

## **Psychotropic Medication**

### **POLICY:**

Based upon each resident's comprehensive assessment, the facility will ensure that residents who have not used psychotropic drugs are not given them unless the medication is necessary to treat a specific condition that is diagnosed and documented in the clinical record. Residents will not receive psychotropic medications unless behavioral programming and/or environmental changes or other non-pharmacological interventions have failed to sufficiently address the resident's target behavioral goals. The facility will monitor psychotropic medications for proper dose, including duplicate therapy, duration, evidence of adequate monitoring for efficacy and adverse consequences and to prevent, identify and respond to adverse consequences. Residents who receive psychotropic medications will receive gradual dose reductions and behavioral interventions unless clinically contraindicated with the intention to decrease or discontinue the use of the psychotropic medication whenever safe and possible. PRN orders for psychotropic medications will be limited to 14 days unless the physician identifies the rationale to extend the medication beyond 14 days. PRN anti-psychotic drugs will be limited to 14 days and will not be renewed unless the physician evaluates the resident for appropriateness of the medication. When selecting medications and non-pharmacological approaches, members of the interdisciplinary team and the resident and resident representative, if applicable, will participate in the care process to identify, assess, advocate for, monitor and communicate the resident's needs and changes of condition.

### **OBJECTIVE AND INTENT OF PSYCHOTROPIC MEDICATION POLICY:**

The objective of this requirement is to monitor and ensure that the resident's drug regimen is managed to promote or maintain the resident's highest practicable mental, physical and psychosocial well-being. The goal is to monitor the resident's use of psychotropic drugs in an effort to assist with stabilizing or improving the resident's outcome, quality of life and functional capacity, while using psychotropic medications only when needed to treat a specific condition that is diagnosed and documented. In addition, providing an interdisciplinary collaborative process to implement a resident-centered plan for gradual dose reductions, non-pharmacological interventions, monitoring and action with PRN orders for psychotropic medications, will assist the care team to identify that their use is limited and necessary.

## DEFINITIONS

**“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-drugreactions/adverse-drug-reactions>.)

**“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, antiemetic’s, 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 wellbeing.

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

**“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. “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.

**“Convenience”** is defined as the result of any action that has the effect of altering a resident’s behavior such that the resident requires a lesser amount of effort or care, and is not in the resident’s best interest.

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).

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

“**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

**“Indication for use”** is defined as 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.

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

**“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.

**Pharmacist:** The facility’s licensed pharmacist, whether employed directly by the facility or through arrangement

**“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.
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**“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.

**Side Effect:** an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence

**“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.

**PROCEDURE:**

**Prior** to the administration of a psychotropic medication, the following includes a process for the IDT and resident/resident representative to participate in the care process:

1. The indication for any psychotropic medication will be thoroughly documented in the clinical record to include an appropriate supporting diagnosis and identification of behavioral symptom(s) being treated. The medical record must show documentation of adequate indication and diagnosed condition.

a. In the event that the resident is admitted to the facility already on a psychotropic medication the attending physician in collaboration with the consultant pharmacist must re-evaluate the use of the psychotropic medication and consider whether the medication can be reduced or discontinued upon admission or soon after. (See PASARR policy and procedure)

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

i. Behavioral symptoms present a danger to the resident or others

ii. Expressions or indications of distress that are significant distress to the resident

iii. If not clinically contraindicated, multiple non-pharmacological approaches have been attempted, but did not relieve the symptoms which present a danger or significant distress; and/or

iv. Gradual Dose Reduction attempted but clinical symptoms returned

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

2. A Psychotropic Drug Assessment will be completed on admission, quarterly, a new medication or renewal order, an irregularity identified in the pharmacist’s medication regimen review and with changes of condition (significant change of condition, new, persistent or recurrently symptom/problem, worsening of an existing problem, unexplained decline in function or cognition). The assessment will be reviewed by the IDT helps to identify resident’s 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. Attempt to identify underlying cause for behavioral symptom(s). This will include an evaluation of a resident's physical, behavioral, mental, and psychosocial signs and symptoms, to identify the underlying cause(s), including adverse consequences of medications. The evaluation will also consider each resident's goals and preferences, allergies to medications and foods, a history of prior and current medications and non-pharmacological interventions, 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 alternative as well as documented indications of distress, delirium, or other changes in functional status. In addition, if resident has a hypnotic medication ordered, a sleep assessment will be completed to identify root cause analysis for sleep concerns and person-centered approaches necessary to keep resident at their highest practicable level.

3. 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.
  - a. 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;
  - b. 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;
  - c. 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
  - d. 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.
  
4. Based upon individualized assessment, determine non-pharmacological approaches that can be implemented prior to the use of psychotropic medications. Identify non-pharmacological interventions that can be utilized to use the lowest possible dose and to work in conjunction with the goal of reduction or discontinuation. Documentation will reflect attempts to



implement care-planned, non-pharmacological approaches and ongoing effectiveness of these interventions.

5. Discussion with the physician on selection and use of the medication(s), including dose and duration, based upon resident's age and clinical condition. Review the risks and benefits of use related to the individualized goals and preferences.

6. Consent: Provide the resident/resident representative with information on the medication, indication, dose, side effects, adverse consequences and goal of treatment. Obtain informed **(Insert specific State requirements for consent here)** consent from the resident and/or resident representative and document education, information regarding the medication indication and directions for use, side effects and potential adverse consequences, risks and benefits of the medication and resident choice. Discuss any advance directives that the resident has formulated to provide care consistent with resident choice. The resident and/or responsible party will be notified regarding dose changes. This will be documented in the nurse notes. Consents and any psychotropic medications will be reviewed quarterly at resident care conference.

7. Ongoing documentation must include a root cause analysis of behavioral indicators or symptoms, monitoring for efficacy and adverse consequences.

8. Identified target behaviors will be monitored each shift along with individualized interventions as well as supporting documentation in the clinical record.

9. The goals of psychotropic medication and non-pharmacologic approaches will be addressed in the resident's care plan. The care plan will also include the type of psychotropic drug(s) to be monitored for side effects daily, such as gait disorders, movement disorders, cognitive or behavior changes, discomfort (pain, constipation etc.), signs of hypotension, dry mouth (cholinergic effects).

10. Baseline Tardive Dyskinesia assessment will be completed with re-assessment every six months and as needed for antipsychotic medications.

11. PRN orders for psychotropic drugs are limited to 14 days. The resident will be monitored for the behavior, non-pharmacological interventions and outcome, and use of the psychotropic drug to report to physician. If the physician believes that the PRN order should be extended beyond the 14 days, the physician must document rationale in the medical record. If the PRN is an antipsychotic medication, the medication will be limited to 14 days and not renewed unless the physician evaluates the resident for appropriateness of the medication and documents in the medical record.

12. Psychotropic medications are reviewed with the nurse's monthly documentation.
13. If a resident declines/refuses treatment, the facility staff and physician will inform the resident of the risks related to the lack of medication and offer relevant alternatives and non-pharmacologic approaches as indicated based upon individualized assessment and condition.
14. The pharmacist performing the monthly medication regimen review will also review the resident's medical record to appropriately monitor the medication regimen and ensure that the medications each resident receives are clinically indicated. Pharmacist will alert facility immediately for any hazards related to FDA boxed warnings and provide directions for monitoring and additions to the plan of care.

### **Gradual Dose Reductions for Psychotropic Medications**

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. 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. 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.

1. **Within the first year** in which a resident is admitted on a **psychotropic** medication or after the prescribing practitioner has initiated a psychotropic 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.
2. 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.
3. 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.

### **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,

1. A. clinician in conjunction with the IDT will 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.
2. Use of psychotropic medication to treat an emergency situation, will 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).
3. 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).

### **References**

CMS State Operations Manual, Appendix PP – Guidance to Surveyors for Long Term Care Facilities:

- <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Advance-Appendix-PP-Including-Phase-2-.pdf>