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MEDICATION &PHARMACY REGULATION OVERVIEW
MODULE I ~ F-TAG329

GENERAL
Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

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

ANTIPSYCHOTIC DRUGS
Based on a comprehensive assessment of a resident, the facility must ensure that:

- 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
- Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

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

- Each resident receives only those medications, in doses and for the duration clinically indicated to treat the resident's assessed condition(s);
- 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;
- 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, such as an 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 such as 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 or concentration of a medication given at one time or over a period of time. The individual dose is the amount, strength or concentration received at each administration.
  - ***Daily Dose*** is the amount received over a 24-hour period.
  - ***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.

- ***Extra Pyramidal 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.
- ***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 such as SSRIs, SNRIs, triptans and certain antibiotics. Symptoms may include restlessness, hallucinations, confusion, loss of coordination, fast heart beat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting and diarrhea.

- ***Tardive Dyskinesia*** refers to abnormal, recurrent, involuntary movements that may be irreversible and typically present as lateral movements of the tongue or jaw, tongue thrusting, chewing, frequent blinking, brow arching, grimacing, and lip smacking, although the trunk or other parts of the body may also be affected.

OVERVIEW

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

A study of 33,301 nursing facility residents found that an average of 6.7 medications were ordered per resident, with 27 percent of residents taking nine or more medications.

Analysis of antipsychotic use by 693,000 Medicare nursing home residents revealed that 28.5 percent of the doses received were excessive and 32.2 percent lacked appropriate indications for use.

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

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

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

Examples of non-pharmacological interventions may include:

- Increasing the amount of resident exercise, intake of liquids and dietary fiber in conjunction with an individualized bowel regimen to prevent or reduce constipation and the use of medications such as 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 such as 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 such as 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, or cautions 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, 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 ~ 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 ~ http://siq.air.org
- National Guideline Clearinghouse ~ www.guideline.gov
- Quality Improvement Organizations, Medicare Quality Improvement Community Initiatives ~ www.medqic.org
- US Dept of Health and Human Services, Food and Drug Administration ~ www.fda.gov/medwatch/safety.htm
- US Dept of Health and Human Services, National Institute of Mental Health ~ 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
- *Bathing Without a Battle* ~ www.bathingwithoutabattle.unc.edu

> ***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 US Dept 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 monitoring of medications for efficacy and clinically significant adverse consequences; and
- 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.

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 as 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:

- Indications for use of medication including initiation or continued use of antipsychotic medication;
- Monitoring for efficacy and adverse consequences;
- Dose including duplicate therapy;
- Duration;
- Tapering of a medication dose/gradual dose reduction for antipsychotic medications; and
- Prevention, identification, and response to adverse consequences.

Indications for Use of Medication ~ including initiation or continued use of 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 or 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 non-pharmacological interventions are considered;
- Whether the signs, symptoms, or related causes are persistent or clinically significant enough, such as causing a functional decline, to warrant the initiation or continuation of medication therapy;
- 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:

- Each resident's goals and preferences;
- Allergies to medications and foods and potential for medication interactions;
- Recognition of the need for end-of-life or palliative care;
- 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;
- A history of prior and current medications and non-pharmacological interventions including therapeutic effectiveness and any adverse consequences; and
- The refusal of care and treatment, including the basis for declining it, and the identification of pertinent alternatives.

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

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

- Admission or re-admission;
- A clinically significant change in condition/status;
- A new, persistent, or recurrent clinically significant symptom or problem;
- A worsening of an existing problem or condition;

- An unexplained decline in function or cognition;
- A new medication order or renewal of orders; and
- An irregularity identified in the pharmacist's monthly medication regimen review.

Specific considerations related to these circumstances may include the following:

- ***Admission or Readmission*** – Some residents may be admitted on medications for an undocumented chronic condition or without a clear indication as to why a medication was begun or should be continued. It is expected that the attending physician, pharmacist, and staff subsequently determine if continuing the medication is justified by evaluating the resident's clinical condition, risks, existing medication regimen, and related factors. If the indications for continuing the medication are unclear, or if the resident's symptoms could represent a clinically significant adverse consequence, additional consideration of the rationale for the medication(s) is warranted.
- ***Multiple Prescribers*** – Regardless of who the prescribers are, the continuation of a medication needs to be evaluated to determine if the medication is still warranted in the context of the resident's other medications and co-morbidities. 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 such that 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 such as excessive heat, noise or overcrowding;
  - Neurological illnesses such as Huntington's disease or Tourette's syndrome;
  - Psychological stressors such as disruption of the resident's customary daily routine, grief over nursing home admission or health status, abuse, taunting or intimidation; or
  - Medical illnesses such as Alzheimer's disease, Lewy body disease, vascular dementia, or frontotemporal dementia.

  Note: See Table I beginning on page 16 in these handouts for key issues related to indications for use of antipsychotic agents, monitoring, and adverse consequences.

Monitoring for Efficacy and Adverse Consequences ~ The information gathered during the initial and ongoing evaluations is essential to:

- Optimize the therapeutic benefit of medication therapy and minimize or prevent potential adverse consequences;
- Establish parameters for evaluating the ongoing need for the medication;
- Verify or differentiate the underlying diagnoses or other underlying causes of signs and symptoms; and

- 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.

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.

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

- Pharmacists;
- Medication references;
- Facility policies and procedures;
- Manufacturers' package inserts and black-box warnings;
- Clinical practice guidelines or clinical standards of practice; 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 such as behavioral monitoring or to treat hypertension such as periodic pulse and blood pressure. 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	Endocrineweb.com/diabetes/diagnosis.html Diabetes.org Diabetes.niddk.nih.gov DiabetesToolbox.com
Alzheimer's Disease and/or Dementia	Mini Mental Status Exam (MMSE)	Determine degree of cognitive impairment	Emedicine.com/med/topic3358.htm FPnotebook.com
Functional Decline	Instrumental Activities of Daily Living (IADL)	Assess functional capabilities	CDC.gov/nchs FPnotebook.com

Common Conditions/ Symptoms	Examples of Tools	Potential Applications	Source/Reference
Functional Decline (continued)	Resident Assessment Instrument (RAI)	Assess aspects of nursing home resident's behavior and function	apadiv20.phhp.ufl.edu/fries.htm careplans.com
	Functional Alzheimer's Screening Test (FAST)	Assess level of function in individuals with dementia	geriatrics.uthscsa.edu/educational/med_students/fastscale_admin.htm
Delirium	Confusion Assessment Method (CAM)	Screen for cognitive impairment and delirium	hartfordign.org med.yale.edu/library/historical
Bipolar Disorder	Mania Rating Scale	Assess severity of mania	brainexplorer.org/brain_disorders/Focus_Bipolar_disorder.shtml
Pain	List of pain scales	Assess pain characteristics such as intensity, impact, timing	chcr.brown.edu/pcoc/Physical.htm
Depression	Geriatric Depression Scale	Screen or monitor individuals at risk for depression	assessmentpsychology.com/geriatricscales.htm hartfordign.org merckmanuals.com/professional/sec23.html
	Cornell Depression in Dementia Scale	Screen or monitor for depression in individuals with cognitive impairment	emoryhealthcare.org
Abnormal Movements	Abnormal Involuntary Movement Scales (AIMS)	Assess presence and severity of involuntary movements that may be due to disease and/or medications	mhsip.org/library/pdfFiles/abnormalinvoluntarymovementscale.pdf
Behavioral Symptoms associated with Dementia	Neuropsychiatric Inventory-Nursing Home Version (NPI-NH)	Screen or monitor for behavior associated with dementia such as hallucinations, agitation or anxiety	ncbi.nlm.nih.gov/pubmed/10648298
	Behavioral Pathology in Alzheimer's Disease Rating Scale (Behave AD)	Provide a global rating of non-cognitive symptoms	alzforum.org/dis/dia/tes/neuropsychological.asp
	Cohen-Mansfield Agitation Inventory (CMAI)	Assess/rate distressed behavior in older individuals	researchinstituteonaging.org geriatrictimes.com/g010533.html

Monitoring involves several steps:

- *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:
  - Black-box warnings;
  - Properties of the medication;

- Clinical condition such as renal disease;
- Medication-medication, medication-food interactions; 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.
  - 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 and/or hypnotics, the facility should review the continued need for them, at least quarterly, 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 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:
  - Decline in function or cognition;
  - Acute onset of signs or symptoms or worsening of chronic disease;
  - 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.

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 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;
- Use of more than one product containing the same medication can lead to excessive doses of a medication, such as concomitant use of acetaminophen and/or hydrocodone and acetaminophen, which may increase the risk of acetaminophen toxicity; or
- Use of medications from different therapeutic categories that have similar effects or properties, such as multiple medications including oxybutynin and diphenhydramine with anticholinergic effects 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.

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, such as 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.

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

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, such as sedatives, hypnotics, antidepressants, or 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 tapering or GDR as required.

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, such as schizophrenia, depression with psychotic features, or bipolar mania, 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.

- *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.
- *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.

Prevention, Identification, and Response to Adverse Consequences ~ Any medication or combination of medications, such as 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, such as 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% (276 out of 546) of all the adverse consequences and 72% of those characterized as fatal, life-threatening, or serious were considered preventable. A second study of two academic-based nursing homes reported that inadequate monitoring, failure to act on the monitoring, and errors in ordering, including wrong dose, wrong medication, and medication-medication interactions were the most frequent causes for the preventable adverse consequences.

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

Refer to Table I (beginning on page 16) and Table II (beginning on page 36) in your handouts for classes of medications that are associated with frequent or severe adverse consequences.

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

TABLE I ~ MEDICATION ISSUES OF PARTICULAR RELEVANCE

This table lists 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	
Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) ▪ Non-selective NSAIDs Aspirin, Diclofenac, Diflunisal, Ibuprofen, Indomethacin, Ketorolac, Meclofenamate, Naproxen, Piroxicam, Salicylates, Tolmetin ▪ Cyclooxygenase-II Inhibitors (COX-2) Celecoxib	Indications NSAID, including COX-2 inhibitors, should be reserved for symptoms and/or inflammatory conditions for which lower risk analgesics, such as acetaminophen, have either failed, or are not clinically indicated. Exception Use of low dose aspirin (81-325mg/day) as prophylactic treatment for cardiovascular events such as myocardial infarct or stroke may be appropriate. Interactions Aspirin may increase the adverse effects of COX-2 inhibitors in the gastrointestinal (GI) tract. Some NSAIDs such as ibuprofen may reduce the cardio protective effect of aspirin. Monitoring Monitor closely for bleeding when ASA > 325 mg/day is being used with another NSAID or when NSAIDs are used with other platelet inhibitors or anticoagulants. Please refer to 42 CFR 483.60(c) F428 for Table of Common Medication-Medication Interactions in Long Term Care. Adverse Consequences May cause gastrointestinal (GI) bleeding in anyone with a prior history of, or with increased risk for, GI bleeding. Compared to nonselective NSAIDs, COX-2 inhibitors may reduce but do not eliminate the risk of gastrointestinal bleeding. May cause bleeding in anyone who is receiving warfarin, heparin, other anticoagulants, or platelets inhibitors such as ticlopidine, clopidogrel, and dipyridamole. Any NSAID may cause or worsen renal failure, increase blood pressure, or exacerbate heart failures. Prolonged use of indomethacin, piroxicam, tolmetin, and meclofenamate should be avoided because of central nervous system side effects, such as headache, dizziness, somnolence, confusion.

MEDICATION	ISSUES AND CONCERNS
Acetaminophen	Dosage / Adverse Consequences Daily doses greater than 4 grams/day from all sources alone or as part of combination products may increase risk of liver toxicity. Monitoring For doses greater than the maximum recommended daily dose, documented assessment should reflect periodic monitoring of liver function and indicate that benefits outweigh risks.
Opioid Analgesics ▪ Short-acting Codeine, Fentanyl, Hydrocodone, Hydromorphone, Meperidine, Morphine, Oxycodone ▪ Long-acting Fentanyl transdermal, Methadone, Morphine sustained release, Oxycodone sustained release	Indications 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. Adverse Consequences 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 (normerperidine) accumulates with repeated use and has been associated with seizures.
Pentazocine	Indications Limited effectiveness because it is a partial opiate agonist-antagonist; is not recommended for use in older individuals. Adverse Consequences 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.
Propoxyphene and Combination Products with Aspirin or Acetaminophen	Indications 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. Adverse Consequences May cause hypotension and central nervous system effects, such as confusion, drowsiness, dizziness, that can lead to other adverse consequences such as falls.
ANTIBIOTICS	
All Antibiotics	Indications Use of antibiotics should be limited to confirmed or suspected bacterial infection. Adverse Consequences 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.

MEDICATION	ISSUES AND CONCERNS
Parenteral Vancomycin and Aminoglycosides	Monitoring 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. Exception Single dose administration prophylaxis Adverse Consequences May cause or worsen hearing loss and renal failure.
Nitrofurantoin	Indications 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. Adverse Consequences May cause pulmonary fibrosis, symptoms including dyspnea and cough, and peripheral neuropathy.
Fluoroquinolones Ciprofloxacin, Levofloxacin, Moxifloxacin, Ofloxacin	Indications Use should be avoided in individuals with prolonged QTc intervals or who are receiving antiarrhythmic agents in class Ia (procainamide), class Ic (flecainide) or class III (amiodarone). Adverse Consequences 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	Monitoring 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. Adverse Consequences Multiple medication interactions exist which either may significantly increase PT/INR results to levels associated with life-threatening bleeding, or decrease PT/INR results to ineffective levels; or increase/decrease the serum concentration of the interacting medication. Please refer to 42 CFR 483.60(c) F428 for Table of Common Medication-Medication Interactions in Long Term Care.
ANTICONVULSANTS	
All Anticonvulsants Carbamazepine, Gabapentin, Lamotrigine, Levetiracetam, Oxcarbazepine, Phenobarbital, Phenytoin, Primidone, Valproic Acid	Indications 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, such as distinguish epilepsy from isolated seizure due to medical cause or distinguish migraine from other causes of headaches, and its potential causes including medications, electrolyte imbalance, or hypocalcaemia.

MEDICATION	ISSUES AND CONCERNS
All Anticonvulsants (continued)	Duration If used to manage behavior, stabilize mood, or treat a psychiatric disorder, refer to Section V Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance. Monitoring 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 such 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 low serum concentrations. Symptom control for seizures or behavior can occur with sub-therapeutic serum medication concentrations. Adverse Consequences May cause liver dysfunction, blood dyscrasias, and serious skin rashes requiring discontinuation of treatment. May cause nausea/vomiting, dizziness, ataxia, somnolence/lethargy, in-coordination, blurred or double vision, restlessness, toxic encephalopathy, anorexia, headaches. These effects can increase the risk for falls.
ANTIDEPRESSANTS	
All Antidepressants Classes ▪ Alpha-Adrenoceptor Antagonist Mirtazapine ▪ Dopamine-reuptake blocking compounds Bupropion ▪ Monoamine Oxidase inhibitors (MAOIs) & Serotonin (5-HT 2) Antagonists Nefazodone, Trazodone ▪ Selective Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs) Duloxetine, Venlafaxine ▪ Selective Serotonin Reuptake Inhibitors (SSRIs) Citalopram, Escitalopram, Fluoxetine, Fluvoxamine, Paroxetine, Sertraline	Indications 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, such as diabetic peripheral neuropathy, migraine headaches, urinary incontinence, and others. Dosage 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. Duration Duration should be in accordance with pertinent literature, including clinical practice guidelines. Prior to discontinuation, many antidepressants, such as SSRIs and TCAs, may need a gradual dose reduction or tapering to avoid a withdrawal syndrome. 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. Monitoring 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.

MEDICATION	ISSUES AND CONCERNS
All Antidepressants Classes (continued) ▪ Tricyclic (TCA) and related compounds	Interactions/Adverse Consequences 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, such as tramadol, St. John's Wort, linezolid, other SSRIs, may increase the risk for serotonin syndrome and seizures.
Monoamine Oxidase Inhibitors (MAOIs) Isocarboxazid, Phenelzine, Tranylcypromine	Indications/Contraindications 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 potential interactions with tyramine or tryptophan-containing foods, other medications, and their profound effect on blood pressure. Adverse Consequences May cause hypertensive crisis if combined with certain foods, cheese, wine. 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. Interactions Should not be administered together or in rapid succession with other MAO inhibitors, tricyclic antidepressants, bupropion, SSRIs, buspirone, sympathomimetics, meperidine, triptans, and other medications that affect serotonin or norepinephrine.
Tricyclic Antidepressants (TCAs) Amitriptyline, Amoxapine, Doxepin, Combination Products such as Amitriptyline and Chlordiazepoxide or Amitriptyline and Perphenazine	Indications Because of strong anticholinergic and sedating properties, TCAs and combination products are rarely the medication of choice in older individuals. Exception Use of TCAs may be appropriate if the resident is being treated for neurogenic pain, such as trigeminal neuralgia or 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. Adverse Consequences Compared to other categories of antidepressants, TCAs cause significant anticholinergic side effects and sedation. Nortriptyline and Desipramine are less problematic.
ANTIDIABETIC MEDICATIONS	
Insulin and Oral Hypoglycemics Acarbose, Acetohexamide, Chlorpropamide, Glimepiride, Glipizide, Glyburide, Metformin, Repaglinide, Rosiglitazone, Tolazamide, Tolbutamide	Monitoring Use of anti-diabetic medications should include monitoring such as periodic blood sugars for effectiveness based on desired goals for that individual and to identify complications of treatment such as hypoglycemia, impaired renal function. Note: Continued or long-term need for sliding scale insulin for non-emergency coverage may indicate inadequate blood sugar control. Residents on rosiglitazone should be monitored for visual deterioration due to new onset and/or worsening of macular edema in diabetic patients.

MEDICATION	ISSUES AND CONCERNS
Insulin and Oral Hypoglycemics (continued) Including combination products Rosiglitazone/ Metformin, Glyburide/Metformin, Glipizide/Metformin, Pioglitazone/ Metformin	Adverse Consequences Metformin has been associated with the development of lactic acidosis (a potentially life threatening metabolic disorder), which is more likely to occur in individuals with: • serum creatinine ≥ 1.5 mg/dL in males or ≥ 1.4 mg/dL in females • abnormal creatinine clearance from any cause, including shock, acute myocardial infarction, or septicemia • age ≥ 80 years unless measurement of creatinine clearance verifies normal renal function • radiologic studies in which intravascular iodinated contrast materials are given • congestive heart failure requiring pharmacological management • acute or chronic metabolic acidosis with or without coma including diabetic ketoacidosis Rosiglitazone and pioglitazone have been associated with edema and weight gain; therefore, their use should be avoided in residents with Stage III or Stage IV heart failure. Sulfonylurea's can cause the syndrome of inappropriate anti-diuretic hormone (SIADH) and result in hyponatremia.
Chlorpropamide and Glyburide	Indications Chlorpropamide and Glyburide are not considered hypoglycemic agents of choice in older individuals because of the long half-life and/or duration of action and increased risk of hypoglycemia. Adverse Consequences May cause prolonged and serious hypoglycemia with symptoms including tachycardia, palpitations, irritability, headache, hypothermia, visual disturbances, lethargy, confusion, seizures, and/or coma.
ANTIFUNGALS	
Imidazoles for Systemic Use Fluconazole, Itraconazole, Ketoconazole	Indications Should be used in lowest possible dose for shortest possible duration, especially in anyone receiving other medications known to interact with these medications. Interactions/Adverse Consequences Interaction with warfarin can cause markedly elevated PT/INR, increasing bleeding risk. Multiple potentially significant medication interactions may occur, for example: • These medications when administered concurrently may increase the effect or toxicity of phenytoin, theophylline, sulfonylureas (hypoglycemics) • Other medications such as rifampin and cimetidine may decrease the effect of these antifungals May cause hepatotoxicity, headaches, GI distress. Monitoring Enhanced monitoring may be required to identify and minimize adverse consequences when these antifungals are given with warfarin (PT/INR), phenytoin (serum phenytoin levels), theophylline (serum theophylline levels) and sulfonylureas (fasting blood glucose).
ANTIMANIC MEDICATIONS	
Lithium	Indications Should generally not be given to individuals with significant renal or cardiovascular disease, severe debilitation, dehydration, or sodium depletion.

MEDICATION	ISSUES AND CONCERNS
Lithium (continued)	Monitoring Toxic levels are very close to therapeutic levels. Serum lithium concentration should be monitored periodically, and dosage adjusted accordingly. Interactions/Adverse Consequences May cause potentially dangerous sodium imbalance. Adverse consequences may occur at relatively low serum concentrations (1–1.5 mEq/L). Serum lithium concentration levels can be affected by many other medications such as thiazide diurectics, ACE inhibitors, NSAIDs.
ANTIPARKINSON MEDICATIONS	
All Classes ▪ Catechol-O-Methyl Transferase (COMT) Inhibitors Entacapone ▪ Dopamine Agonists Bromocriptine, Ropinirole, Ramipexole ▪ MAO Inhibitors Selegiline ▪ Others Amantadine ▪ Various Dopaminergic Combinations Carbidopa/Levodopa, Carbidopa/Levodopa/Entacapone	Adverse Consequences May cause significant confusion, restlessness, delirium, dyskinesia, nausea, dizziness, hallucinations, agitation. Increased risk of postural hypotension and falls, especially when given in conjunction with antihypertensive medications.
ANTIPSYCHOTIC MEDICATIONS	
All Classes ▪ First Generation Agents (conventional) Chlorpromazine, Fluphenazine, Haloperidol, Loxapine, Mesoridazine, Molindone, Perphenazine, Promazine, Thioridazine, Thiothixene, Trifluoperazine, Triflupromazine ▪ Second Generation Agents (atypical) Aripiprazole, Clozapine, Olanzapine, Quetiapine, Risperidone, Ziprasidone	Indications An antipsychotic medication should be used only for the following conditions and/or 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: • Schizophrenia • Schizo-affective disorder • Delusional disorder • Mood disorders such as mania, bipolar disorder, depression with psychotic features, and treatment refractory major depression • Schizophreniform disorder • Psychosis NOS • Atypical psychosis • Brief psychotic disorder • Dementing illnesses with associated behavioral symptoms • Medical illnesses or delirium with manic or psychotic symptoms and/or treatment-related psychosis or mania such as thyrotoxicosis, neoplasms or high dose steroids

MEDICATION	ISSUES AND CONCERNS
All Classes (continued)	In addition, the use of an antipsychotic must meet the criteria and applicable, additional requirements listed below: • Criteria ~ since diagnoses alone do not warrant the use of antipsychotic medications, the clinical condition must also meet at least one of the following criteria: o The symptoms are identified as being due to mania or psychosis such as auditory, visual, or other hallucinations; delusions such as paranoia or grandiosity; or o The behavioral symptoms present a danger to the resident or to others; or o The symptoms are significant enough that the resident is experiencing one or more of the following: inconsolable or persistent distress such as fear, continuously yelling, screaming, distress associated with end-of-life, or crying; a significant decline in function; and/or substantial difficulty receiving needed care such as not eating resulting in weight loss, fear and not bathing leading to skin breakdown or infection. • Additional Requirements o Acute Psychiatric Situations ~ when an antipsychotic medication is being initiated or used to treat an acute psychiatric emergency, such as a recent or abrupt onset or exacerbation of symptoms, related to one or more of the aforementioned conditions/diagnoses, that use must meet one of the above criteria and all of the following additional requirements: ▪ The acute treatment period is limited to seven days or less; and ▪ A clinician in conjunction with the interdisciplinary team must evaluate and document the situation within 7 days, to identify and address any contributing and underlying causes of the acute psychiatric condition and verify the continuing need for antipsychotic medication; and ▪ Pertinent non-pharmacological interventions must be attempted, unless contraindicated, and documented following the resolution of the acute psychiatric situation. o Enduring Psychiatric Conditions ~ Antipsychotic medications may be used to treat an enduring such as a non-acute, chronic, or prolonged condition, if the clinical condition/diagnosis meets the criteria listed above. In addition, before initiating or increasing an antipsychotic medication for enduring conditions, the target behavior must be clearly and specifically identified and monitored objectively and qualitatively, in order to ensure the behavioral symptoms are: ▪ Not due to a medical condition or problem, such as a headache or joint pain, fluid or electrolyte imbalance, pneumonia, hypoxia, unrecognized hearing or visual impairment, that can be expected to improve or resolve as the underlying condition is treated; and ▪ Persistent or likely to reoccur without continued treatment; and ▪ Not sufficiently relieved by non-pharmacological interventions; and ▪ Not due to environmental stressors, such as alteration in the resident's customary location or daily routine, unfamiliar care provider, hunger or thirst, excessive noise for that individual, inadequate or inappropriate staff response, physical barriers, that can be addressed to improve the psychotic symptoms or maintain safety; and

MEDICATION	ISSUES AND CONCERNS
All Classes (continued)	▪ Not due to psychological stressors, such as loneliness, taunting, or abuse, or anxiety or fear stemming from misunderstanding related to his or her cognitive impairment, such as the mistaken belief that this is not where he/she lives or inability to find his or her clothes or glasses, that can be expected to improve or resolve as the situation is addressed. After initiating or increasing the dose of an antipsychotic medication, the behavioral symptoms must be reevaluated periodically to determine the effectiveness of the antipsychotic and the potential for reducing or discontinuing the dose. Exception When antipsychotic medications are used for behavioral disturbances related to Tourette's disorder, or for non-psychiatric indications such as movement disorders associated with Huntington's disease, hiccups, nausea and vomiting associated with cancer or cancer chemotherapy, or adjunctive therapy at end of life. Inadequate Indications In many situations, antipsychotic medications are not indicated. They should not be used if the only indication is one or more of the following: 1) wandering; 2) poor self-care; 3) restlessness; 4) impaired memory; 5) mild anxiety; 6) insomnia; 7) unsociability; 8) inattention or indifference to surroundings; 9) fidgeting; 10) nervousness; 11) uncooperativeness; or 12) verbal expressions or behavior that are not due to the conditions listed under 'Indications' and do not represent a danger to the resident or others. Dosage Doses for acute indications such as delirium may differ from those used for long-term treatment, but should be the lowest possible to achieve the desired therapeutic effects. *Daily Dose Thresholds for Antipsychotic Medications Used to Manage Behavioral Symptoms Related to Dementing Illnesses* First Generation Chlorpromazine 75 mg Fluphenazine 4 mg Haloperidol 2 mg Loxapine 10 mg Molindone 10 mg Perphenazine 8 mg Pimozide * Prochloroperazine * Thioridazine 75 mg Thiothixene 7 mg Trifluoperazine 8 mg Second Generation 10 mg Aripiprazole 50 mg Clozapine 7.5 mg Olanzapine 150 mg Quetiapine 2 mg Risperidone * Ziprasidone *Not customarily used for the treatment of behavioral symptoms Duration If used to manage behavior, stabilize mood, or treat a psychiatric disorder, refer to Section V Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance.

MEDICATION	ISSUES AND CONCERNS
All Classes (continued)	Monitoring/Adverse Consequences The facility assures that residents are being adequately monitored for adverse consequences such as anticholinergic effects (Table II), akathisia, neuroleptic malignant syndrome (NMS), cardiac arrhythmias, death secondary to heart-related events such as heart failure or sudden death, falls, lethargy, increase in total cholesterol and triglycerides, parkinsonism, blood sugar elevation including diabetes mellitus, orthostatic hypotension, cerebrovascular event such as a stroke or transient ischemic attack (TIA) in older individuals with dementia, tardive dyskinesia or excessive sedation. When antipsychotics are used without monitoring they may be considered unnecessary medications because of inadequate monitoring.
ANXIOLYTICS	
All Anxiolytics ▪ Benzodiazepines, short-acting Alprazolam, Estazolam, Lorazepam, Oxazepam, Temazepam ▪ Benzodiazepines, long-acting Chlordiazepoxide, Clonazepam, Clorazepate, Diazepam, Flurazepam, Quazepam ▪ Buspirone ▪ Other Antidepressants except Bupropion	Indications Anxiolytic medications should only be used when • The 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: ▪ Generalized anxiety disorder ▪ Panic disorder ▪ Symptomatic anxiety that occurs in residents with another diagnosed psychiatric disorder ▪ Sleep disorders, see also Sedatives/Hypnotics ▪ Acute alcohol or benzodiazepine withdrawal ▪ Significant anxiety in response to a situational trigger ▪ Delirium, dementia, and other cognitive disorders with associated behaviors that are quantitatively and objectively documented; are persistent; are not due to preventable or correctable reasons; and constitute clinically significant distress or dysfunction to the resident or represent a danger to the resident or others. • Evidence exists that other possible reasons for the individual's distress have been considered; and • Use results in maintenance or improvement in the individual's mental, physical or psychosocial well-being such as reflected on the MDS or other assessment tools; or • There are clinical situations that warrant the use of these medications such as: ▪ a long-acting benzodiazepine is being used to withdraw a resident from a short-acting benzodiazepine ▪ used for neuromuscular syndromes such as cerebral palsy, tardive dyskinesia, restless leg syndrome or seizure disorders ▪ symptom relief in end of life situations Dosage Dosage is less than, or equal to, the following listed total daily doses unless higher doses as evidenced by the resident's response and/or the resident's clinical record are necessary to maintain or improve the resident's function. Duration If used to manage behavior, stabilize mood, or treat a psychiatric disorder, refer to Section V Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance. Adverse Consequences May increase risk of confusion, sedation, and falls.

Medication	Issues and Concerns
All Anxiolytics (continued)	*Total Daily Dose Thresholds for Anxiolytic Medications* Flurazepam 15 mg; Quazepam 7.5 mg Chlordiazepoxide 20 mg; Estazolam 0.5 mg Clorazepate 15 mg; Alprazolam 0.75 mg Diazepam 5 mg; Oxazepam 30 mg Clonazepam 1.5 mg; Lorazepam 2 mg
Diphenhydramine and Hydroxyzine	Indications Not appropriate for use as an anxiolytic.
Meprobamate	Indications Highly addictive and sedating medication; not indicated for use in older individuals. Dosage/Duration 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	Adverse Consequences Cardiac antiarrhythmics can have serious adverse effects in older individuals, including impaired mental function, falls, appetite, behavior, and heart function.
Amiodarone	Indications 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, such as rate control and anticoagulation, are equally effective and less toxic. Dosage/Monitoring 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. Interactions/Adverse Consequences May cause potentially fatal toxicities, including pulmonary toxicity, such as 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 interactions; for example, with digoxin and warfarin. Toxicity increases with higher doses and longer duration of use.
Disopyramide	Adverse Consequences Disopyramide has potent negative inotropic effects such as decreased force of heart contraction, which may induce heart failure in older individuals, and is also strongly anticholinergic.
All Antihypertensives	Dosage/Monitoring 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 such as clonidine or beta blockers gradual tapering may be required to avoid adverse consequences caused by abrupt cessation.

MEDICATION	ISSUES AND CONCERNS
All Antihypertensives (continued)	Interactions/Adverse Consequences May cause dizziness, postural hypotension, fatigue, and an increased risk for falls Many other medications may interact with antihypertensives to potentiate their effect such as levodopa or nitrates.
Alpha Blockers Alfuzosin, Doxazosin, Prazosin, Tamsulosin, Terazosin	Adverse Consequences 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 Benazepril, Captopril, Enalapril, Fosinopril, Lisinopril, Ramipril Angiotensin II Receptor Blockers Candesartan, Eprosartan, Irbesartan, Losartan, Olmesartan, Valsartan	Monitoring Monitoring of serum potassium is necessary especially in individuals receiving ACE inhibitors with potassium, or potassium sparing diuretics. Adverse Consequences May cause angioedema which include the 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.
Beta Adrenergic Blockers ▪ Nonselective: Propranolol ▪ Cardioselective: Atenolol, Esmolol, Metoprolol, Nadolol, Timolol	Adverse Consequences May cause or exacerbate: ▪ Bradycardia, especially in individuals receiving other medications that affect cardiac conduction such as 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
Calcium Channel Blockers	Adverse consequences May cause clinically significant constipation. May cause peripheral edema. Some agents may cause generalized aching, headache, muscle pain. Short acting/immediate release nifedipine increases the risk of cardiac complications and should not be used.
Methyldopa Including combination products such as methyldopa/hydrochlorothiazide	Indications Alternate treatments for hypertension are preferred Adverse Consequences May cause bradycardia and excessive sedation; may exacerbate depression in older individuals
Digoxin	Indications 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.

MEDICATION	ISSUES AND CONCERNS
Digoxin (continued)	Dosage Daily doses in older individuals should ordinarily not exceed 0.125 mg/day except when used to control atrial arrhythmia and ventricular rate. Monitoring 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 or 'digoxin level'. Adverse consequences may occur even with therapeutic serum concentration, especially in older individuals. Interactions/Adverse Consequences May interact with many other medications, possibly resulting in digoxin toxicity or elevated serum concentrations of other medications. 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.
Diuretics Bumetanide, Ethacrynic Acid, Furosemide, Hydrochlorothiazide, Metolazone, Spironolactone, Torsemide, Triamterene	Adverse Consequences May cause fluid and electrolyte imbalance, such as hypo/hypernatremia, hypo/hyperkalemia, or dehydration, hypotension; may precipitate or exacerbate urinary incontinence, falls.
Nitrates Isosorbide Mononitrate, Isosorbide Dinitrate, Nitroglycerin	Adverse Consequences May cause headaches, dizziness, lightheadedness, faintness, or symptomatic orthostatic hypotension, especially when initially started or when taken in combination with antihypertensive medications.
CHOLESTEROL LOWERING MEDICATIONS	
HMG-CoA Reductase Inhibitors (Statins) Atorvastatin, Fluvastatin, Lovastatin, Pravastatin, Rosuvastatin, Simvastatin	Monitoring Liver function monitoring should be performed consistent with manufacturer's recommendations, generally accepted as prior to initiation of therapy, at 12 weeks following both initiation of therapy and any increase in dose, and periodically such as semiannually thereafter. Adverse Consequences May impair liver function; liver function tests should be monitored as indicated above. May cause muscle pain, myopathy, and rhabdomyolysis, which is the breakdown of skeletal muscle that can precipitate kidney failure especially in combination with other cholesterol lowering medications.
Cholestyramine	Interactions May reduce the absorption of other medications being taken concurrently. Other medications, including diuretics, beta-blockers, corticosteroids, thyroid hormones, digoxin, valproic acid, NSAIDs, sulfonylureas, and warfarin should be administered one hour before or four hours after cholestyramine administration to avoid this interaction. Adverse Consequences May cause constipation, dyspepsia, nausea or vomiting, abdominal pain.
Fibrates Fenofibrate, Clofibrate	Monitoring Fenofibrate and clofibrate require regular monitoring of liver tests as well as evaluating the complete blood count (CBC) prior to and after initiation.

MEDICATION	ISSUES AND CONCERNS
Niacin	Monitoring Monitor glucose and liver function tests regularly Adverse Consequences Interferes with glucose control and can aggravate diabetes Can exacerbate active gallbladder disease and gout Flushing is common
COGNITIVE ENHANCERS	
Cholinesterase Inhibitors Donepezil, Galantamine, Rivastigmine	Indications As the underlying disorder progresses into advanced stages, the continued use of the medication should be reevaluated. Adverse Consequences May affect cardiac conduction, especially in individuals who already have a cardiac conduction disorder or who are taking other medications that affect heart rate. May cause insomnia, dizziness, nausea, vomiting, diarrhea, anorexia, and weight loss. Should be used with caution in individuals with severe asthma or obstructive pulmonary disease.
NMDA Receptor Antagonists Memantin	Indication As the underlying disorder progresses into advanced stages, the continued use of the medication should be reevaluated. Adverse Consequences May cause restlessness, distress, dizziness, somnolence, hypertension, headache, hallucinations, or increased confusion.
COUGH, COLD AND ALLERGY MEDICATIONS	
All Cough, Cold and Allergy Medications	Indications/Duration Should be used only for a limited duration, usually less than 14 days, unless there is documented evidence of enduring symptoms that cannot otherwise be alleviated and for which a cause cannot be identified and corrected.
Antihistamine H-1 Blockers Chlorpheniramine, Cyproheptadine, Diphenhydramine, Hydroxyzine, Meclizine, Promethazine	Indications H-1 blocker antihistamines have strong anticholinergic properties and are not considered medications of choice in older individuals. If appropriate and effective, topical instead of oral diphenhydramine should be considered for allergic reactions involving the skin. Dosage/Duration Should be used in the smallest possible dosage for the shortest possible duration, especially in individuals who are susceptible to anticholinergic side effects or who are receiving other medications with anticholinergic properties. Refer to Table II. Adverse Consequences May cause excessive sedation, confusion, cognitive impairment, distress, dry mouth, constipation, urinary retention. These may lead to other adverse consequences such as falls.
Oral Decongestants Pseudoephedrine	Adverse Consequences May cause dizziness, nervousness, insomnia, palpitations, urinary retention, and elevated blood pressure. Should be used with caution in individuals who have insomnia or hypertension.

MEDICATION	ISSUES AND CONCERNS
GASTROINTESTINAL MEDICATIONS	
Phenothiazine-Related Antiemetics Prochlorperazine, Promethazine	Indications Use with caution in individuals with Parkinson's disease, narrow-angle glaucoma, BPH, seizure disorder. Adverse Consequences 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, and 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	Adverse Consequences Relatively ineffective antiemetic that can cause significant extrapyramidal side effects in addition to lethargy, sedation, and confusion. Exception May be indicated in patients with Parkinson's Disease taking apomorphine.
Metoclopramide	Indications 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. Adverse Consequences 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. Monitoring It is essential to closely monitor at-risk individuals for adverse consequences.
Proton Pump Inhibitors (PPI) Esomeprazole, Lansoprazole, Omeprazole, Rabeprazole	Indications 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. Duration If used for greater than 12 weeks, clinical rationale for continued need and/or documentation should support an underlying chronic disease such as GERD or risk factors such as chronic NSAID use. Dosage Dosing of histamine-H2 antagonists should be based on renal function. Interactions Cimetidine has higher incidence of medication interactions and should be avoided in older individuals.

MEDICATION	ISSUES AND CONCERNS
Proton Pump Inhibitors (PPI) (continued)	Adverse Consequences 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	
All Glucocorticoids except topical or inhaled dosage forms Dexamethasone, Hydrocortisone, Methylprednisolone, Prednisone	Duration/Monitoring Necessity for continued use should be documented, along with monitoring for and management of adverse consequences. Adverse Consequences Intermediate- or longer-term use may cause hyperglycemia, psychosis, edema, insomnia, hypertension, osteoporosis, mood lability, or depression.
HEMATINICS	
Erythropoiesis Stimulants Darbepoetin, Erythropoietin	Indications Assessment of causes and categories of anemia should precede or accompany the use of this medication. Monitoring 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. Adverse Consequences May cause or worsen hypertension. Excessive dose or duration can lead to polycythemia, dangerous thrombotic events including myocardial infarction and stroke.
Iron	Indications Iron therapy is not indicated in anemia of chronic disease when iron stores and transferrin levels are normal or elevated. Dosage/Duration 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. Monitoring Baseline serum iron or ferritin level and periodic CBC or hematocrit/ hemoglobin. Adverse Consequences May cause constipation, dyspepsia. Can accumulate in tissues and cause multiple complications if given chronically despite normal or high iron stores.
LAXATIVES	
All Categories including bulk producing laxatives, hyperosmolar agents, saline laxatives, stimulant laxatives, emollient laxatives	Adverse Consequences May cause flatulence, bloating, and 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.

MEDICATION	ISSUES AND CONCERNS
MUSCLE RELAXANTS	
All Muscle Relaxants Baclofen, Carisoprodol, Chlorzoxazone, Cyclobenzaprine, Dantrolene, Metaxalone, Methocarbamol, Orphenadrine	Indications/Adverse Consequences Most are poorly tolerated by older individuals due to anticholinergic side effects, refer to 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. Exception Periodic use such as once every three months for a short duration of not more than seven days may be appropriate, when other interventions or alternative medications are not effective or not indicated.
OREXIGENICS APPETITE STIMULANTS	
All Appetite Stimulants Megestrol Acetate, Oxandrolone, Dronabinol	Indications 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. Monitoring Appetite and weight should be monitored at least monthly and agent should be discontinued if there is no improvement. Adverse Consequences 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	
Bisphosphonates Alendronate, Ibandronate, Risedronate	Dosage These medications must be taken according to very specific directions, including time of day, position, and timing relative to other medications and food. Monitoring Individuals receiving these medications should be monitored closely for gastrointestinal complications, including esophageal or gastric erosion. Adverse Consequences Potential to cause gastrointestinal symptoms including dysphagia, esophagitis, gastritis, or esophageal and gastric ulcers, especially when given to individuals who are also taking oral corticosteroids, aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs).
PLATELET INHIBITORS	
Ticlopidine	Indication Use may be appropriate in individuals who have had a previous stroke or have evidence of stroke precursors such as a transient ischemic attacks (TIAs) and who cannot tolerate aspirin or another platelet inhibitor.

MEDICATION	ISSUES AND CONCERNS
Ticlopidine (continued)	Adverse Consequences 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.
All Platelet Inhibitors Dipyridamole, Dipyridamole Extended Release and Aspirin as a fixed-dose combination, Aspirin, Clopidogrel	Interactions/Adverse Consequences May cause thrombocytopenia and increase risk of bleeding. Common side effects include headache, dizziness, and vomiting. See discussion at NSAIDs regarding aspirin. Concurrent use with warfarin or NSAIDs may increase risk of bleeding.
RESPIRATORY MEDICATIONS	
Theophylline	Interactions Potentially significant interactions with many other medications may occur, especially various antibiotics, seizure medications, and cardiac medications. Monitoring/Adverse Consequences 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 ▪ Anticholinergic Ipratopium, Tiotropium ▪ Beta 2 Agonists Albuterol, Formoterol, Pirbuterol Acetate, Salmeterol ▪ Corticosteroids Beclomethasone, Budesonide, Flunisolide, Fluticasone, Triamcinolone Acetonide ▪ Miscellaneous Cromolyn, Nedocromil Sodium	Adverse Consequences Inhaled anticholinergics can cause xerostomia or 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	
All Hypnotics ▪ Benzodiazepine Hypnotics Estazolam, Flurazepam, Quazepam, Temazepam, Triazolam ▪ Non-Benzodiazepine Hypnotics Eszopiclone, Zaleplon, Zolpidem ▪ Melatonin Receptor Agonists Ramelteon ▪ Other Hypnotics Chloral Hydrate	Indications Most cases of insomnia such as secondary or co-morbid insomnia are associated with underlying conditions such as psychiatric disorders including depression, urinary frequency, pain, cardiopulmonary disorders (COPD or CHF), obstructive sleep apnea, and restless leg syndrome. Insomnia may be further described by the duration of symptoms. Before initiating medications to treat insomnia, other factors potentially causing insomnia should be evaluated, including, for example: * environment, such as excessive heat, cold, or noise; lighting * inadequate physical activity * facility routines that may not accommodate residents' individual needs such as time for sleep, awakening, toileting, or medication treatments

MEDICATION	ISSUES AND CONCERNS
All Hypnotics (continued) ▪ Miscellaneous Agents Used for Sleep Sedating Antidepressants such as Trazodone, Sedating Antihistamines such as Hydroxyzine	∗ provision of care in a manner that disrupts sleep ∗ pain and discomfort ∗ underlying conditions (secondary or co-morbid insomnia) such as psychiatric disorders, depression, cardiopulmonary disorders (COPD or CHF), urinary frequency, pain, obstructive sleep apnea, and restless leg syndrome It is expected that interventions such as sleep hygiene approaches, individualizing the sleep and wake times to accommodate the person's wishes and prior customary routine, and maximizing treatment of any underlying conditions are implemented to address the causative factor(s). These guidelines apply to any medication that is being used to treat insomnia. Initiation of medications to induce or maintain sleep should be preceded or accompanied by other interventions to try to improve sleep. All sleep medications should be used in accordance with approved product labeling; for example, timing and frequency of administration relative to anticipated waking time. The use of sedating medications for individuals with diagnosed sleep apnea requires careful assessment, documented clinical rationale, and close monitoring. Exceptions Use of a single dose sedative for dental or medical procedures. During initiation of treatment for depression, pain or other comorbid condition(s), short-term use of a sleep medication may be necessary until symptoms improve or the underlying aggravating factor can be identified and/or effectively treated. Dosage *Daily Dose Thresholds for Sedative-Hypnotic Medications* 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 *These medications are not considered medications of choice for the management of insomnia, especially in older individuals. Duration If used to induce sleep or treat a sleep disorder, refer to Section V Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance.
Barbiturates Amobarbital, Butabarbital, Pentobarbital, Secobarbital, Phenobarbital, Amobarbital-Secobarbital, Barbiturates with other medications	Note: Refers to barbiturates used to induce sleep or treat anxiety disorder Indications Barbiturates should not be initiated in any dose for any individuals to treat anxiety or insomnia; as they are highly addictive and cause numerous adverse effects, especially in older individuals. Exception These guidelines do not apply to the use of phenobarbital to treat seizure disorders. Refer to the Anticonvulsant section. Interactions/Adverse Consequences May increase the metabolism of many medications such as anticonvulants and antipsychotics which may lead to decreased effectiveness and subsequent worsening of symptoms or decreased control of underlying illness.

MEDICATION	ISSUES AND CONCERNS
Barbiturates (continued)	Interactions/Adverse Consequences (continued) 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.
THYROID MEDICATIONS	
All Thyroid Medications Levothyroxin, Triidothryonine	Interactions Many clinically significant medication interactions have been identified; therefore, re-evaluation of medication doses is indicated. Dosage Initiation of thyroid supplementation should occur at low doses and be increased gradually to avoid precipitating cardiac failure or adrenal crisis. Monitoring Assessment of thyroid function using 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.
URINARY INCONTINENCE MEDICATIONS	
Urinary Incontinence Types and Agents ▪ Urge Incontinence ∗ Anticholinergics ~ Darifenacin, Oxybutynin, Tolterodine, Trospium ∗ Tricyclic Antidepressants ~ Desipramine, Imipramine ▪ Stress Incontinence ∗ Alpha adrenergic agonists ~ Pseudoephedrine ▪ Mixed Incontinence ∗ Estrogen Replacement Agents ∗ Imipramine ▪ Overflow Incontinence ∗ Alpha Adrenergic Antagonists, refer to Antihypertensives ∗ Bethanechol Chloride	Indications Before or soon after initiating medication(s) to manage urinary incontinence, assessment of underlying causes and identification of the type/category of urinary incontinence needs to be documented. These medications have specific, limited indications based on the cause and type/category of incontinence. Monitoring Ongoing assessments of the effects of the medication on the individual's urinary incontinence as well as lower urinary tract symptoms should be done periodically. Adverse Consequences Anticholinergics and TCAs may cause anticholinergic effects. Refer to Table II. Estrogen Replacement Agents: oral agents may cause systemic side effects and increased risks such as deep venous thrombosis or 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.

EXAMPLES OF MEDICATIONS WITH ANTICHOLINERGIC PROPERTIES

ANTIHISTAMINES, H-1 BLOCKERS

Chlorpheniramine	Diphenhydramine
Cyproheptadine	Hydroxyzine

CARDIOVASCULAR MEDICATIONS

Digoxin	Furosemide
Disopyramide	Nifedipine

ANTIDEPRESSANTS

Amoxapine	Imipramine
Amitriptyline	Nortriptyline
Clomipramine	Protriptyline
Desipramine	Paroxetine
Doxepin	

GASTROINTESTINAL MEDICATIONS

Antispasmodic Medications	*Antidiarrheal Medications*
Belladonna	Atropine
Chlordiazepoxide	Diphenoxylate
Clidinium	
Dicyclomine	*Antiulcer Medications*
Hyoscyamine	Cimetidine
Propantheline	Ranitidine

ANTIPARKINSON MEDICATIONS

Amantadine	Biperiden
Benztropine	Trihexyphenidyl

ANTIPSYCHOTIC MEDICATIONS

Chlorpromazine	Olanzapine
Clozapine	Thioridazine

MUSCLE RELAXANTS

Cyclobenzaprine	Orphenadrine
Dantrolene	

URINARY INCONTINENCE

Oxybutynin	Tolterodine
Probantheline	Trospium
Solifenacin	

ANTIVERTIGO MEDICATIONS

Meclizine	Scopolamine

PHENOTHIAZINE ANTIEMETICS

Prochlorperazine	Promethazine

POTENTIAL ADVERSE CONSEQUENCES OF MEDICATIONS WITH ANTICHOLINERGIC PROPERTIES	
Blood pressure, increased Breathing difficulty, changes Clumsiness or unsteadiness Convulsions Delirium Digestive system changes Bloating; Bowel motility, decreased; Constipation; Ileus, Paralytic/Adynamic; Nausea or vomiting; Swallowing difficulty with dry mouth Dizziness Drowsiness Fever Headache Heart rate, increased	Lethargy, fatigue Mental status/behavior changes Attention, impaired; Distress, excitement, nervousness; Cognitive decline; Confusion/disorientation; Hallucinations; Memory loss; Restlessness or irritability Mucous membrane dryness: mouth, nose Muscle weakness, severe Skin, changes Dryness; Sweating, decreased; Flushing; Warmth, excessive Speech, slurring Urinary retention or difficulty Vision impairment, changes in acuity Blurring; Eye pain; Glaucoma, worsening; Light sensitivity

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:
  - Non-pharmacological approaches when clinically indicated, in an effort to reduce the need for or the dose of a medication;
  - Only those medications that are clinically indicated in the dose and for the duration to meet his or her assessed needs; 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 this protocol during every initial and standard survey. In addition, this protocol may be used on revisits or abbreviated survey such as a 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 including 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.

- *Observation and Record Review*
  Use the following table 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

Determine if the resident has been transferred to acute care since the last survey and/or has recently as in the previous 3 months experienced a change in condition or currently has signs and symptoms, such as:

- 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, such as 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

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.

REVIEW FOR HOW FACILITY MANAGED MEDICATIONS FOR THE RESIDENT

Review the record (including the care 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:

- 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 response to medications and progress toward therapeutic goals and emergence of medication-related adverse consequences
- Adverse consequences, if and potentially medication-related, note if there was recognition, evaluation, reporting, and management by the facility and physician action regarding potential medication-related adverse consequences

- *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 consequence 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.

- *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.
  - 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; such as 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 the 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:

- Use of the appropriate dose;
- An adequate indication for use;
- 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;
- Reduction of dose or discontinuation of the medication in the presence of adverse consequences, as indicated; and

- Provision of behavioral interventions and gradual dose reduction for individuals receiving antipsychotics unless clinically contraindicated in an effort to reduce or discontinue the medication.

Criteria for Compliance ~ 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 goals(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, then cite F329.

Non-Compliance ~ 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.
  - Failure to provide a clear clinical rationale for continuing a medication that may be causing an adverse consequence.
  - 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.
  - Prescribing or administering a medication despite an allergy to that medication, or without clarifying whether a true allergy existed as opposed to other reactions such as an idiosyncratic reaction or other side effect.
  - Initiation of an antipsychotic medication to manage distressed behavior without considering a possible underlying medical cause, such as an UTI or congestive heart failure, or environmental or psychosocial stressor.
- *Inadequate Monitoring* – Examples of noncompliance related to inadequate monitoring include, but are not limited to:
  - Failure to monitor a medication consistent with the current standard of practice or manufacturer's guidelines.
  - 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 such as for the relief of pain or normalization of thyroid function or the emergence of an adverse consequence.
  - 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:
  - Failure to consider periodically the continued necessity of the dose or the possibility of tapering a medication.
  - 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 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:
    - Failure to re-evaluate the rationale for continuing antipsychotic medication initiated in an emergency after the acute phase has stabilized.
    - Use of an antibiotic beyond the recommended clinical guidelines or the facility policy without adequate reassessment of the resident and determination of continuing need.
- *Adverse Consequences* – Examples of noncompliance related to adverse consequences include, but are not limited to:
  - 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.
  - Failure to act upon a report of the risk for or presence of clinically significant adverse consequence(s) such as discontinuing a medication or reducing the dose or providing clinical justification for why the benefit outweighs the adverse consequences.
- *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:
  - Prolonged or indefinite antipsychotic use without attempting gradual dose reductions.
  - Failure to attempt GDR in the absence of identified and documented clinical contraindications.
  - 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.

- *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)&(4) and (d)(2); F154 Notice of Rights and Services; F155 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)&(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 such as a MAR, physician order sheets, or 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.

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:

- *Presence of potential or actual harm/negative outcomes(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, such as 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.

♦ *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.

♦ *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 and respond to signs and symptoms of neuroleptic malignant syndrome (NMS).
  - Failure to recognize developing serotonin syndrome, such as confusion, motor restlessness, or tremor, in a resident receiving a SSRI, leading to the addition of medications with additive serotonin effect or medication to suppress the symptoms.
  - 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 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 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.
- Facility failure to take appropriate action such as 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.

  Note: If Severity Level 3 has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 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:
  - 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 take appropriate action such as changing or suspending administration of the warfarin dose for a resident who has an INR greater than 4 and less than 9 without any bleeding.
  - 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. For example 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 Considerations ~ 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.