplements, potassium-sparing diuretics including spironolactone
<p>Beta adrenergic blockers, e.g.,</p> <p>Nonselective, e.g.,</p> <ul style="list-style-type: none"> • propranolol <p>Cardioselective, e.g.,</p> <ul style="list-style-type: none"> • atenolol • esmolol • metoprolol • nadolol • timolol 	<p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause or exacerbate: <ul style="list-style-type: none"> ○ Bradycardia, especially in individuals receiving other medications that affect cardiac conduction (e.g., calcium channel blockers); ○ Dizziness, fatigue; depression, bronchospasm (especially, but not exclusively, propranolol); or ○ Cardiac decompensation that may require adjusting dose in residents with acute heart failure • May mask tachycardia associated with symptomatic hypoglycemia • May have increased effect or may accumulate in individuals with hepatic impairment
<p>Calcium channel blockers, e.g.,</p> <ul style="list-style-type: none"> • nifedipine • isradipine • amlodipine • nisoldipine 	<p>Adverse consequences</p> <ul style="list-style-type: none"> • May cause clinically significant constipation • May cause peripheral edema • Some agents may cause generalized aching,

Medication	Issues and Concerns
<ul style="list-style-type: none"> • diltiazem • verapamil 	<p>headache, muscle pain</p> <ul style="list-style-type: none"> • Short acting/immediate release nifedipine increases the risk of cardiac complications and should not be used
<p>methyldopa</p> <p>Including combination products such as methyldopa/hydrochlorothiazide</p>	<p>Indications</p> <ul style="list-style-type: none"> • Alternate treatments for hypertension are preferred <p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause bradycardia and excessive sedation; may exacerbate depression in older individuals
<p>digoxin</p>	<p>Indications</p> <ul style="list-style-type: none"> • Digoxin is indicated only for the following diagnoses: congestive heart failure, atrial fibrillation, paroxysmal supraventricular tachycardia, or atrial flutter • Should be used with caution in individuals with impaired renal function <p>Dosage</p> <ul style="list-style-type: none"> • Daily doses in older individuals should ordinarily not exceed 0.125 mg/day except when used to control atrial arrhythmia and ventricular rate <p>Monitoring</p> <ul style="list-style-type: none"> • 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”) • Adverse consequences may occur even with therapeutic serum concentration, especially in older individuals <p>Interactions/Adverse Consequences</p> <ul style="list-style-type: none"> • May interact with many other medications, possibly resulting in digoxin toxicity or elevated serum concentrations of other medications

Medication	Issues and Concerns
	<ul style="list-style-type: none"> • May cause significant bradycardia, especially when used in individuals taking other medications affecting cardiac conduction • Toxicity may cause fatigue, nausea, vomiting, anorexia, delirium, cardiac arrhythmia
<p>Diuretics, e.g.,</p> <ul style="list-style-type: none"> • bumetanide • ethacrynic acid • furosemide • hydrochlorothiazide • metolazone • spironolactone • torsemide • triamterene 	<p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause fluid and electrolyte imbalance (hypo/hypermnatremia, hypo/hyperkalemia, dehydration, etc.), hypotension; may precipitate or exacerbate urinary incontinence, falls
<p>Nitrates, e.g.,</p> <ul style="list-style-type: none"> • isosorbide mononitrate • isosorbide dinitrate • nitroglycerin 	<p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause headaches, dizziness, lightheadedness, faintness, or symptomatic orthostatic hypotension, especially when initially started or when taken in combination with antihypertensive medications
<p>Cholesterol lowering medications</p>	
<p>HMG-CoA Reductase Inhibitors (“statins”), e.g.,</p> <ul style="list-style-type: none"> • atorvastatin • fluvastatin • lovastatin • pravastatin • rosuvastatin • simvastatin 	<p>Monitoring</p> <ul style="list-style-type: none"> • Liver function monitoring should be performed consistent with manufacturer’s recommendations, generally accepted as: <ul style="list-style-type: none"> ○ Prior to initiation of therapy, at 12 weeks following both initiation of therapy and any increase in dose, and periodically (e.g., semiannually) thereafter <p>Adverse Consequences</p> <ul style="list-style-type: none"> • May impair liver function; liver function tests should be monitored as indicated above • May cause muscle pain, myopathy, and rhabdomyolysis (breakdown of skeletal muscle) that can precipitate kidney failure especially in combination with other cholesterol lowering

Medication	Issues and Concerns
	medications.
cholestyramine	<p>Interactions</p> <ul style="list-style-type: none"> • May reduce the absorption of other medications being taken concurrently. Other medications, including diuretics, beta-blockers, corticosteroids, thyroid hormones, digoxin, valproic acid, NSAIDs, sulfonyleureas, and warfarin should be administered one hour before or four hours after cholestyramine administration to avoid this interaction <p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause constipation, dyspepsia, nausea or vomiting, abdominal pain
fibrates, e.g., <ul style="list-style-type: none"> • fenofibrate • clofibrate 	<p>Monitoring</p> <ul style="list-style-type: none"> • Fenofibrate and clofibrate require regular monitoring of liver tests as well as evaluating the complete blood count (CBC) prior to and after initiation
niacin	<p>Monitoring</p> <ul style="list-style-type: none"> • Monitor glucose and liver function tests regularly <p>Adverse Consequences</p> <ul style="list-style-type: none"> • Interferes with glucose control and can aggravate diabetes • Can exacerbate active gallbladder disease and gout • Flushing is common
Cognitive Enhancers	
Cholinesterase inhibitors, e.g., <ul style="list-style-type: none"> • donepezil • galantamine • rivastigmine 	<p>Indications</p> <ul style="list-style-type: none"> • As the underlying disorder progresses into advanced stages, the continued use of the medication should be reevaluated <p>Adverse Consequences</p> <ul style="list-style-type: none"> • May affect cardiac conduction, especially in individuals who already have a cardiac conduction

Medication	Issues and Concerns
	<p>disorder or who are taking other medications that affect heart rate</p> <ul style="list-style-type: none"> • 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
<p>NMDA receptor antagonists, e.g.,</p> <ul style="list-style-type: none"> • memantine 	<p>Indications</p> <ul style="list-style-type: none"> • As the underlying disorder progresses into advanced stages, the continued use of the medication should be reevaluated <p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause restlessness, distress, dizziness, somnolence, hypertension, headache, hallucinations, or increased confusion
Cough, cold, and allergy medications	
<p>All cough, cold, allergy medications</p>	<p>Indications/Duration</p> <ul style="list-style-type: none"> • 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
<p>Antihistamine H-1 blockers, e.g.,</p> <ul style="list-style-type: none"> • chlorpheniramine • cyproheptadine • diphenhydramine • hydroxyzine • meclizine • promethazine 	<p>Indications</p> <ul style="list-style-type: none"> • 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 <p>Dosage/Duration</p> <ul style="list-style-type: none"> • 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

Medication	Issues and Concerns
	<p>with anticholinergic properties (see Table II)</p> <p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause excessive sedation, confusion, cognitive impairment, distress, dry mouth, constipation, urinary retention. These may lead to other adverse consequences such as falls
<p>Oral decongestants, e.g.,</p> <ul style="list-style-type: none"> • pseudoephedrine 	<p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause dizziness, nervousness, insomnia, palpitations, urinary retention, elevated blood pressure • Should be used with caution in individuals who have insomnia or hypertension
Gastrointestinal medications	
<p>Phenothiazine-related antiemetics, e.g.,</p> <ul style="list-style-type: none"> • prochlorperazine • promethazine 	<p>Indications</p> <ul style="list-style-type: none"> • Use with caution in individuals with Parkinson’s disease, narrow-angle glaucoma, BPH, seizure disorder <p>Adverse Consequences</p> <ul style="list-style-type: none"> • 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
trimethobenzamide	<p>Adverse Consequences</p> <ul style="list-style-type: none"> • Relatively ineffective antiemetic that can cause

Medication	Issues and Concerns
	<p>significant extrapyramidal side effects in addition to lethargy, sedation, confusion</p> <p>Exception: May be indicated in patients with Parkinson's Disease taking apomorphine</p>
<p>metoclopramide</p>	<p>Indications</p> <ul style="list-style-type: none"> • High-risk medication with limited clinical indication and limited demonstrated effectiveness* • Not recommended for first-line treatment of gastroesophageal reflux disease, especially in older individuals • When used for diabetic gastroparesis, or other indications, relative benefits and risks should be assessed and documented <p>* Lata, P.F., Pigarelli, D.L. (2003). Chronic metoclopramide therapy for diabetic gastroparesis. <i>Ann Pharmacotherapy</i>, 37(1), pp. 122-126.</p> <p>Adverse Consequences</p> <ul style="list-style-type: none"> • Especially in older individuals, metoclopramide may cause restlessness, drowsiness, insomnia, depression, distress, anorexia, and extrapyramidal symptoms, and may lower the seizure threshold • May increase seizures in individuals with seizure disorders or exacerbate symptoms in individuals with Parkinson's Disease <p>Monitoring</p> <ul style="list-style-type: none"> • It is essential to closely monitor at-risk individuals for adverse consequences
<p>Proton pump inhibitors (PPI), e.g.,</p> <ul style="list-style-type: none"> • esomeprazole • lansoprazole • omeprazole • rabeprazole 	<p>Indications</p> <ul style="list-style-type: none"> • Indication for use should be based on clinical symptoms and/or endoscopic findings • 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

Medication	Issues and Concerns
<p>H-2 antagonists, e.g.,</p> <ul style="list-style-type: none"> • cimetidine • famotidine • ranitidine 	<p>Duration</p> <ul style="list-style-type: none"> • 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) <p>Dosage</p> <ul style="list-style-type: none"> • Dosing of histamine-H2 antagonists should be based on renal function <p>Interactions</p> <ul style="list-style-type: none"> • Cimetidine has higher incidence of medication interactions and should be avoided in older individuals <p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause or exacerbate headache, nausea, vomiting, flatulence, dysphagia, abdominal pain, diarrhea, or other gastrointestinal symptoms • H-2 antagonists may cause confusion • PPIs may increase the risk of clostridium difficile colitis
Glucocorticoids	
<p>All glucocorticoids (except topical or inhaled dosage forms), e.g.,</p> <ul style="list-style-type: none"> • dexamethasone • hydrocortisone • methylprednisolone • prednisone 	<p>Duration/Monitoring</p> <ul style="list-style-type: none"> • Necessity for continued use should be documented, along with monitoring for and management of adverse consequences <p>Adverse Consequences</p> <ul style="list-style-type: none"> • Intermediate- or longer-term use may cause hyperglycemia, psychosis, edema, insomnia, hypertension, osteoporosis, mood lability, or depression
Hematinics	
<p>Erythropoiesis stimulants, e.g.,</p>	<p>Indications</p> <ul style="list-style-type: none"> • Assessment of causes and categories of anemia

Medication	Issues and Concerns
<ul style="list-style-type: none"> • darbepoetin • erythropoietin 	<p>should precede or accompany the use of this medication</p> <p>Monitoring</p> <ul style="list-style-type: none"> • 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 <p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause or worsen hypertension • Excessive dose or duration can lead to polycythemia, dangerous thrombotic events including myocardial infarction and stroke
<p>Iron</p>	<p>Indications</p> <ul style="list-style-type: none"> • Iron therapy is not indicated in anemia of chronic disease when iron stores and transferrin levels are normal or elevated <p>Dosage/Duration</p> <ul style="list-style-type: none"> • 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 <p>Monitoring</p> <ul style="list-style-type: none"> • Baseline serum iron or ferritin level and periodic CBC or hematocrit/ hemoglobin <p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause constipation, dyspepsia • Can accumulate in tissues and cause multiple complications if given chronically despite normal or high iron stores
<p>Laxatives</p>	

Medication	Issues and Concerns
<p>All categories including bulk producing laxatives, hyperosmolar agents, saline laxatives, stimulant laxatives, emollient laxatives</p>	<p>Adverse Consequences</p> <ul style="list-style-type: none"> • May cause flatulence, bloating, abdominal pain • Bulk forming laxatives and stool softeners may cause accumulation of stool and possible bowel obstruction, if not used with adequate fluids or in individuals with other causes of impaired bowel motility
Muscle relaxants	
<p>All muscle relaxants, e.g.,</p> <ul style="list-style-type: none"> • baclofen • carisoprodol • chlorzoxazone • cyclobenzaprine • dantrolene • metaxalone • methocarbamol • orphenadrine 	<p>Indications/Adverse Consequences</p> <ul style="list-style-type: none"> • Most are poorly tolerated by older individuals due to anticholinergic side effects (see Table II), sedation, or weakness • Long-term use in individuals with complications due to multiple sclerosis, spinal cord injuries, cerebral palsy, and other select conditions may be indicated, although close monitoring is still warranted • Abrupt cessation of some muscle relaxants may cause or predispose individuals to seizures or hallucinations <p>Exception: Periodic use (once every three months) for a short duration (not more than seven days) may be appropriate, when other interventions or alternative medications are not effective or not indicated</p>
Orexigenics (appetite stimulants)	
<p>All appetite stimulants, e.g.,</p> <ul style="list-style-type: none"> • megestrol acetate • oxandrolone • dronabinol 	<p>Indications</p> <ul style="list-style-type: none"> • Use should be reserved for situations where assessment and management of underlying correctable causes of anorexia and weight loss is not feasible or successful, and after evaluating potential benefits/risks <p>Monitoring</p> <ul style="list-style-type: none"> • Appetite and weight should be monitored at least monthly and agent should be discontinued if there

Medication	Issues and Concerns
	<p>is no improvement.</p> <p>Adverse Consequences</p> <ul style="list-style-type: none"> • Megesterol acetate may cause fluid retention, adrenal suppression, and symptoms of adrenal insufficiency • 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
Osteoporosis medications	
<p>Bisphosphonates, e.g.,</p> <ul style="list-style-type: none"> • alendronate • ibandronate • risedronate 	<p>Dosage</p> <ul style="list-style-type: none"> • These medications must be taken according to very specific directions, including time of day, position, and timing relative to other medications and food <p>Monitoring</p> <ul style="list-style-type: none"> • Individuals receiving these medications should be monitored closely for gastrointestinal complications, including esophageal or gastric erosion <p>Adverse Consequences</p> <ul style="list-style-type: none"> • 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)
Platelet inhibitors	
<p>All platelet inhibitors, e.g.,</p> <ul style="list-style-type: none"> • dipyridamole • dipyridamole extended-release and aspirin (as fixed-dose combination) 	<p>Interactions/Adverse Consequences</p> <ul style="list-style-type: none"> • May cause thrombocytopenia and increase risk of bleeding • Common side effects include headache, dizziness, and vomiting

Medication	Issues and Concerns
<ul style="list-style-type: none"> • aspirin • clopidogrel 	<ul style="list-style-type: none"> • See discussion at NSAIDs regarding aspirin • Concurrent use with warfarin or NSAIDs may increase risk of bleeding
ticlopidine	<p>Indication</p> <ul style="list-style-type: none"> • 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 <p>Adverse Consequences</p> <ul style="list-style-type: none"> • Associated with more severe side effects and considerably more toxic than other platelet inhibitors; use should be avoided in older individuals • Most serious side effects involve the hematologic system, including potentially life-threatening neutropenia • May also cause nausea, vomiting, and diarrhea
Respiratory medications	
theophylline	<p>Interactions</p> <ul style="list-style-type: none"> • Potentially significant interactions with many other medications may occur, especially various antibiotics, seizure medications, and cardiac medications <p>Monitoring/Adverse Consequences</p> <ul style="list-style-type: none"> • 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 • Periodic monitoring of serum concentrations helps identify or verify toxicity
Inhalant medications classes, e.g.,	Adverse Consequences

Medication	Issues and Concerns
<p>Anticholinergic, e.g.,</p> <ul style="list-style-type: none"> • ipratropium • tiotropium <p>Beta 2 agonists, e.g.,</p> <ul style="list-style-type: none"> • albuterol • formoterol • pirbuterol acetate • salmeterol <p>Corticosteroids, e.g.,</p> <ul style="list-style-type: none"> • beclomethasone • budesonide • flunisolide • fluticasone • triamcinolone acetonide <p>Miscellaneous, e.g.,</p> <ul style="list-style-type: none"> • cromolyn • nedocromil sodium 	<ul style="list-style-type: none"> • 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)	
<p>All hypnotics</p> <p>Benzodiazepine hypnotics, e.g.,</p> <ul style="list-style-type: none"> • estazolam • flurazepam • quazepam • temazepam • triazolam <p>Non-benzodiazepine hypnotics, e.g.,</p> <ul style="list-style-type: none"> • eszopiclone • zaleplon • zolpidem <p>Melatonin receptor agonists, e.g.,</p> <ul style="list-style-type: none"> • ramelteon <p>Other hypnotics, e.g.,</p>	<p>Indications</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ 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

Medication	Issues and Concerns
<ul style="list-style-type: none"> • chloral hydrate <p>Miscellaneous agents used for sleep, e.g.,</p> <ul style="list-style-type: none"> • sedating antidepressants (e.g., trazodone) • sedating antihistamines (e.g., hydroxyzine) 	<p>sleep, awakening, toileting, medication treatments)</p> <ul style="list-style-type: none"> ○ provision of care in a manner that disrupts sleep ○ caffeine or medications known to disrupt sleep ○ pain and discomfort ○ underlying conditions (secondary or comorbid insomnia) such as psychiatric disorders (e.g., depression), cardiopulmonary disorders (e.g., COPD, CHF), urinary frequency, pain, obstructive sleep apnea, and restless leg syndrome <ul style="list-style-type: none"> • 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 <p>Exceptions:</p> <ul style="list-style-type: none"> • 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

Medication	Issues and Concerns																																
	aggravating factor can be identified and/or effectively treated																																
	<p>Dosage</p> <p>Daily Dose Thresholds For Sedative-Hypnotic Medications</p> <table border="1" data-bbox="667 514 1336 1167"> <thead> <tr> <th data-bbox="667 514 1003 577">Generic Medication</th> <th data-bbox="1003 514 1336 577">Oral Dosage</th> </tr> </thead> <tbody> <tr> <td data-bbox="667 577 1003 619">chloral hydrate*</td> <td data-bbox="1003 577 1336 619">500 mg</td> </tr> <tr> <td data-bbox="667 619 1003 661">diphenhydramine*</td> <td data-bbox="1003 619 1336 661">25 mg</td> </tr> <tr> <td data-bbox="667 661 1003 703">estazolam</td> <td data-bbox="1003 661 1336 703">0.5 mg</td> </tr> <tr> <td data-bbox="667 703 1003 745">eszopiclone</td> <td data-bbox="1003 703 1336 745">1 mg</td> </tr> <tr> <td data-bbox="667 745 1003 787">flurazepam*</td> <td data-bbox="1003 745 1336 787">15 mg</td> </tr> <tr> <td data-bbox="667 787 1003 829">hydroxyzine*</td> <td data-bbox="1003 787 1336 829">50 mg</td> </tr> <tr> <td data-bbox="667 829 1003 871">lorazepam</td> <td data-bbox="1003 829 1336 871">1 mg</td> </tr> <tr> <td data-bbox="667 871 1003 913">oxazepam</td> <td data-bbox="1003 871 1336 913">15 mg</td> </tr> <tr> <td data-bbox="667 913 1003 955">quazepam*</td> <td data-bbox="1003 913 1336 955">7.5 mg</td> </tr> <tr> <td data-bbox="667 955 1003 997">ramelteon</td> <td data-bbox="1003 955 1336 997">8 mg</td> </tr> <tr> <td data-bbox="667 997 1003 1039">temazepam</td> <td data-bbox="1003 997 1336 1039">15 mg</td> </tr> <tr> <td data-bbox="667 1039 1003 1081">triazolam*</td> <td data-bbox="1003 1039 1336 1081">0.125 mg</td> </tr> <tr> <td data-bbox="667 1081 1003 1123">zaleplon</td> <td data-bbox="1003 1081 1336 1123">5 mg</td> </tr> <tr> <td data-bbox="667 1123 1003 1165">zolpidem IR</td> <td data-bbox="1003 1123 1336 1165">5 mg</td> </tr> <tr> <td data-bbox="667 1165 1003 1207">zolpidem CR</td> <td data-bbox="1003 1165 1336 1207">6.25 mg</td> </tr> </tbody> </table> <p data-bbox="667 1167 1336 1281">* These medications are not considered medications of choice for the management of insomnia, especially in older individuals.</p> <p data-bbox="667 1291 1336 1417">Reference: www.ahrq.gov/downloads/pub/evidence/pdf/insomnia/insomnia.pdf</p>	Generic Medication	Oral Dosage	chloral hydrate*	500 mg	diphenhydramine*	25 mg	estazolam	0.5 mg	eszopiclone	1 mg	flurazepam*	15 mg	hydroxyzine*	50 mg	lorazepam	1 mg	oxazepam	15 mg	quazepam*	7.5 mg	ramelteon	8 mg	temazepam	15 mg	triazolam*	0.125 mg	zaleplon	5 mg	zolpidem IR	5 mg	zolpidem CR	6.25 mg
Generic Medication	Oral Dosage																																
chloral hydrate*	500 mg																																
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zolpidem IR	5 mg																																
zolpidem CR	6.25 mg																																
	<p>Duration</p> <ul data-bbox="659 1501 1317 1648" style="list-style-type: none"> • 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 																																
<p>Barbiturates, e.g.,</p> <ul data-bbox="302 1732 521 1879" style="list-style-type: none"> • amobarbital • butobarbital • pentobarbital • secobarbital 	<p>NOTE: Refers to barbiturates used to induce sleep or treat anxiety disorder</p> <p>Indications</p> <ul data-bbox="659 1837 1365 1879" style="list-style-type: none"> • Barbiturates should not be initiated in any dose for 																																

Medication	Issues and Concerns
<ul style="list-style-type: none"> • phenobarbital • amobarbital-secobarbital • barbiturates with other medications 	<p>any individuals to treat anxiety or insomnia; as they are highly addictive and cause numerous adverse effects, especially in older individuals</p> <p>Exception: These guidelines do not apply to the use of phenobarbital to treat seizure disorders (see Anticonvulsant section)</p> <p>Interactions/Adverse Consequences</p> <ul style="list-style-type: none"> • May increase the metabolism of many medications (e.g., anticonvulsants, antipsychotics), which may lead to decreased effectiveness and subsequent worsening of symptoms or decreased control of underlying illness • May cause hypotension, dizziness, lightheadedness, “hangover” effect, drowsiness, confusion, mental depression, unusual excitement, nervousness, headache, insomnia, nightmares, and hallucinations • May increase the risk for falls
<p>Thyroid medications</p>	
<p>All thyroid medications, e.g.,</p> <ul style="list-style-type: none"> • levothyroxine • triiodothyronine 	<p>Interactions</p> <ul style="list-style-type: none"> • Many clinically significant medication interactions have been identified; therefore, re-evaluation of medication doses is indicated <p>Dosage</p> <ul style="list-style-type: none"> • Initiation of thyroid supplementation should occur at low doses and be increased gradually to avoid precipitating cardiac failure or adrenal crisis <p>Monitoring</p> <ul style="list-style-type: none"> • 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
<p>Urinary incontinence medications</p>	

Medication	Issues and Concerns
<p>Urinary Incontinence Types and Agents, e.g.,</p> <p>Urge incontinence:</p> <p>Anticholinergics, e.g.,</p> <ul style="list-style-type: none"> • darifenacin • oxybutynin • tolterodine • trospium <p>Tricyclic antidepressants, e.g.,</p> <ul style="list-style-type: none"> • desipramine • imipramine <p>Stress incontinence:</p> <p>Alpha adrenergic agonists, e.g.,</p> <ul style="list-style-type: none"> • pseudoephedrine <p>Mixed incontinence, e.g.,</p> <ul style="list-style-type: none"> • estrogen replacement agents • imipramine <p>Overflow incontinence, e.g.,</p> <ul style="list-style-type: none"> • alpha adrenergic antagonists (see antihypertensives) • bethanechol chloride 	<p>Indications</p> <ul style="list-style-type: none"> • 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 <p>Monitoring</p> <ul style="list-style-type: none"> • 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 <p>Adverse Consequences</p> <ul style="list-style-type: none"> • 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^{11, 12}.

Examples of Medications with Anticholinergic Properties

ANTI-HISTAMINES (H-1 BLOCKERS)

chlorpheniramine cyproheptadine
diphenhydramine hydroxyzine

CARDIOVASCULAR MEDICATIONS

furosemide digoxin
nifedipine disopyramide

ANTIDEPRESSANTS

amoxapine amitriptyline
clomipramine desipramine
doxepin imipramine
nortriptyline protriptyline
paroxetine

GASTROINTESTINAL MEDICATIONS

Antidiarrheal Medications
diphenoxylate atropine

Antispasmodic Medications
belladonna clidinium
chlordiazepoxide dicyclomine
hyoscyamine propantheline

Antiulcer Medications
cimetidine ranitidine

ANTIPARKINSON MEDICATIONS

amantadine benzotropine
biperiden trihexyphenidyl

ANTIPSYCHOTIC MEDICATIONS

chlorpromazine clozapine
olanzapine thioridazine

MUSCLE RELAXANTS

cyclobenzaprine dantrolene
orphenadrine

URINARY INCONTINENCE

oxybutynin probantheline
solifenacin tolterodine
trospium

ANTIVERTIGO MEDICATIONS

meclizine scopolamine

PHENOTHIAZINE ANTIEMETICS

prochlorperazine promethazine

Potential Adverse Consequences of Medications with Anticholinergic Properties

Blood pressure, increased
Clumsiness or unsteadiness

Breathing difficulty, changes
Convulsions

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

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

ENDNOTES

- ¹¹ Tune, L. Carr, S., Hoag, E. & Cooper, T. (1992). Anticholinergic effects of drugs commonly prescribed for the elderly: Potential means for assessing risk of delirium. *American Journal of Psychiatry*, 149, pp. 1393-1394.
- ¹² Tune, L.E. (2000). Serum anticholinergic activity levels and delirium in the elderly. *Seminars in Clinical Neuropsychiatry*, 5, pp. 149-153.

INVESTIGATIVE PROTOCOL UNNECESSARY MEDICATIONS - MEDICATION REGIMEN REVIEW

Because they are closely related, the investigations of the requirements for medication regimen review and the review for unnecessary medications have been merged.

Objectives

- To determine whether each resident receives or is provided:
 - Only those medications that are clinically indicated in the dose and for the duration to meet his or her assessed needs;
 - Non-pharmacological approaches when clinically indicated, in an effort to reduce the need for or the dose of a medication; and
 - Gradual dose reduction attempts for antipsychotics (unless clinically contraindicated) and tapering of other medications, when clinically indicated, in an effort to discontinue the use or reduce the dose of the medication.

- To determine if the facility in collaboration with the prescriber:
 - Identifies the parameters for monitoring medication(s) or medication combinations (including antipsychotics) that pose a risk for adverse consequences; and for monitoring the effectiveness of medications (including a comparison with therapeutic goals); and
 - Recognizes and evaluates the onset or worsening of signs or symptoms, or a change in condition to determine whether these potentially may be related to the medication regimen; and follows-up as necessary upon identifying adverse consequences.

- To determine if the pharmacist:
 - Performed the monthly medication regimen review, and identified any existing irregularities regarding indications for use, dose, duration, and the potential for, or the existence of adverse consequences or other irregularities; and
 - Reported any identified irregularities to the attending physician and director of nursing.

- To determine whether the facility and/or practitioner acted on the report of any irregularity.

Use

Use this protocol during every initial and standard survey. In addition, this protocol may be used on revisits or abbreviated survey (complaint investigation) as necessary.

NOTE: This review is not intended to direct medication therapy. However, surveyors are expected to review factors related to the implementation, use, and monitoring of medications.

The surveyor is not expected to prove that an adverse consequence was directly caused by a medication or combination of medications, but rather that there was a failure in the care process related to considering and acting upon such possibilities.

If during the course of this review, the surveyor needs to contact the attending physician regarding questions related to the medication regimen, it is recommended that the facility's staff have the opportunity to provide the necessary information about the resident and the concerns to the physician for his/her review prior to responding to the surveyor's inquiries.

Procedures

Review the medications (prescription, over-the-counter medications, and nutritional supplements such as herbal products) currently ordered and/or discontinued by the prescriber at least back to the most recent signed recapitulation/reorder of all medications. Obtain a copy of the current orders if necessary. Gather information regarding the resident's mental, physical, functional, and psychosocial status and the medication-related therapeutic goals identified in the care plan as the basis for further review.

1. Observation and Record Review

Use the table below to guide observations, record review, and interviews with the resident or representative and relevant staff. Observe whether the medication-related interventions are consistently implemented over time and across various shifts. Note deviations from the care plan as well as potential medication-related adverse consequences. Verify observations by gathering additional information; for example, additional record reviews and/or interviews with the resident or representative, relevant staff, and practitioners.

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS	REVIEW FOR HOW FACILITY MANAGED MEDICATIONS FOR THE RESIDENT
Determine if the resident has been transferred to	Review the record (including the care

<p align="center">SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS</p>	<p align="center">REVIEW FOR HOW FACILITY MANAGED MEDICATIONS FOR THE RESIDENT</p>
<p>acute care since the last survey and/or has recently (e.g., the previous 3 months) experienced a change in condition or currently has signs and symptoms, such as:</p> <ul style="list-style-type: none"> • Anorexia and/or unplanned weight loss, or weight gain • Behavioral changes, unusual behavior patterns (including increased distressed behavior) • Bleeding or bruising, spontaneous or unexplained • Bowel dysfunction including diarrhea, constipation and impaction • Dehydration, fluid/electrolyte imbalance • Depression, mood disturbance • Dysphagia, swallowing difficulty • Falls, dizziness, or evidence of impaired coordination • Gastrointestinal bleeding • Headaches, muscle pain, generalized or nonspecific aching or pain • Mental status changes, (e.g., new or worsening confusion, new cognitive decline, worsening of dementia (including delirium)) • Rash, pruritus • Respiratory difficulty or changes • Sedation (excessive), insomnia, or sleep disturbance • Seizure activity • Urinary retention or incontinence <p>If observations or record review indicate symptoms or changes in condition that may be related to medications (refer to Tables I and II, supplemented with current medication references), determine whether the facility considered medications as a potential cause of the change or symptom.</p>	<p>plan, comprehensive assessment, and other parts of the record as appropriate) to determine whether it reflects the following elements related to medication management for the resident:</p> <ul style="list-style-type: none"> • Clinical indications for use of the medication • Consideration of non-pharmacological interventions • Dose, including excessive dose and duplicate therapy • Duration, including excessive duration • Consideration of potential for tapering/GDR or rationale for clinical contraindication • Monitoring for and reporting of: <ul style="list-style-type: none"> ○ Response to medications and progress toward therapeutic goals ○ Emergence of medication-related adverse consequences • Adverse consequences, if present and potentially medication-related, note if there was: <ul style="list-style-type: none"> ○ Recognition, evaluation, reporting, and management by the facility ○ Physician action regarding potential medication-related adverse consequences

2. Interview

Interview the resident and or family/responsible party, to the extent possible, to determine:

- His/her participation in care planning and decision making, including discussions of the goals related to the use of medications;
- Whether approaches other than medications (as indicated) were discussed; and
- His/her evaluation of the results of the medication therapy and other approaches (such as decreasing symptoms of pain, improving functional ability).

If during the review, you identify concerns about the lack of indication for use; the dose or duration of a medication; lack of monitoring; failure to implement the care plan; or condition changes or functional decline that may be related to the medication regimen, interview knowledgeable staff to determine:

- Whether the resident has experienced any changes in the functioning or amount of activity that he/she is able to do;
- The clinical rationale for the use of the medication, dose or duration and how the interdisciplinary team is monitoring the resident's response to the medication;
- What process is in place to assure the care plan interventions for medication use are being implemented;
- Whether they were aware that the signs and symptoms may be adverse consequences related to the medication regimen;
- Whether the staff had contacted the attending physician to discuss the signs and symptoms and the current medication regimen;
- Whether and how the physician responded when informed of suspected adverse medication consequences; and
- Whether the pharmacist performed a medication regimen review and identified related signs and symptoms, or the staff informed the pharmacist of them if they occurred after the last pharmacist visit.

Interview the physician, as appropriate, to determine:

- Whether staff notified him/her of potential medication-related issues and concerns;
- His/her assessment of the significance of medication-related issues and concerns; and
- Rationale for his/her management of the resident's medications and/or medication-related issues or concerns.

3. Medication Regimen Review (MRR)

Review for compliance with the MRR requirements at F428. Determine:

- If the pharmacist had identified and reported to the director of nursing and attending physician any irregularities with the medication regimen such as:
 - The emergence or existence of clinically significant adverse consequences;
 - Excess dose or duration, lack of monitoring, lack of indication for use, lack of GDR (as indicated) or behavioral interventions for residents receiving antipsychotics, medication interactions potentially affecting the medication's effectiveness; and
- Whether the attending physician and the director of nursing acted on any irregularities identified in the report. The responses from the attending physician could include the following:
 - Changed the medication regimen in response to the concern raised in the report (or after additional review of the situation);
 - Provided a clinically pertinent rationale that is relevant to that specific resident's signs and symptoms, prognosis, test results, etc., documenting or indicating why the benefit of the medication(s) or dose(s) outweighed the risks of the adverse consequence;
 - Provided a clinically pertinent rationale for why any gradual dose reduction (for antipsychotic medications) and/or tapering (for other medications) is contraindicated, even for a trial period; or
 - Provided a clinically pertinent rationale for why a particular medication, dose, or duration is appropriate for a resident despite its risks (for example, the resident has had recurrent seizures unless he/she receives anticonvulsant dosing that exceeds the usual recommended serum medication concentration level or therapeutic

range, and the attending physician and facility have been monitoring for and addressing adverse consequences).

- If the pharmacist identified a suspected adverse consequence, and the attending physician did not respond, determine if staff followed up with the attending physician.

NOTE: If the staff and pharmacist identify a medication that they believe may be causing a serious adverse consequence or a risk of clinically significant adverse consequences for the resident, and the attending physician did not address the risks or harm to the resident, determine what steps staff took; e.g., contacting the medical director to review the situation and address the issue with the attending physician, as necessary. See guidance at 42 CFR 483.75(i) Medical Director (F501) for additional guidance.

If problems are identified with the MRR, interview the pharmacist, as indicated, to determine:

- How he/she conducts the MRR, including the frequency and extent of the medication review and under what circumstances a review might be conducted more often than monthly;
- How the facility communicates with him/her regarding medication-related issues in specific residents; and
- How he/she approaches the MRR process for short stay residents.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation (F329)

The unnecessary medication requirement has six aspects in order to assure that medication therapy is appropriate for the individual resident. The facility must assure that medication therapy (including antipsychotic agents) is based upon:

- An adequate indication for use;
- Use of the appropriate dose;
- Provision of behavioral interventions and gradual dose reduction for individuals receiving antipsychotics (unless clinically contraindicated) in an effort to reduce or discontinue the medication;
- Use for the appropriate duration;

- Adequate monitoring to determine whether therapeutic goals are being met and to detect the emergence or presence of adverse consequences; and
- Reduction of dose or discontinuation of the medication in the presence of adverse consequences, as indicated.

Criteria for Compliance

Compliance with 42 CFR 483.25(l), F329, Unnecessary Medications

For a resident who has been, or is, receiving medication(s), the facility is in compliance if they, in collaboration with the prescriber:

- Assessed the resident to ascertain, to the extent possible, the causes of the condition or symptoms requiring treatment, including recognizing, evaluating, and determining whether the condition or symptoms may have reflected an adverse medication consequence;
- Based on the assessment, determined that medication therapy was indicated and identified the therapeutic goals for the medication;
- Utilized only those medications in appropriate doses for the appropriate duration, which are clinically necessary to treat the resident's assessed condition(s);
- Implemented a gradual dose reduction and behavioral interventions for each resident receiving antipsychotic medications unless clinically contraindicated;
- Monitored the resident for progress towards the therapeutic goal(s) and for the emergence or presence of adverse consequences, as indicated by the resident's condition and the medication(s); and
- Adjusted or discontinued the dose of a medication in response to adverse consequences, unless clinically contraindicated.

If not, cite F329.

Noncompliance for F329

After completing the investigation, determine whether or not compliance with the regulation exists. Noncompliance for F329 may include:

- **Inadequate Indications for Use** – Examples of noncompliance related to a medication being used without adequate indications include, but are not limited to:

- Failure to document a clinical reason or demonstrate a clinically pertinent rationale, verbally or in writing, for using medication(s) for a specific resident.
 - Prescribing or administering a medication despite an allergy to that medication, or without clarifying whether a true allergy existed as opposed to other reactions (e.g., idiosyncratic reaction or other side effect).
 - Failure to provide a clear clinical rationale for continuing a medication that may be causing an adverse consequence.
 - Initiation of an antipsychotic medication to manage distressed behavior without considering a possible underlying medical cause (e.g., UTI, congestive heart failure) or environmental or psychosocial stressor.
 - Initiation of a medication presenting clinically significant risks without considering relative risks and benefits or potentially lower risk medications.
 - Concomitant use of two or more medications in the same pharmacological class without a clinically pertinent explanation.
- **Inadequate Monitoring** – Examples of noncompliance related to inadequate monitoring include, but are not limited to:
 - Failure to monitor the responses to or effects of a medication and failure to respond when monitoring indicates a lack of progress toward the therapeutic goal (e.g., relief of pain or normalization of thyroid function) or the emergence of an adverse consequence.
 - Failure to monitor a medication consistent with the current standard of practice or manufacturer's guidelines.
 - Failure to carry out the monitoring that was ordered or failure to monitor for potential clinically significant adverse consequences. For example, use of warfarin in conjunction with:
 - Inadequate or absent monitoring of PT/INR during treatment; and/or
 - Failure to recognize and monitor the increased risk of adverse consequences when the resident is receiving other medications that are known to increase the risk of bleeding or to interact with warfarin and increase PT/INR.

Excessive Dose (including duplicate therapy) – Examples of noncompliance related to excessive dose include, but are not limited to:

- Giving a total amount of any medication at one time or over a period of time that exceeds the amount recommended by the manufacturer's recommendations, clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or standards of practice for a resident's age and condition, without a documented clinically pertinent rationale.
 - Failure to consider periodically the continued necessity of the dose or the possibility of tapering a medication.
 - Failure to provide and/or document a clinical rationale for using multiple medications from the same pharmacological class.
- **Excessive Duration** – Examples of noncompliance related to excessive duration include, but are not limited to:
 - Continuation beyond the manufacturer's recommended time frames, the stop date or duration indicated on the medication order, facility-established stop order policies, or clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or current standards of practice, without documented clinical justification.
 - Continuation of a medication after the desired therapeutic goal has been achieved without evaluating whether the medication can offer any additional benefit, for example:
 - Use of an antibiotic beyond the recommended clinical guidelines or the facility policy without adequate reassessment of the resident and determination of continuing need.
 - Failure to re-evaluate the rationale for continuing antipsychotic medication initiated in an emergency after the acute phase has stabilized.
- **Adverse Consequences** – Examples of noncompliance related to adverse consequences include, but are not limited to:
 - Failure to act upon (i.e., discontinue a medication or reduce the dose or provide clinical justification for why the benefit outweighs the adverse consequences) a report of the risk for or presence of clinically significant adverse consequence(s);

- Failure to respond to actual or potentially clinically significant adverse consequences related to the use of warfarin when the PT/INR exceeds the target goal.
- **Antipsychotic Medications without Gradual Dose Reduction and Behavioral Interventions unless Clinically Contraindicated** – Examples of noncompliance related to this requirement include, but are not limited to:
 - Failure to attempt GDR in the absence of identified and documented clinical contraindications.
 - Prolonged or indefinite antipsychotic use without attempting gradual dose reductions.
 - Failure to implement behavioral interventions to enable attempts to reduce or discontinue an antipsychotic medication.

Potential Tags for Additional Investigation

If noncompliance with §483.25(l) has been identified, then concerns with additional requirements may also have been identified. The surveyor is cautioned to investigate these related additional requirements before determining whether noncompliance with the additional requirements may be present. Examples of some of the related requirements that may be considered when noncompliance has been identified include the following:

- 42 CFR 483.10(b)(11), F157, Notification of Changes
 - Review whether the facility contacted the attending physician regarding a significant change in the resident's condition in relation to a potential adverse consequence of a medication, or if the resident has not responded to medication therapy as anticipated and/or indicated.
- 42 CFR 483.10 (b)(3) and (4), F154, F155, Notice of Rights and Services and (d)(2) Free Choice
 - Determine whether the resident was advised of her/his medical condition and therapy and was informed about her/his treatment including medications and the right to refuse treatments.
- 42 CFR 483.20(b), F272, Comprehensive Assessments
 - Review whether the facility's initial and periodic comprehensive assessments include an assessment of the resident's medication regimen.
- 42 CFR 483.20(k)(1) and (2), F279, F280, Comprehensive Care Plans

- Review whether the resident's comprehensive care plan: a) was based on the assessment of the resident's conditions, risks, needs, and behavior; b) was consistent with the resident's therapeutic goals; (c) considered the need to monitor for effectiveness based on those therapeutic goals and for the emergence or presence of adverse consequences; and (d) was revised as needed to address medication-related issues.
- 42 CFR 483.25(a)(1), F310, Decline in ADL
 - Review whether the facility had identified, evaluated, and responded to a new or rapidly progressive decline in function, development or worsening of movement disorders, increased fatigue and activity intolerance that affected the resident's ADL ability in relation to potential medication adverse consequences.
- 42 CFR 483.25(d), F315, Urinary Incontinence
 - Review whether the facility had identified, evaluated, and responded to a change in urinary function or continence status in relation to potential medication adverse consequences.
- 42 CFR 483.25(f)(1)&(2), F319, F320, Mental and Psychosocial Functioning
 - Review whether the facility had identified, evaluated, and responded to a change in behavior and/or psychosocial changes, including depression or other mood disturbance, distress, restlessness, increasing confusion, or delirium in relation to potential medication adverse consequences.
- 42 CFR 483.25(i)(1), F325, Nutritional Parameters
 - Review if the facility had identified, evaluated, and responded to a change in nutritional parameters, anorexia or unplanned weight loss, dysphagia, and/or swallowing disorders in relation to potential medication adverse consequences.
- 42 CFR 483.25(j), F327, Hydration
 - Review if the facility had identified, evaluated, and responded to a change in hydration or fluid or electrolyte balance (for example, high or low sodium or potassium) in relation to potential medication adverse consequences.
- 42 CFR 483.40(a), F385, Physician Supervision

- Review if the attending physician supervised the resident's medical treatment, including assessing the resident's condition and medications, identifying the clinical rationale, and monitoring for and addressing adverse consequences.
- 42 CFR 483.40(b), F386, Physician Visits
 - Review if the attending physician or designee reviewed the resident's total program of care and wrote, signed, and dated progress notes covering pertinent aspects of the medication regimen and related issues.
- 42 CFR 483.60(c), F428, Medication Regimen Review
 - Review whether the licensed pharmacist has provided consultation regarding the integrity of medication-related records (e.g., MAR, physician order sheets, telephone orders), and potential or actual medication irregularities.
- 42 CFR 483.75(i), F501, Medical Director
 - Review whether the medical director, when requested by the facility, interacted with the attending physician regarding a failure to respond or an inadequate response to identified or reported potential medication irregularities and adverse consequences; and whether the medical director collaborated with the facility to help develop, implement, and evaluate policies and procedures for the safe and effective use of medications in the care of residents.

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirement, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F329 exists, the team must determine the severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The key elements for severity determination for F329 are as follows:

1. Presence of potential or actual harm/negative outcome(s) due to a failure related to unnecessary medications.

Examples of actual or potential harm/negative outcomes for F329 may include, but are not limited to:

- Potential for life-threatening toxicity from excessive dose or lack of indication for the use of digoxin.

- Complications (such as diarrhea with life threatening fluid loss, nephrotoxicity, hearing loss, or anaphylactic shock) from use of an antibiotic when no clear indication for use has been established or response to the use has not been monitored.
- Fractures or falls with injury resulting from the continuing use of medications (e.g., hypnotics/sedatives, antipsychotics, antidepressants, antihypertensives) in the presence of predisposing risks or adverse consequences such as persistent dizziness or recurrent falling without intervening or reevaluating the need for and dose of the medication believed to be the cause of the gait instability.

2. Degree of potential or actual harm/negative outcome(s) due to a failure related to unnecessary medications.

Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or
- If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.

3. The immediacy of correction required.

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

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F329. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

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

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

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed, caused, or resulted in, or is likely to allow, cause, or result in serious injury, harm, impairment, or death to a resident; and
- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples may include, but are not limited to:

- Failure to assess or respond appropriately for a resident taking warfarin who had an elevated INR of 9 or greater with or without bleeding, or the elevated INR persisted without assessment/follow-up.
- Failure to monitor PT/INR for a resident on anticoagulant therapy in accordance with current standards of practice and to recognize and/or respond to a life threatening adverse consequence related to anticoagulation.
- Failure to recognize developing serotonin syndrome (e.g., confusion, motor restlessness, tremor) in a resident receiving a SSRI, leading to the addition of medications with additive serotonin effect or medication to suppress the symptoms.
- Failure to recognize and respond to signs and symptoms of neuroleptic malignant syndrome (NMS).
- In the presence of gastrointestinal bleeding, the failure to recognize medication therapies (such as NSAIDs or COX-2 inhibitors, bisphosphonates) as potentially causing or contributing to the gastrointestinal bleed, resulting in the continued administration of the medication, until the resident required hospitalization for severe bleeding.

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

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Level 3 indicates noncompliance that resulted in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:

- Facility failure to take appropriate action (e.g., suspending administration of the anticoagulant) in response to an INR greater than 4 and less than 9 for a resident

who is receiving warfarin until spontaneous bruising or frank bleeding occurs, resulting in the need to transfuse or hospitalize the resident.

- Facility failure to evaluate the medication regimen as a potential cause of seizure activity resulting in the addition of anticonvulsants to treat recent-onset seizures that can be adverse consequences of medications.
- Facility failure to implement a GDR that was not contraindicated in a resident receiving prolonged, continuous antipsychotic therapy resulting in functional decline, somnolence, lethargy, tremors, increased falling, or impaired ambulation.

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

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

Level 2 indicates noncompliance that resulted in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided. Examples may include, but are not limited to:

- Facility failure to take appropriate action (e.g., change or suspend administration of the warfarin dose) for a resident who has an INR greater than 4 and less than 9 without any bleeding.
- Failure to monitor INR for a resident who has been stabilized on warfarin, but who has not had bleeding.
- Facility failure to identify and act upon minor symptoms of allergic response to medications, such as a rash.
- Facility failure to monitor for response to therapy or for the emergence or presence of adverse consequences before the resident has experienced an adverse consequence or decline in function (e.g., monitoring periodically for symptoms of behavioral distress in someone receiving psychopharmacological medication; monitoring thyroid function at least annually in an individual receiving thyroid hormone replacement; and monitoring hydration status and basic metabolic profile for a resident receiving diuretics or ACE inhibitors, who had a change in mental status after the onset of diarrhea).

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

The failure of the facility to provide appropriate care and services to manage the resident's medication regimen to avoid unnecessary medications and minimize negative outcome places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F329 - Additional Example under Investigative Protocol

The following example illustrates the differences between compliance, and non-compliance at severity levels 4, 3 and 2 related to the use of antipsychotic medication when circumstances and outcomes change:

F329 – Compliance Example

An 89 year old male was re-admitted to the nursing home from the hospital. Upon readmission, diagnoses included pneumonia, CHF, and dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden development, one day after admission, of delirium with psychotic features. The resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident's infection stabilized, he was discharged back to the nursing home.

Upon readmission to the nursing home, the nurse practitioner contacted the hospitalist by telephone to review the case. They agreed that if the resident did not exhibit signs/symptoms of acute delirium over the next week, it would be reasonable to taper and discontinue the antipsychotic medication. The nurse practitioner communicated this information to the nursing staff and consultant pharmacist – the nursing staff included this information in the plan of care. After a week, no target behaviors were observed. The medication was tapered and discontinued, with ongoing monitoring in place for the potential recurrence of symptoms. The facility has met the criteria for compliance.

F329 - Level 4 Severity Non-compliance Example

An 89 year old male was re-admitted to the nursing home from the hospital. Admitting diagnoses included pneumonia, CHF, and dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden development, one day after admission, of delirium with psychotic features. The resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident's infection stabilized, he was discharged back to the nursing home.

Approximately 4 months after nursing home readmission, the resident was still receiving the antipsychotic medication. Staff was monitoring for the identified target behaviors; however, documentation revealed that the resident had not exhibited any of the target behaviors for over 3 months. The facility failed to evaluate and/or consider gradual dose reductions, and had not attempted alternative approaches in an effort to discontinue the medication. The consultant pharmacist had recommended gradual dose reductions, but the physician had indicated that the medication was to be continued.

The record indicated that the resident was exhibiting orthostatic hypotension and was at high risk for falling. In addition, he was no longer attending group activities as he was sleeping off and on throughout the day. Staff had identified that the resident, who had been ambulatory with one staff person at admission, was no longer ambulating, was weaker and was in a recliner in his room during the day and evening. The resident had several areas on his hips and coccyx which were identified as Stage III pressure ulcers; he was losing weight due to decreased appetite and was drinking insufficient amounts of fluids.

When interviewed, staff stated that they believed the resident's decline was related to his dementia. They had not considered reducing or discontinuing the medication and failed to recognize that the medication had been initially ordered for delirium in the hospital, a condition that could potentially be time-limited and in many cases resolves completely.

The facility failed to evaluate for the ongoing indication of use of the antipsychotic after symptoms were no longer present, had not monitored for the presence of adverse consequences, had not attempted gradual dose reductions nor implemented any behavioral interventions. The facility staff had not contacted the medical director to evaluate the resident's response and consider discussing the case with the attending physician. Following additional investigation, it was determined that the quality assessment and assurance (QAA) committee did not conduct any oversight or monitoring of residents who were receiving antipsychotics to assure that there were appropriate clinical indications for use and that behavioral interventions and gradual dose reductions were attempted.

Why is this Immediate Jeopardy?

This resident is now so compromised (he has developed pressure ulcers, has reduced food and fluid intake, is experiencing blood pressure fluctuations and is at risk for falls) that immediate action is required to prevent a serious illness or injury. While immediate jeopardy may exist when only one resident is affected, in this case the lack of systems and processes for review of psychopharmacological medications in residents with dementia indicates that other residents on these medications could potentially be at risk for serious harm as well.

F329 - Level 3 Severity Non-compliance Example

An 89 year old male was re-admitted to the nursing home from the hospital. Admitting diagnoses included pneumonia, heart failure, dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden development, one day after admission, of delirium with psychotic features. The resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident's infection stabilized, he was discharged back to the nursing home.

Approximately 3 months after nursing home readmission, the resident was still receiving the antipsychotic medication. The record indicated that the resident was now having difficulty with mobility and was more dependent on staff for ADLs such as bed mobility and transfers. Staff had identified that the resident was in a recliner in his room during the day and evening and was drowsy more often throughout the day. Staff documented that the resident had a small stage II pressure ulcer.

Staff was monitoring the identified target behaviors and documentation revealed the resident had not exhibited the target behaviors for the past 3 months. However, the facility failed to evaluate and/or consider gradual dose reductions, and had not attempted behavioral interventions in an effort to discontinue the medication. Staff failed to recognize that the medication had initially been ordered for delirium in the hospital, a condition that could potentially be time-limited and in many cases resolves completely.

Why is this level 3 Severity?

The staff had not identified/evaluated the causal factors for the ongoing use of the medication, nor the potential that the medication could have been contributing to the resident's decline in ADLs, alertness and skin condition. Staff failed to recognize that the medication had initially been ordered for delirium in the hospital, a condition that could potentially be time-limited and in many cases resolves completely. The facility failed to consider a gradual dose reduction. The resident had actual harm (ADL decline, stage II pressure ulcer) that could have been related to the medication. However, this is not a level 4 severity because the requirement for immediacy is not met.

Level 2 Severity

An 89 year old male was re-admitted to the nursing home sub-acute unit from the hospital. Admitting diagnoses included pneumonia, heart failure, dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden development, one day after admission, of delirium with psychotic features. The resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident's infection stabilized, he was discharged back to the nursing home.

Approximately 3 months after admission, the resident was still receiving the antipsychotic medication and staff was monitoring for target behaviors and for the presence of adverse consequences. The record revealed that the resident had not had any adverse consequences and was no longer exhibiting the target behaviors. However, the facility failed to evaluate and/or consider gradual dose reductions, and had not attempted behavioral interventions in an effort to discontinue the medication. Staff failed to recognize that the medication had been initially ordered for delirium in the hospital, a condition that could potentially be time-limited and in many cases resolves completely.

Why is this level 2 Severity?

While the resident is at risk for potential for more than minimal harm from ongoing use of an antipsychotic medication without a clear clinical indication, the staff did not document any actual harm.

This is only one example. Specific evidence may differ in actual situations and surveyors should evaluate each situation individually as no one example applies to every situation.