F758

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§483.45(c)(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:

(i) Anti-psychotic;
(ii) Anti-depressant;
(iii) Anti-anxiety; and
(iv) Hypnotic.

§483.45(e) Psychotropic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that--

§483.45(e)(1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;

§483.45(e)(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;

§483.45(e)(3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and

§483.45(e)(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in §483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.

§483.45(e)(5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.

INTENT: (*F757)* §483.45(d) Unnecessary drugs and *(F758) §*483.45(c)(3) and (e)Psychotropic Drugs

The intent of *these* requirements is that:

- each resident's entire drug/medication regimen is managed and monitored to promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being;
- the facility implements gradual dose reductions (GDR) and non-pharmacological interventions, unless contraindicated, prior to initiating or instead of continuing psychotropic medication; and
- PRN orders for psychotropic medications are only used when the medication is necessary and PRN use is limited.

NOTE: For concerns related to unnecessary medications, excluding psychotropic medications, surveyors should assess compliance with §483.45(d), F757.

For concerns related to psychotropic medications only, including the unnecessary medication requirements, surveyors should assess compliance with §§483.45(c) and (e), F758.

The Guidance for these two tags is combined to avoid unnecessary duplication.

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

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

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

DEFINITIONS *(F757)* §483.45 (d) Unnecessary Drugs and *(F758) §*483.45(c)(3) and (e) Psychotropic Drugs

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

"Adverse consequence"is a broad term referring to unwanted, uncomfortable, or dangerous effects that a drug may have, such as impairment or decline in an individual's mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease) (adapted from The Merck Manual Professional Version, http://www.merckmanuals.com/professional/clinical-pharmacology/adverse-drug-reactions/adverse-drug-reactions.)

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, hallucinations, flushing, and increased blood pressure. Types of medications that may produce anticholinergic side effects include:

- Antihistamines, antidepressants, anti-psychotics, antiemetics, muscle relaxants; and
- Certain medications used to treat cardiovascular conditions, Parkinson's disease, urinary incontinence, gastrointestinal issues and vertigo.

"Behavioral interventions"are individualized, non-pharmacological approaches to care that are provided as part of a supportive physical and psychosocial environment, directed toward understanding, preventing, relieving, and/or accommodating a resident's distress or loss of abilities, as well as maintaining or improving a resident's mental, physical or psychosocial well-being.

"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.

"Dose"*is the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.*

"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.*

"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, and accepted standards of practice for a resident's age and condition.*

"Expressions or indications of distress"refers to a person's attempt to communicate unmet needs, discomfort, or thoughts that he or she may not be able to articulate. The expressions may present as crying, apathy, or withdrawal, or as verbal or physical actions such as: pacing, cursing, hitting, kicking, pushing, scratching, tearing things, or grabbing others.

"Extrapyramidal symptoms (EPS)"are neurological side effects that can occur at any time from the first few days of treatment with antipsychotic medication 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.

"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.

"Psychotropic drug"is defined in the regulations at §483.45(c)(3), as "any drug that affects brain activities associated with mental processes and behavior." Psychotropic drugs include, but are not limited to the following categories: anti-psychotics, anti-depressants, anti-anxiety, and hypnotics.

"Serotonin Syndrome"is a potentially serious clinical condition resulting from overstimulation of serotonin receptors. It is commonly related to the use of multiple serotonin-stimulating medications (e.g., SSRIs, SNRIs, triptans, certain antibiotics). Symptoms may include restlessness, hallucinations, confusion, loss of coordination, fast heartbeat, 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.

GUIDANCE *(F757)* §483.45(d) Unnecessary Drugs and *(F758)* §483.45(c)(3) and (e) Psychotropic Drugs

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, arresting or slowing a disease process, reducing or eliminating symptoms, or as part of diagnosing or preventing a disease or symptom.

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, hip fractures, and death. The Beers Criteria for Potentially Inappropriate Medication Use in Older Adults provides information on safely prescribing medications for older adults,

http://www.healthinaging.org/medications-older-adults/.

NOTE: References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

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 (especially psychotropic medications), it is important for the IDT to implement non-pharmacological approaches designed to meet the individual needs of each resident. Educating facility staff and providers about the importance of implementing individualized, non-pharmacological approaches to care prior to the use of medications may minimize the need for medications or reduce the dose and duration of those medications. Additional information as well as examples of non-pharmacological interventions may be found in other guidance for regulations at *(F741)* §483.40, Behavioral Health Services and *(F679)* §483.*24*, Quality of Life.

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, symptoms, and expressions, 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 or providers can increase the resident's chances of receiving unnecessary medications.

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: *https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program or search for "FDA Safety Alerts for Human Medical Products."*. 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). Federal regulations at 21 CFR 201.57 (a)(4) and (c)(1) also require manufacturers to place statements about serious problems or contraindications in a prominently displayed box that appears on the medication labelling and in greater detail in the full prescribing information that accompanies the medication. The boxed warning is reserved for prescription drugs that pose a significant risk of serious or life-threatening adverse effects, based on medical studies.

The facility's pharmacist is a valuable source of information about medications. Listings

or descriptions of most significant risks, recommended doses, medication interactions, cautions, etc. can be found in widely available, standard references, and computer software and systems that provide up-to-date information. It is important to note that some of the medication information found in many of these references is not specific to older adults or individuals residing in nursing homes. A list of resources and tools is provided at the end of this guidance.

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 as well as documenting medication management steps. The attending physician plays a key leadership role in medication management by developing, monitoring, and modifying the medication regimen in conjunction with residents, their families, and/or representative(s) and other professionals and direct care staff (the IDT).

When selecting medications and non-pharmacological approaches, members of the IDT, including the resident, his or her family, and/or representative(s), 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:

- Involvement of the resident, his or her family, and/or the resident representative in the medication management process.
- Selection of medications(s) based on assessing relative benefits and risks to the individual resident;
- Evaluation of a resident's physical, behavioral, mental, and psychosocial 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 and based on assessing relative benefit and risks to, and preferences and goals of, the individual resident;
- The use of non-pharmacological approaches, unless contraindicated, to minimize the need for medications, permit use of the lowest possible dose, or allow medications to be discontinued; and
- The monitoring of medications for efficacy and adverse consequences.
- Resident Choice –If a resident declines treatment, the facility staff and physician should inform the resident about the risks related to the lack of the medication, 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.
- Advance Directives – A resident's advance directives may include withdrawing or withholding medications. Whether or not a resident has an advance directive, the facility is responsible for giving treatment, support, and other care that is consistent with the resident's condition and applicable care instructions, according to the resident's care plan. If there are concerns regarding Resident Choice or Advance Directives, consider investigating the requirements at §483.10, Resident Rights and §483.21, Care Planning.

The resident's medical record documents and communicates to the entire team the basic elements of the care process and the resident's goals and preferences. 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).

The regulations associated with medication management include consideration of:

- Indication and clinical need for medication;
- Dose (including duplicate therapy);
- Duration;
- Adequate monitoring for efficacy and adverse consequences; and
- Preventing, identifying, and responding to adverse consequences.

With regard to psychotropic medications, the regulations additionally require:

- Giving psychotropic medications only when necessary to treat a specific diagnosed and documented condition;
- Implementing GDR and other non-pharmacologic interventions for residents who receive psychotropic medications, unless contraindicated; and
- Limiting the timeframe for PRN psychotropic medications, which **are not** antipsychotic medications, to 14 days, unless a longer timeframe is deemed appropriate by the attending physician or the prescribing practitioner.
- Limiting PRN psychotropic medications, which **ar**e antipsychotic medications, to 14 days and not entering a new order without first evaluating the resident.

NOTE: While there may be isolated situations where a pharmacological intervention is required first, these situations do not negate the obligation of the facility to develop and implement non-pharmacological interventions. For additional information related to situations where a non-pharmacological intervention may be contraindicated, refer to §483.40(a)(2), Implementing non-pharmacological interventions.

Indication for Use

The resident's medical record must show documentation of adequate indications for a medication's use and the diagnosed condition for which a medication is prescribed. An evaluation of the resident by the IDT helps to identify his/her needs, goals, 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 selecting initial medications and/or non-pharmacological approaches and when deciding whether to modify or discontinue a current medication. The evaluation also clarifies:

- Whether other causes for the symptoms (including expressions or indications of distress that could mimic a psychiatric disorder) have been ruled out;

- Whether the physical, mental, behavioral, and/or psychosocial signs, symptoms, or related causes are persistent or clinically significant enough (e.g., causing functional decline) to warrant the initiation or continuation of medication therapy;
- Whether non-pharmacological approaches are implemented, unless clinically contraindicated for the resident or declined by the resident;
- Whether a particular medication is clinically indicated to manage the symptom or condition; and
- Whether the intended or actual benefit is understood by the resident and, if appropriate, his/her family and/or representative(s) and is sufficient to justify the potential risk(s) or adverse consequences associated with the selected medication, dose, and duration.

The content and extent of the evaluation may vary with the situation and may employ various assessment instruments and diagnostic tools. Examples of information to be considered and evaluated may include, but are not limited to, the following:

- An appropriately detailed evaluation of mental, physical, psychosocial, and functional status, including comorbid conditions and pertinent psychiatric symptoms and diagnoses and a description of resident complaints, symptoms, and signs (including the onset, scope, frequency, intensity, precipitating factors, and other important features);
- Each resident's goals and preferences;
- Allergies to medications and foods and potential for medication interactions;
- A history of prior and current medications and non-pharmacological interventions (including therapeutic effectiveness and any adverse consequences);
- Recognition of the need for end-of-life or palliative care; and
- The basis for declining care, medication, and treatment and the identification of pertinent alternatives.
- Documentation of indications of distress, delirium, or other changes in functional status.

Circumstances that warrant evaluation of the resident and medication(s) 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 medication regimen review. See F756 for guidance related to the medication regimen review.
- Orders for PRN psychotropic and/or antipsychotic medications which are not prescribed to treat a diagnosed specific condition or do not meet the PRN requirements for psychotropic and antipsychotic medications.

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, preferences, goals, and related factors.
- Multiple prescribers – Regardless of who the prescribers are, the continuation of a medication needs to be evaluated to determine if the medication is still warranted in the context of the resident's other medications and comorbidities. Medications prescribed by a specialist or begun in another care setting, such as the hospital, need to have a clinically pertinent documented rationale in the resident's medical record.
- New medication order as an emergency measure – When a resident is experiencing an acute medical problem or psychiatric emergency (e.g., the resident's expression or action 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. If the new medication is a psychotropic or antipsychotic medication ordered on a PRN basis, the PRN order(s) must be consistent with the requirements for PRN use of psychotropic and antipsychotic medications at §483.45(e)(3), (4), and (5). When psychopharmacological medications are used as an emergency measure, adjunctive approaches, such as individualized, non-pharmacological approaches and techniques must be implemented. Longer term management options should be discussed with the resident, their family, and/or representative(s).
- Psychiatric disorders or expressions and/or indications of distress – As with all symptoms, it is important to seek the underlying cause of the distress. Some examples of potential causes include delirium, pain, psychiatric or neurological illness, environmental or psychological stressors, dementia, or substance intoxication or withdrawal. Non-pharmacologic approaches, unless clinically contraindicated, must be implemented to address expressions or indications of distress. However, medications may be effective when the underlying cause of a resident's distress has been determined, non-pharmacologic approaches to care have been ineffective, or expressions of distress have worsened. Medications may be unnecessary and are likely to cause harm when given without a clinical indication, at too high of a dose, for too long after the resident's distress has been resolved, or if the medications are not monitored. All approaches to care, including medications, need to be monitored for efficacy, risks, benefits, and harm and revised as necessary.

NOTE: Permission given by or a request made by the resident and/or representative does not serve as a sole justification for the medication itself.

Dose
Medications are prescribed 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 IDT about the resident, including the resident's preferences and goals, the type of medication(s), and therapeutic goals being considered or used.

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

Duplicate therapy is generally not indicated, unless current clinical standards of practice and documented clinical rationale confirm the benefits of multiple medications from the same class or with similar therapeutic effects. Some examples of potentially problematic duplicate therapy include use of more than one product containing the same medication, concomitant use of drugs within the same class, or medications from different therapeutic categories with similar effects or properties. Additionally, the risk for duplication is particularly high during transitions of care, especially if medications are not tracked closely between locations or within the care settings. Documentation is necessary to clarify the rationale for and benefits of duplicate therapy and the approach to monitoring for benefits and adverse consequences.

Duration
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. Regarding PRN medications, it is important that the medical record include documentation related to the attending physician's or other prescriber's evaluation of the resident and of indication(s), specific circumstance(s) for use, and the desired frequency of administration for each medication. As part of the evaluation, gathering and analyzing information helps define clinical indications and provide baseline data for subsequent monitoring. Common considerations for appropriate duration may include:

- A medication initiated as a result of a time-limited condition (for example, delirium, pain, infection, nausea and vomiting, cold and cough symptoms, or itching) is then discontinued when the condition has resolved, or there is documentation indicating why continued use is still relevant. Failure to review whether the underlying cause has resolved may lead to excessive duration.
- A medication administered beyond the stop date established by the prescriber, without evidence of clinical justification for continued use of the medication, may be considered excessive duration.
- A medication, which is prescribed on a PRN basis, is requested by the resident and/ or/administered by staff on a regular basis, indicating a more regular

schedule *or other change in medication regimen* may be needed.

Monitoring for Efficacy and Adverse Consequences
The information gathered during the initial and ongoing evaluations and through conversations with the resident and, as appropriate, his or her family or representative is essential to:

- Verify or differentiate the underlying diagnoses or other underlying causes of signs and symptoms.
- Incorporate into a comprehensive care plan that reflects person-centered 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 warnings of adverse consequences that may be rare, but have sudden onset, or that may be irreversible. If the facility has established protocols for monitoring specific medications and the protocols are accessible for staff use, the care plan may refer staff to these protocols;
- Optimize the therapeutic benefit of medication therapy and minimize or prevent potential adverse consequences;
- Establish parameters for evaluating the ongoing need for the medication; and
- Track progress and/or decline towards the therapeutic goal.

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

- Manufacturers' package inserts and boxed warnings;
- Facility policies and procedures;
- Pharmacists;
- Clinical practice guidelines or clinical standards of practice;
- Medication references; and
- Clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.

Monitoring and accurate documentation of the resident's response to any medication(s) is essential to evaluate the ongoing benefits as well as risks of various medications. Monitoring should also include evaluation of the effectiveness of non-pharmacological approaches, such as prior to administering PRN medications.

Monitoring involves several steps, including:

- Identifying the essential information and how it will be obtained and reported-- It is important to consider who is responsible for obtaining the information, which information should be collected, and how the information will be documented. The information that is collected depends on therapeutic goals, detection of potential or actual adverse consequences, and consideration of risk factors, such as:

- Medication-medication, medication-food interactions;
- Clinical condition (for example renal disease);
- Properties of the medication;
- Boxed warnings; and
- Resident's 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, achievement of resident goals, 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 and choices. Monitoring involves three aspects:
  - Periodic planned evaluation of progress toward the therapeutic goals;
  - Continued vigilance for adverse consequences; and
  - Evaluation of identified adverse consequences.
- 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.
- 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, the pharmacist, and the resident to consider whether current medications and doses continue to be appropriate or should be reduced, changed, or discontinued. Serum concentration monitoring may be necessary for some medications. Abnormal or toxic serum concentrations must be evaluated for dosage adjustments. If serum concentrations are within normal ranges, each resident should still be evaluated for effectiveness and side effects.
- Re-evaluating and updating monitoring approaches-- Modification of monitoring may be necessary when the resident experiences changes, such as:
  - Acute onset of signs or symptoms or worsening of chronic disease;
  - Addition or discontinuation of medications and/or non-pharmacological approaches, for example, a resident who takes warfarin regularly starts on a medication that interacts with warfarin, therefore more frequent blood work may be needed;
  - 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.

Adverse consequences related to medications are common enough to warrant serious attention and close monitoring. An HHS Office of the Inspector General (OIG) report released in February 2014 found approximately one in five SNF residents experienced at least one adverse *event* during their SNF stay. Thirty-seven percent of these events were related to medications and were often preventable. See the full

report, "Adverse Events in Skilled Nursing Facilities: National Incidence among Medicare Beneficiaries" at http://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf.

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;
- 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.
- Responding to the resident's reported experience with medications and treatments they have received.

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, psychotropic medications, anti-infectives, and anticonvulsants.[1] Adverse consequences can range from minimal harm to functional decline, hospitalization, permanent injury, and death. Use of a tool, such as the CMS Adverse Drug Event Trigger Tool, may assist in identifying resident risk factors and triggers for adverse drug events as well as *in determining* whether a facility has systems and processes in place to minimize risk factors and mitigate harm to residents. The tool is available on the CMS Nursing Home Quality Assurance and Performance Improvement website, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/Adverse-Drug-Event-Trigger-Tool.pdf. *Additionally, as part of a facility's QAPI program, a facility may track its use of certain classes of medications, such as antipsychotics, through reports from the long-term care pharmacist which could identify trends and reduce adverse events.*

One common adverse consequence is delirium, which presents as an alteration in attention and awareness associated with a change in cognition not explained by a current or emerging neurocognitive disorder. Delirium may result from medications as well as other factors including electrolyte imbalances or infections. While delirium is not always preventable, identifying and addressing risk factors may reduce the occurrence. 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.[2]

Delirium may go undiagnosed, be misinterpreted as dementia, or misdiagnosed as a psychiatric disorder, such as bipolar disorder. Delirium develops rapidly over a short period of time, such as hours or days, and usually follows a fluctuating course throughout the day. Additionally, the resident may have difficulty paying attention and be less aware of his or her surroundings. Delirium can be characterized as hyperactive (e.g., extreme

restlessness, climbing out of bed), hypoactive (e.g., sluggish and lethargic), or mixed (e.g., normal level of activity with lowered awareness). Delirium is particularly common post-hospitalization; signs and symptoms may be subtle and therefore are often missed. Although generally thought to be short lived, delirium can persist for months. Recognizing delirium is critical, as failure to act quickly to identify and treat the underlying causes may result in poor health outcomes or death.

Negative psychosocial outcomes can also occur in relation to unnecessary medications, including psychotropic medications. These adverse consequences may include: suicidal ideation, recurrent debilitating anxiety, extreme aggression or agitation, significant decline in former social patterns, social withdrawal, psychomotor agitation or retardation, inability to think or concentrate, and apathy.

Psychotropic Medications and Antipsychotic Medications (F758 Only Guidance)

*In accordance with §483.45(d)(4) and a*s clarified in the section *above* on Indication for Use, residents must not receive any medications which are not clinically indicated to treat a specific condition. The medical record must show documentation of the diagnosed condition for which a *psychotropic* medication is prescribed *(§483.45(e)(1))*. All medications included in the psychotropic medication definition may affect brain activities associated with mental processes and behavior. *Use of psychotropic medications, other than antipsychotics, should not increase when efforts to decrease antipsychotic medications are being implemented. Risks associated with psychotropic medications still exist regardless of the indication for their use (e.g., nausea, insomnia, itching), therefore the requirements pertaining to psychotropic medications in §483.45(e) apply to the four categories of drugs (anti-psychotic, anti-depressant, anti-anxiety and hypnotic) listed in §483.45(c)(3)**without exception.***

Other medications not classified as anti-psychotic, anti-depressant, anti-anxiety, or hypnotic medications can also affect brain activity and should not be used as a substitution for another psychotropic medication listed in §483.45(c)(3), unless prescribed with a documented clinical indication consistent with accepted clinical standards of practice and *in accordance with §483.45(d)(4). Categories of medications which affect brain activity include antihistamines, anti-cholinergic medications and central nervous system agents used to treat conditions such as seizures, mood disorders, pseuodobulbar affect, and muscle spasms or stiffness. The requirements pertaining to psychotropic medications apply to these types of medications when their documented use appears to be a substitution for another psychotropic medication rather than for the original or approved indication.*

For example, if a resident is prescribed valproic acid and the medical record shows no history of seizures but there is documentation that the medication is being used to treat agitation or other expressions of distress, then the use of valproic acid should be consistent with the psychotropic medication requirements under §483.45(e). Residents who take these medications must be monitored for any adverse consequences, specifically increased confusion or over-sedation, *as required by §483.45(d)(3). Concerns related to the use of the medications noted here would be investigated at F757, Unnecessary*

Medications, if the medication is being used for its original or approved indication and not primarily as a psychotropic medication.

The regulations and guidance concerning psychotropic medications are not intended to supplant the judgment of a physician or prescribing practitioner in consultation with facility staff, the resident and his/her representatives and in accordance with appropriate standards of practice. Rather, the regulations and guidance are intended to ensure psychotropic medications are used only when the medication(s) is appropriate to treat a resident's specific, diagnosed, and documented condition and the medication(s) is beneficial to the resident, as demonstrated by monitoring and documentation of the resident's response to the medication(s). *Concerns related to inappropriate prescribing of psychotropic medications may require referrals by the facility and/or the survey team to State Medical Boards or Boards of Nursing.*

Note:*CMS is aware of situations where practitioners have potentially misdiagnosed residents with a condition for which antipsychotics are an approved use (e.g., new diagnosis of schizophrenia) which would then exclude the resident from the long-stay antipsychotic quality measure.*

For these situations, please refer to the following regulations:

- *§483.21(b)(3)(i), F658, to determine if the**practitioner's diagnostic practices** meet professional standards.*
- *§483.20(g), F641 to determine if the**facility completed an assessment**which accurately reflects the resident's status.*

Use of Psychotropic Medications in Specific Circumstances
Acute or Emergency Situations: When a psychotropic medication is being initiated or used to treat an emergency situation (i.e., acute onset or exacerbation of symptoms or immediate threat to health or safety of resident or others) related to a documented condition or diagnosis, a clinician in conjunction with the IDT must evaluate and document the situation to identify and address any contributing and underlying causes of the acute condition and verify the need for a psychotropic medication. Use of psychotropic medication to treat an emergency situation must be consistent with the requirements regarding PRN orders for psychotropic and antipsychotic medications and any continued use must be consistent with the requirements for gradual dose reduction (GDR).

Enduring Conditions: Psychotropic medications may be used to treat an enduring (i.e., non-acute; chronic or prolonged) condition. Before initiating or increasing a psychotropic medication for enduring conditions, the resident's symptoms and therapeutic goals must be clearly and specifically identified and documented. Additionally, the facility should ensure that the resident's expressions or indications of distress are:

- Not due to a medical condition or problem (e.g., pain, fluid or electrolyte imbalance, infection, obstipation, medication side effect or poly-pharmacy) that

can be expected to improve or resolve as the underlying condition is treated or the offending medication(s) are discontinued;

- Not due to environmental stressors alone (e.g., alteration in the resident's customary location or daily routine, unfamiliar care provider, hunger or thirst, excessive noise for that individual, inadequate or inappropriate staff response), that can be addressed to improve the symptoms or maintain safety;
- Not due to psychological stressors alone (e.g., loneliness, taunting, abuse), anxiety or fear stemming from misunderstanding related to his or her cognitive impairment (e.g., the mistaken belief that this is not where he/she lives or inability to find his or her clothes or glasses, unaddressed sensory deficits) that can be expected to improve or resolve as the situation is addressed; and
- Persistent--The medical record must contain clear documentation that the resident's distress persists and his or her quality of life is negatively affected and, unless contraindicated, that multiple, non-pharmacological approaches have been attempted and evaluated in any attempts to discontinue the psychotropic medication.

New Admissions: Many residents are admitted to a SNF/NF already on a psychotropic medication. The medication may have been started in the hospital or the community, which can make it challenging for the IDT to identify the indication for use. However, the attending physician in collaboration with the consultant pharmacist must re-evaluate the use of the psychotropic medication and consider whether or not the medication can be reduced or discontinued upon admission or soon after admission. Additionally, the facility is responsible for:

- Preadmission screening for mental illness and intellectual disabilities, see §483.20(k), F645 and F646; and
- Obtaining physician's orders for the resident's immediate care, see §483.20(a), F635.

Monitoring of Psychotropic Medications: When monitoring a resident receiving psychotropic medications, the facility must evaluate the effectiveness of the medications as well as look for potential adverse consequences. After initiating or increasing the dose of a psychotropic medication, the behavioral symptoms must be reevaluated periodically (e.g., at least during quarterly care plan review, if not more often) to determine the potential for reducing or discontinuing the dose based on therapeutic goals and any adverse effects or functional impairment.

If the record shows evidence of *prescribing multiple psychotropic medications,* or switching from one type of psychotropic medication to another category of psychotropic medication, surveyors must review the medical record to determine whether the prescribing practitioner provided a rationale.

Potential Adverse Consequences: The facility assures that residents are being adequately monitored for adverse consequences such as:

- **General**: anticholinergic effects which may include flushing, blurred vision, dry mouth, altered mental status, difficulty urinating, falls, excessive sedation, constipation
- **Cardiovascular:**signs and symptoms of cardiac arrhythmias such as irregular heart beat or pulse, palpitations, lightheadedness, shortness of breath, diaphoresis, chest or arm pain, increased blood pressure, orthostatic hypotension
- **Metabolic:**increase in total cholesterol and triglycerides, unstable or poorly controlled blood sugar, weight gain
- **Neurologic:**agitation, distress, EPS, neuroleptic malignant syndrome (NMS), parkinsonism, tardive dyskinesia, cerebrovascular event (e.g., stroke, transient ischemic attack (TIA).

If psychotropic medication*(s) are* identified as possibly causing or contributing to adverse consequences as identified above, the facility and prescriber must determine whether the medication*(s)* should be continued and document the rationale for the decision. *Use of multiple psychotropic medications can increase the risk of adverse consequences and/or confound the effects of individual medications although there may be infrequent times when use of multiple psychotropic medications is indicated, such as to treat multiple symptoms of a condition or to address side effects.* Additionally, the medical record should show evidence that the resident, family member or representative is aware of and involved in the decision. In some cases, the benefits of treatment may outweigh the risks or burdens of treatment, so the medication*(s)* may be continued.

Antipsychotic Medications

As with all medications, the indication for any prescribed first generation (also referred to as typical or conventional antipsychotic medication) or second generation (also referred to as atypical antipsychotic medication) antipsychotic medication must be thoroughly documented in the medical record. While antipsychotic medication may be prescribed for expressions or indications of distress, the IDT must first identify and address any medical, physical, psychological causes, and/or social/environmental triggers. Any prescribed antipsychotic medication must be administered at the lowest possible dosage for the shortest period of time and is subject to the GDR requirements for psychotropic medications.

Antipsychotic medications (both first and second generation) have serious side effects and can be especially dangerous for elderly residents. When antipsychotic medications are used without an adequate rationale, or for the sole purpose of limiting or controlling expressions or indications of distress without first identifying the cause, there is little chance that they will be effective, and they commonly cause complications such as movement disorders, falls with injury, cerebrovascular adverse events (cerebrovascular accidents (CVA, commonly referred to as stroke), and transient ischemic events) and increased risk of death. The FDA Boxed Warning which accompanies second generation anti-psychotics states, "Elderly patients with dementia-related psychosis treated with atypical anti-psychotic drugs are at an increased risk of death," https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053171.htm. The FDA issued a similar Boxed Warning for first

generation antipsychotic drugs, https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124830.htm. .

Diagnoses alone do not necessarily warrant the use of an antipsychotic medication. Antipsychotic medications may be indicated if:

- behavioral symptoms present a danger to the resident or others;
- expressions or indications of distress that are significant distress to the resident;
- if not clinically contraindicated, multiple non-pharmacological approaches have been attempted, but did not relieve the symptoms which are presenting a danger or significant distress; and/or [3]
- GDR was attempted, but clinical symptoms returned.

If antipsychotic medications are prescribed, documentation must clearly show the indication for the antipsychotic medication, the multiple attempts to implement care-planned, non-pharmacological approaches, and ongoing evaluation of the effectiveness of these interventions.

Gradual Dose Reduction for Psychotropic Medications

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 the required GDR or tapering of 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 approaches 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 physical, mental, and psychosocial well-being, and to consider whether the medications should be continued, reduced, discontinued, or otherwise modified. Examples of these opportunities include:

- During the monthly medication regimen review, the pharmacist evaluates resident-related information for dose, duration, continued need, and the emergence of adverse consequences for all medications;
- When evaluating the resident's progress, the attending physician or prescribing practitioner reviews the total plan of care, orders, the resident's response to medication(s), and determines whether to continue, modify, or stop a medication; and
- During the quarterly MDS review, the facility evaluates mood, function, behavior, and other domains that may be affected by medications.

The time frames and duration of attempts to taper any medication must be consistent with accepted standards of practice and depend on factors including the coexisting medication regimen, the underlying causes of symptoms, individual risk factors, and pharmacologic characteristics of the medications. Some medications (e.g., antidepressants,

sedative/hypnotics, opioids) require more gradual tapering so as to minimize or prevent withdrawal symptoms or other adverse consequences. Close monitoring while medications are tapered will enable facility staff to determine whether a resident is experiencing side effects, changes in behavior, or withdrawal symptoms that originally prompted prescribing of the drug. However, some residents with specific, enduring, progressive, or terminal conditions such chronic depression, Parkinson's disease psychosis, or recurrent seizures may need specific types of psychotropic medications or other medications which affect brain activity indefinitely.

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

Dose reductions should occur in modest increments over adequate periods of time to minimize withdrawal symptoms and to monitor symptom recurrence. Compliance with the requirement to perform a GDR may be met if, for example, within the first year in which a resident is admitted on a psychotropic medication or after the prescribing practitioner has initiated a psychotropic medication, a facility attempts a GDR in two separate quarters (with at least one month between the attempts), unless clinically contraindicated. Additional information related to gradual dose reduction may be found The American Psychiatric Association Practice Guidelines on the use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia, 2016, https://psychiatryonline.org/doi/full/10.1176/appi.books.9780890426807.ap02 and at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3119470/, Discontinuing Medications: A Novel Approach for Revising the Prescribing Stage of the Medication-Use Process (2008).

For any individual who is receiving a psychotropic medication to treat expressions or indications of distress related to dementia, the GDR may be considered clinically contraindicated for reasons that include, but that are not limited to:

- 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 a psychotropic medication to treat a disorder other than expressions or indications of distress related to dementia (for example, schizophrenia, bipolar mania, depression with psychotic features, or another medical condition, other than dementia, which may cause psychosis), the GDR may be considered clinically contraindicated for reasons that include, but that are not limited to:

- 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 exacerbate an underlying medical or 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 exacerbate an underlying medical or psychiatric disorder.

PRN Orders for Psychotropic and Antipsychotic Medications

In certain situations, psychotropic medications may be prescribed on a PRN basis, such as while the dose is adjusted, to address acute or intermittent symptoms, or in an emergency. However, residents must not have PRN orders for psychotropic medications unless the medication is necessary to treat a diagnosed specific condition. The attending physician or prescribing practitioner must document the diagnosed specific condition and indication for the PRN medication in the medical record. *(§483.45(e)(3))*

The table below explains additional limitations for PRN psychotropic (other than antipsychotic medications) and PRN antipsychotic medications.

Type of PRN order	**Time Limitation**	**Exception**	**Required Actions**
PRN orders for psychotropic medications, excluding antipsychotics	14 days	Order may be extended beyond 14 days if the attending physician or prescribing practitioner believes it is appropriate to extend the order.	Attending physician or prescribing practitioner should document the ationale for the extended time period in the medical record and indicate a specific duration.
PRN orders for antipsychotic medications only	14 days	None	If the attending physician or prescribing practitioner wishes to write a new order for the PRN antipsychotic, the attending physician or prescribing practitioner must first evaluate the esident to determine if the new order for the PRN antipsychotic is appropriate.

The required evaluation of a resident before writing a new PRN order for an antipsychotic entails the attending physician or prescribing practitioner directly examining the resident and assessing the resident's current condition and progress to determine if the PRN antipsychotic medication is still needed. As part of the evaluation, the attending physician or prescribing practitioner should, at a minimum, determine and document the following in the resident's medical record:

- Is the antipsychotic medication still needed on a PRN basis?
- What is the benefit of the medication to the resident?
- Have the resident's expressions or indications of distress improved as a result of the PRN medication?

NOTE: Report of the resident's condition from facility staff to the attending physician or prescribing practitioner does not constitute an evaluation.

KEY ELEMENTS OF NONCOMPLIANCE
If any of the elements the sections below involve psychotropic medications, investigate F758. For all other medications, investigate F757.

To cite deficient practice at F757and/or F758, the surveyor's investigation will generally show:

Inadequate Indications for Use

- Failure to document a clinical reason or a clinically pertinent rationale, for using medication(s) for a specific resident or for continuing medication(s) that may be causing an adverse consequence; or
- Prescribing or administering a medication despite an allergy to that medication, or without clarifying whether a true allergy existed; or
- Failure to consider relative risks and benefits or potentially lower risk medications before initiating medication(s) that present clinically significant risks; or
- Failure to provide a clinically pertinent explanation for concomitant use of two or more medications in the same pharmacological class; or
- Failure to consider other factors that may be causing expressions or indications of distress before initiating a psychotropic medication, such as an underlying medical condition (e.g., urinary tract infection, dehydration, delirium), environmental (lighting, noise) or psychosocial stressors; or
- Administering a psychotropic medication(s), which the resident has not previously received, when it is not necessary to treat a specific condition that has been diagnosed and documented in the clinical record; or
- Failure to attempt non-pharmacological approaches, unless clinically contraindicated, in efforts to discontinue psychotropic medications.

NOTE:*For concerns related to a medication that involves an inadequate indication for use and evidence shows the medication is also being used for the purpose of discipline or*

staff convenience rather than to treat the resident's medical symptoms, surveyors should evaluate whether evidence shows the medication is being used to sedate the resident or restrict the resident's movement or cognition and assess compliance with §483.10(e)(1) and §483.12(a)(2), F605, Right to Be Free From Chemical Restraints, instead of citing both at F605 and F757 or F758 for the same evidence.

NOTE:*Instances of prescribing antibiotics unnecessarily should be cited at §483.45(d), F757. The findings may support citing F881 as well, in which case the surveyor must also show that the facility is not implementing part or all of the Antibiotic Stewardship Program (e.g., antibiotic use protocols that utilize an infection assessment tool, monitoring of antibiotic use, or feedback and education to prescribing providers).*

Inadequate Monitoring–

- Failure to monitor the responses to or effects of a medication, or
- Failure to respond when monitoring indicates a lack of progress toward the therapeutic goal (e.g., relief of pain or normalization of thyroid function) or the emergence of an adverse consequence; or
- Failure to monitor for changes in psychosocial engagement resulting from adverse consequences of medications, (e.g., resident no longer participates in activities because medication causes confusion or lethargy); or
- Failure to monitor a medication consistent with the current standard of practice or manufacturer's guidelines; or
- Failure to carry out the monitoring that was ordered or failure to monitor for potential adverse consequences; or
- Failure to consider whether the onset or worsening of symptoms, or a change of condition, may be related to a medication; or
- Failure to monitor effectiveness of non-pharmacological approaches, unless clinically contraindicated, before prescribing and administering medications.

NOTE: Additional information as well as examples of non-pharmacological approaches may be found in other guidance for regulations at §483.40, Behavioral Health Services and §483.25, Quality of Care and Quality of Life.

Excessive Dose (including duplicate therapy)–

- Giving a total amount of any medication at one time or over a period of time that exceeds *the amount prescribed by the prescribing practitioner,* 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; or
- Failure to consider periodically the continued necessity of the dose or the possibility of tapering a medication; or
- Failure to provide and/or document a clinical rationale for using multiple medications from the same pharmacological class.

- Failure to consider each resident's clinical condition as a factor in determining an appropriate dose, as adverse consequences may occur even when medication serum concentration levels are in the therapeutic range.

Excessive Duration–

- 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; or
- Continuation of a medication after the desired therapeutic goal has been achieved, without evaluating whether there is a continued need for the medication, for example, use of an antibiotic beyond the recommended clinical guidelines or the facility policy without adequate reassessment and evaluation of the resident.

Adverse Consequences

- Failure to act upon (i.e., discontinue a medication or reduce the dose or provide clinical justification for why the benefit outweighs the adverse consequences) or report the presence of adverse consequence(s); or
- Failure to monitor for the presence of adverse consequences related to the use of medications *(e.g.*, particularly high risk medications, such as warfarin, insulin, opioids, or medications requiring monitoring of blood work); or
- Failure to respond to the presence of adverse consequences related to the use of medications (*e.g.*, particularly high risk medications, such as warfarin, insulin, or opioids).

Psychotropic Medications

- Failure to present to the attending physician or prescribing practitioner the need to attempt GDR in the absence of identified and documented clinical contraindications; or
- Use of psychotropic medication(s) without documentation of the need for the medication(s) to treat a specific diagnosed condition; or
- PRN psychotropic medication ordered for longer than 14 days, without a documented rationale for continued use; or
- Failure to implement person-centered, non-pharmacological approaches in the attempt to reduce or discontinue a psychotropic medication *(§§483.40(a)(2) and 483.45(e)(2))*; or
- Administering a new PRN antipsychotic medication for which the resident had a previous PRN order (for 14 days) but the medical record does not show that the attending physician or prescribing practitioner evaluated the resident for the appropriateness of the new order for the medication.

PROCEDURES: §483.45(d) Unnecessary drugs and §§483.45(c)(3) and (e) Psychotropic Drugs

Investigating Concerns Related to Medication Regimen Review, Unnecessary Medications, and Psychotropic Medications

Use the Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element (CE) Pathway along with the interpretive guidelines when determining if the facility meets the requirements for, and when investigating concerns related to, Medication Regimen Review, Unnecessary Medications, and Psychotropic Medications.

Review the medications (prescription, over-the-counter medications, and nutritional supplements such as herbal products) currently ordered and/or discontinued by the prescriber at least back to the most recent signed recapitulation 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.

Use the table below to guide observations, record review, and interviews with the resident or representative and relevant staff. Symptoms and signs described in the table may also be related to a resident's condition or disease. The surveyor may seek clarification about the basis of specific signs and symptoms from the attending physician and/or pharmacist.

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS	REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT
Determine if the resident has been transferred to acute care since the last survey and/or has recently (e.g., the previous 3 months) experienced a change in condition or currently has signs and symptoms, such as: • Anorexia and/or unplanned weight loss, or weight gain • Apathy • Behavioral changes, unusual patterns (including increased expressions or indications of distress, social isolation or withdrawal) • Bleeding or bruising, spontaneous or unexplained • Bowel dysfunction including diarrhea, constipation and impaction • Dehydration, fluid/electrolyte imbalance • Depression, mood disturbance • Dysphagia, swallowing difficulty	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 • Implementation of person-centered, non-pharmacological approaches to care • 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:

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS	REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT
• Falls, dizziness, or evidence of impaired coordination • Gastrointestinal bleeding • Headaches, muscle pain, generalized or nonspecific aching or pain • Lethargy • Mental status changes, (e.g., new or worsening confusion, new cognitive decline, worsening of dementia (including delirium), inability to concentrate) • Psychomotor agitation (e.g., restlessness, inability to sit still, pacing, hand-wringing, or pulling or rubbing of the skin, clothing, or other objects). • Psychomotor retardation (e.g., slowed speech, thinking, and body movements) • 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, determine whether the facility considered medications as a potential cause of the change or symptom.	○ Response to medications and progress toward therapeutic goals and resident's goals ○ Emergence of medication-related adverse consequences • Adverse consequences, if present and potentially medication-related, note if there was: ○ Recognition, evaluation, reporting, and management by the IDT ○ Physician action regarding potential medication-related adverse consequences • The residents goals and preferences for medications and treatments

Interview the resident, his or her family, and representative(s) and the IDT, as needed to gather information about use of medications *and any possible side effects* in the nursing home. *Evaluate if the resident may have experienced psychosocial harm related to side effects of medications. Did side effects such as sedation, lethargy, agitation, mental status changes, or behavior changes:*

- *affect a resident's abilities to perform activities of daily living or to interact with others,*
- *cause the resident to withdraw or decline from usual social patterns,*
- *show the resident has decreased engagement in activities,*
- *cause diminished ability to think or concentrate.*

For a resident who is unable to communicate psychosocial outcomes related to medication side effects, the surveyor should consider how a reasonable person would experience the changes caused by medication side effects as explained in the Psychosocial Outcome Severity Guide, on the CMS Nursing Homes Survey Resources website.

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

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

Examples of some of the related requirements that may be considered when concerns have been identified include the following:

- 42 CFR 483.10(g)(14), F580, 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 (c), F552, Planning and Implementing Care
  - 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 483.24(c), F679, Activities
  - Review whether the facility provides activities that address a resident's needs and may permit discontinuation or reduction of psychotropic medications. Review also whether adverse consequences of medications interfere with a resident's ability to participate in activities.
- 42 CFR 483.24(a), F676, Activities of Daily Living
  - 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 483.40, F740, Behavioral Health Services
  - 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 483.30(a), F710, 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 483.30(b), F711, Physician Visits and 42 CFR 483.30(c), F712, Frequency of 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 483.70(h), F841, 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.
- *42 CFR §483.80(a)(3), F881, Antibiotic Stewardship Program*
  - *Review whether the facility has developed and implemented their antibiotic stewardship program (e.g., antibiotic use protocols that utilize an infection assessment tool, monitoring of antibiotic use, feedback and education to prescribing providers).*

DEFICIENCY CATEGORIZATION

See also the Psychosocial Outcome Severity Guide *on the CMS Nursing Homes Survey Resources website* for additional information on evaluating the severity of psychosocial outcomes.

Examples of noncompliance that demonstrate severity at Level 4 *immediate jeopardy to resident health or safety* include, but are not limited to:

- Facility failure to take appropriate action (e.g., suspending administration of the anticoagulant) in response to an elevated *International Normalized Ratio* (INR) for a resident who is receiving warfarin, resulting in either the potential or actual need to transfuse or hospitalize the resident.
- Failure to respond appropriately to an INR level that is above or below the target range for treatment of atrial fibrillation, prevention of deep vein thrombosis (DVT) or pulmonary embolus, or other documented indication.
- Failure to recognize developing serotonin syndrome (e.g., confusion, motor restlessness, tremor) in a resident receiving a SSRI antidepressant, leading to the

addition of medications with additive serotonin effect or medication to suppress the symptoms.

- Failure to recognize and respond to signs and symptoms of neuroleptic malignant syndrome (NMS).
- In the presence of initial gastrointestinal bleeding, i.e. blood in stool, the failure to recognize medication therapies (such as NSAIDs or COX-2 inhibitors, bisphosphonates) as potentially causing or contributing to the gastrointestinal bleed, resulting in the continued administration of the medication, until the resident required hospitalization for severe bleeding.
- Failure to recognize that use of an antipsychotic medication, originally prescribed for agitation, has caused significant changes in the resident's quality of life. The resident no longer participates in activities that they previously enjoyed, has difficulty concentrating and carrying on conversations, and spends most of the day isolated in his or her room, sleeping in a recliner or in bed. *Continued u*se of the antipsychotic medication without an adequate clinical indication, GDR attempts, and *evidence of* non-pharmacological approaches resulted in psychosocial harm.
- Failure to re-evaluate the appropriateness of *continued administration of* a PRN antipsychotic medication, originally prescribed for acute delirium, which resulted in *the likelihood of* significant side effects from the medication.

Examples of Level 3, Actual harm (physical or psychosocial) that are not immediate jeopardy, include, but are not limited to:

- The facility failed to evaluate a resident's new medication regimen as the source of a resident's recent nausea. The prescriber then added a medication to treat the nausea, which caused agitation and insomnia.
- Failure to evaluate a resident for a GDR for a psychotropic medication originally prescribed to treat delirium. Delirium symptoms subsided but the resident remained drowsy and inactive.

Examples of Level 2, No actual harm with a potential for more than minimal harm that is not immediate jeopardy, may include but are not limited to:

- Facility failure to identify and act upon minor symptoms of allergic response to medications, such as a rash with mild itching to the abdomen and no other symptoms, causing minimal discomfort.

- Facility failure to monitor for response or for the emergence or presence of adverse consequences for a resident who has not yet experienced an adverse consequence or decline in function, such as by monitoring hydration status and basic metabolic profile for a resident receiving diuretics or ACE inhibitors.

Severity Level 1: No Actual Harm with Potential for Minimal Harm
Severity Level 1 does not apply for this regulatory requirement because 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.

RESOURCES AND TOOLS

The following resources and tools provide information on medications including box warnings, appropriate dosing, medication categories, drug interactions, and medication safety information. Some of these resources also assist in identifying the correct class of a medication (e.g., identifying whether a medication is an antipsychotic or other category of psychotropic medication). Additionally, the list includes some of the recognized clinical resources available for understanding the overall treatment and management of medical problems, symptoms and medication consequences and precautions.

- U.S. Department of Health and Human Services, National Institute of Mental Health Web site, which includes publications and clinical research information www.nimh.nih.gov
- MedlinePlus, https://www.nlm.nih.gov/medlineplus/druginformation.html
- National Library of Medicine Drug Information Portal, http://druginfo.nlm.nih.gov/drugportal/drug/categories (medication class information).
- The Food and Drug Administration (FDA) webpage, Medwatch: The FDA Safety Information and Adverse Event Reporting Program, http://www.fda.gov/Safety/MedWatch/default.htm
- The University of Maryland Medical Center Drug Interaction Tool, http://umm.edu/health/medical/drug-interaction-tool
- American Medical Directors Association, www.amda.com
- American Society of Consultant Pharmacists, www.ASCP.com

This list is not all-inclusive. CMS is not responsible for the content or accessibility of pages found at these sites. URL addresses were current as of the date of this publication.

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