**F605**

*(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)*

**§483.10(e) Respect and Dignity.**

**The resident has a right to be treated with respect and dignity, including:**

**§483.10(e)(1) The right to be free from any . . . chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms, consistent with §483.12(a)(2).**

**§483.12**

**The resident has the right to be free from abuse, neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom from corporal punishment, involuntary seclusion and any physical or chemical restraint not required to treat the resident's medical symptoms.**

**§483.12(a) The facility must—. . .**

**§483.12(a)(2) Ensure that the resident is free from . . . chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms.**

**. . . .**

***§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(d) Unnecessary drugs—General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—***

***(1) In excessive dose (including duplicate drug therapy); or***
***(2) For excessive duration; or***
***(3) Without adequate monitoring; or***
***(4) Without adequate indications for its use; or***
***(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or***
***(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.***

***§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***

*The intent of these requirements is to ensure residents only receive psychotropic medications when other nonpharmacological interventions are clinically contraindicated. Also, residents must only remain on psychotropic medications when a gradual dose reduction and behavioral interventions have been attempted and/or deemed clinically contraindicated. Additionally, medication should only be used to treat resident's medical symptoms and not used for discipline or staff convenience, which would be deemed a chemical restraint.*

***NOTE:***

- ***For concerns related to unnecessary medications, excluding psychotropic medications, surveyors should assess compliance with §483.45(d), F757.***
- ***This guidance uses the terms "medications," and, "drugs," interchangeably.***
- ***For purposes of this guidance, references to "the pharmacist" mean the facility's licensed pharmacist, whether employed directly by the facility or under arrangement.***

*The regulations and guidance are not intended to supplant the judgment of a practitioner in consultation with facility staff, the resident, and his/her representatives and in accordance with professional standards of practice. Rather, the regulations and guidance are intended to ensure psychotropic medications are used only when a practitioner determines that 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). However, surveyors must review the resident's medical record for evidence which supports and documents the clinical indication for psychotropic medication use.*

## *DEFINITIONS*

***"Adequate Indications for use"*** *refers to the identified, documented clinical rationale for administering a medication that is based upon an assessment of the resident's condition and therapeutic goals, and after any other treatments have been deemed clinically contraindicated. For psychotropic medications, without documentation in the record explaining that the practitioner has determined that other treatments have been deemed clinically contraindicated, the indication for use is* ***inadequate.*** *Also, adequate indication for use means that the medication administered 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.*

***"Adverse consequence"*** *refers to unwanted, unintended, 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) refers to 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"*** *refers to 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"*** *refers to individualized, nonpharmacological 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.*

*"**Chemical restraint**" refers to any drug used for discipline or that makes it more convenient (i.e., less effort) for staff to care for a resident, and not required to treat medical symptoms. This includes instances when a psychotropic medication may be approved to treat certain symptoms, however, nonpharmacological interventions should be used or attempted, unless clinically contraindicated, because they are less dangerous to a resident's health and safety. In these instances, a medication would be deemed not required to treat a resident's symptoms, because a safer alternative should be used. For example, if a nonpharmacological intervention should be used or attempted and is not clinically contraindicated, but a medication is administered and has the effect consistent with the definition of convenience (defined below), the medication would be classified as a chemical restraint.*

***"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)"** refers to 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)"** refers to 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.*

*"**Medical symptom**" refers to an indication or characteristic of a medical, physical, or psychological condition.*

***"Neuroleptic Malignant Syndrome (NMS)"** refers to 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" or "psychotropic medication"** 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"*** *refers to 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***

***Chemical Restraints and Unnecessary 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. Psychotropic medications have the potential to create symptoms consistent with sedation, creating convenience for staff (as explained below), which would be considered a chemical restraint. In order to keep residents free from chemical restraints used for discipline or convenience and that are not required to treat the resident's medical symptoms, the facility must prevent the unnecessary use of psychotropic medications. Therefore, noncompliance with the requirements to keep residents free from chemical restraints and prevent the unnecessary use of psychotropic medications are both cited at this F-tag. Furthermore, if a surveyor identifies that a medication has caused symptoms consistent with prolonged sedation that is not addressed (e.g., excessive sleeping, drowsiness, withdrawal, decreased participation in activities), noncompliance is cited, at a minimum of* ***severity level 3 (harm)****.*

***Applicability of the Definition of Psychotropic Medications***
*In accordance with §483.45(d)(4) and §483.45(e)(1), residents are not given any medications which are not adequately clinically indicated and necessary to treat a specific condition. The medical record must include documentation of the adequate clinical indication and necessity for prescribed psychotropic medication. (§483.45(e)(1)). The definition of "psychotropic medication" at 483.45(c)(3) is any medication that may affect brain activities associated with mental processes and behavior. Associated risks (e.g., nausea, insomnia, itching) exist regardless of the indication for their use, therefore the psychotropic medication requirements 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 in these four categories 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, pseudobulbar 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 (an anti-convulsant medication) and the medical record shows no history of seizures or migraine headaches, but there is documentation that the medication is being used to treat a mental health disorder, then the use of valproic acid in this example is considered a psychotropic medication and subject to the requirements under §483.45(e).*

***Chemical Restraints: Convenience and Discipline***

*In accordance with §483.10(e)(1) and §483.12(a)(2), residents have the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms. Facilities are responsible for knowing the effects medications have on their residents. If a medication has a sedating or subduing effect on a resident and is not being administered to treat a medical symptom, the medication is acting as a chemical restraint. These effects could indicate an intentional action to discipline or make care more convenient for staff. or the facility did not intend to sedate or subdue a resident, but an unnecessary medication is being administered that has that effect.*

***Convenience*** *refers to the unnecessary administration of a medication that causes (intentionally or unintentionally) a change in a resident's behavior (e.g., sedation) such that the resident is subdued and/or requires less effort from staff. Therefore, if a medication causes symptoms consistent with sedation (e.g., excessive sleeping, drowsiness, withdrawal, decreased activity), it may take less effort to meet a resident's behavioral needs, which meets the definition of convenience.*

***Discipline*** *refers to any action, such as the administration of a medication, taken by facility staff for the purpose of punishing or penalizing residents.*
*For example:*

- *A resident has been wandering into other resident's rooms and staff administer a medication to restrict the resident to their room.*
- *Staff become upset with a resident who resists receiving a bath and pinches staff. The staff did not assess the resident's needs or implement non-pharmacological interventions to address their resistance to bathing. Instead, staff administer medication to subdue the resident prior to providing the next bath.*

*A medication used for staff convenience or to discipline and is not required to treat medical symptoms, may cause:*

- *Sedation, such as sleeping during hours that he/she would not ordinarily sleep;*
- *Withdrawal from activities and socializing;*
- *Loss of autonomy and dignity;*
- *Confusion, cognitive decline, and depression;*
- *Weight loss, decline in skin integrity, or continence level; and/or*
- *Decline in physical functioning including an increased dependence in activities of daily living.*

*These effects may result in convenience for the staff, as the resident may require staff to exert less effort than previously. Even if a medication was initially administered for a medical symptom, the continued administration of a medication in the absence of such symptom, that sedates a resident or otherwise makes it easier to care for them, would be deemed a chemical restraint.*

***Comprehensive Assessment and Behavioral (Nonpharmacological) Interventions***

*The indications for initiating, maintaining, or discontinuing medication(s), as well as the use of non-pharmacological approaches, in accordance with §483.45(e)(2), are determined by evaluating the resident's physical, behavioral, mental, and psychosocial signs and symptoms in order to identify and rule out any underlying medical conditions, including the assessment of relative benefits and risks, and the preferences and goals for treatment. The use of non-pharmacological approaches must be attempted, unless clinically contraindicated, to minimize the need for psychotropic medications, use the lowest possible dose, or discontinue the medications. The resident's medical record should include documentation of this evaluation and the rationale for chosen treatment options.*

*Additionally, the facility should ensure that the resident's behaviors (expressions or indications of distress), which may have prompted the initiation or change in a psychotropic medication, are not:*

- *Upsetting to the resident or a safety concern to the resident or others;*
- *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;*
- *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; and*
- *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.*

*Circumstances that warrant evaluation of a resident's underlying medical condition and medication(s) include:*

- *Admission or re-admission: Some residents may be admitted to the facility on psychotropic medications that were started in the hospital or the community without a clear documented indication (i.e., history of schizophrenia without documentation to support the diagnosis per the DSM-5-TR) for why the medication was begun or should be continued.The prescribing practitioner and the IDT should subsequently determine if continuing the medication is justified by conducting a comprehensive medical and psychiatric evaluation;*
- *A new or worsening change in condition/status;*

- *An irregularity identified in the pharmacist's medication regimen review. See F756 for guidance related to the medication regimen review; and*
- *New medication order as an emergency measure – When a resident is experiencing an acute medical problem or psychiatric emergency and the acute phase has stabilized, the staff and prescriber should consider whether medications are still relevant.*

*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 (Activities).*

***Determining the Necessity to use Psychotropic Medications***

*§483.45(e)(1) prohibits the use of psychotropic drugs unless the medication is* ***necessary*** *to treat a specific condition as diagnosed and documented in the clinical record. Also, §483.10(e)(1) and §483.12(a)(2) prohibit the use of medications that are not required to treat the resident's medical symptoms. These prohibitions include instances when a medication may be approved to treat certain symptoms or conditions, however alternative interventions should be used or attempted first, unless clinically contraindicated, because they are less dangerous to a resident's health and safety.*

*Proper psychotropic 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 psychotropic 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 have serious side effects, such as sedation, depression, confusion, immobility, falls, and hip fractures, which can be especially dangerous for elderly residents with dementia, in addition to an increased risk of death. The American Geriatrics Society 2023 updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults provides information on safely prescribing medications for older adults,* https://agsjournals.onlinelibrary.wiley.com/doi/full/10.1111/jgs.18372.

*Diagnoses alone do not necessarily warrant the use of a psychotropic medication. Psychotropic 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 medical symptoms which are presenting a danger or significant distress; and/or*
- *GDR was attempted, but clinical symptoms returned.*

*Therefore, if a resident is receiving a psychotropic medication, regardless of whether the medication is approved for the resident's condition, there must be documentation that the facility has attempted behavioral (nonpharmacological) interventions, and that these interventions have been deemed clinically contraindicated. If a facility has documentation that other interventions were attempted and were not successful at treating the resident's condition, this would serve as evidence that the medication was necessary to treat the resident (notwithstanding other requirements). Documentation from a physician could also describe that alternative treatments*

*are clinically contraindicated, including the rationale for how this conclusion was reached. However, without evidence that non-pharmacological interventions had been ruled out to treat the resident, the psychotropic medication would be deemed **not necessary** to treat the resident, and noncompliance would be cited.*

*If the record shows evidence of prescribing multiple psychotropic medications or switching from one type of psychotropic medication, specifically an antipsychotic medication, to another category of psychotropic medication, the medical record should show a rationale for the change in medication regimen.*

*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. Psychotropic medications should be the last resort for treatment.*

*Concerns related to inappropriate prescribing of psychotropic medications should be investigated through record review and interviews with the practitioner(s), facility medical director, consultant pharmacist, other appropriate nursing home staff and the resident. If the facility is unable to provide documentation which supports the prescribing of the antipsychotic medication(s) in question, which may include but is not limited to evaluation of the resident's physical, behavioral, mental, psychosocial status, and comorbid conditions, indications of distress, changes in functional status, resident complaints, behaviors, symptoms, and state PASARR evaluation, then non-compliance exists.*

*CMS is aware of situations where residents are given a diagnois of schizophrenia without sufficient supporting documentation that meets the criteria in the current version of the DSM for diagnosing schizophrenia. If the non-compliance causes actual harm or the likelihood of serious harm to one or more residents or the surveyor identifies a pattern (e.g., three or more) by the same practitioner prescribing antipsychotic medication for any new diagnosis (such as schizophrenia) with lack of supporting documentation, the survey team should discuss their findings with their state survey agency for consideration to refer the individual to the State Medical Board or Board of Nursing.*

*When concerns related to inappropriate prescribing of psychotropic medications are identified, surveyors should also review:*

- *F658: to determine if the documentation supports a diagnosis in accordance with standards of practice.*
- *F641: to determine if the facility completed an assessment which accurately reflects the resident's status.*
- *F644: to determine if the facility made a referral to the state designated authority when a newly evident or possible serious mental disorder was identified (PASARR).*
- *F841: to evaluate the medical director's oversight of medical care.*

*Mental Disorders should be diagnosed , using evidence-based criteria and professional standards, such as the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), and documented in the resident's medical record.*

***Resident's Right to be Informed***

*In accordance with the requirements at §483.10(c), residents have the right to be informed of and participate in their treatment. Prior to initiating or increasing a psychotropic medication, the resident, family, and/or resident representative must be informed of the benefits, risks, and alternatives for the medication, including any black box warnings for antipsychotic medications, in advance of such initiation or increase. The resident has the right to accept or decline the initiation or increase of a psychotropic medication. To demonstrate compliance, the resident's medical record must include documentation that the resident or resident representative was informed in advance of the risks and benefits of the proposed care, the treatment alternatives or other options and was able to choose the option he or she preferred. A written consent form may serve as evidence of a resident's consent to psychotropic medication, but other types of documentation are also acceptable. If a psychotropic medication has been initiated or increased, and there is not documentation demonstrating compliance with the resident's right to be informed and participate in their treatment, noncompliance with §483.10(c) exists and F552 must be cited.*

***Dose and Duration***

*The dose and duration of medications, in accordance with §483.45(d)(1) and (d)(2), are based on a variety of factors, including the resident's diagnoses, signs and symptoms, current condition, age, coexisting medication regimen, review of lab and other test results, input from the Interdisciplinary Team (IDT) about the resident, including the resident's preferences and goals, the type of medication(s), and therapeutic goals being considered or used.*

***Dose** refers to 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.*

***Polypharmacy** refers to the use of five or more medications for an individual which can increase the risk of adverse outcomes such as falls, frailty, disability, and mortality in older adults. Polypharmacy also increases the possibility of prescribing cascades when additional drugs are prescribed to treat the adverse effects of one of the current medications.*

***Duplicate therapy** refers to two or more medications of the same pharmacological class/category without a clear distinction of when one medication should be administered over another. 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 medication containing the same ingredient, use of more than one drug~~s~~ within the same class, or medications from different therapeutic categories with similar effects or properties.*

*The risk for polypharmacy and duplicate therapy 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 each medication and the approach to monitor the benefits and any adverse consequences.*

***Excessive dose*** *refers to 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.*

***NOTE:*** *If the resident's condition has not responded to treatment or has declined despite treatment, it is important to re-evaluate both the medication and the dose. The clinical rationale for continued use of a medication(s) should be documented in the medical record. Examples of inappropriate duration may include:*

- *The initiation of a psychotropic medication was indicated but was not used for the lowest dose and least amount of time.*
- *A medication was initiated because of a time-limited condition (for example, delirium, pain, infection, nausea and vomiting, cold and cough symptoms, or itching). However, there was no documentation showing that the original condition had been monitored or evaluated. The medication continued to be administered while the original condition may have resolved, leading to excessive duration.*
- *A medication was administered beyond the stop date established by the prescriber, without evidence of clinical indication for continued use of the medication.*

***Gradual Dose Reduction***

*In accordance with §483.45(e)(2), residents who use psychotropic drugs receive gradual dose reductions (GDRs), unless clinically contraindicated, in an effort to discontinue these drugs. For any resident who is receiving a psychotropic medication, the facility must show evidence that a GDR has been attempted unless clinically contraindicated. If there is no evidence of a GDR and there is no description of the clinical contraindications, then noncompliance exists.*

*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 or could have dangerous side effects. 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.*

*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. 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).*

*Some medications (e.g., antidepressants, sedative/hypnotics, opioids) require more gradual tapering to minimize or prevent withdrawal symptoms or other adverse consequences. Additionally, some residents with specific, enduring, progressive, or terminal conditions such as chronic depression, Parkinson's disease psychosis, or recurrent seizures may need specific types of psychotropic medications or other medications which affect brain activity indefinitely.*

*For any individual who is receiving a psychotropic medication, a GDR may be considered clinically contraindicated for reasons that include, but that are not limited to, the following:*

- *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, exacerbate an underlying medical or psychiatric disorder or increased distressed behavior.*

***GDR Documentation***

- *Medical record documentation should reflect the date of the GDR attempt, the outcome of the dose reduction attempt, and the plan regarding future GDR attempts.*
- *Physician documentation should contain the rationale for why GDR attempts are clinically contraindicated for the resident.*

***For residents currently receiving antipsychotic medications:***
*Surveyors may use the MDS assessment to guide their review and determine what portion of the medical record is needed to review documentation of a GDR attempt or a clinical contraindication rationale.*

*Review the most recent Resident Assessment Instrument or MDS Section N, item N0450 for a date that a GDR was attempted or a date that the physician determined that a GDR was contraindicated. Review the portion of the medical record that corresponds with the MDS dates to ensure the GDR was attempted or that a clinical contraindication rationale was provided.*

*If there is no documented date for a GDR or a clinical contraindication on the most recent MDS assessment, review the medical record to determine if a GDR may have been attempted or a clinical contraindication rationale provided since the last MDS assessment and the time of the survey. If there is no evidence of a GDR and there is no description of the clinical contraindications, then noncompliance exists.*

*Additionally, surveyors should investigate compliance with F641 if there are discrepancies in GDR documentation between the medical record and the MDS assessment(s).*

***Monitoring and Adverse Consequences***

*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, in accordance with §483.45(d)(3) and (d)(5), as well as documenting medication management steps. Monitoring and accurate documentation of the resident's response to any treatment (such as, lab results, vital signs, progress notes, behavior flow sheets, medication administration records and the consultant pharmacist's drug regimen review) is essential to evaluate the ongoing effectiveness, benefits as well as risks of non-pharmacological approaches and psychotropic medications.*

***NOTE:** The facility's pharmacist is a valuable source of information about medications. The pharmacist and attending physician must adhere to the requirements for reporting and responding to identified irregularities (See F756 Drug Regimen Review).*

*When there are multiple prescribers, 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 be clinically indicated, and documented in the resident's medical record. If it is determined through monitoring that changes in the resident's treatment plan need to be made, surveyors must review the medical record to determine whether the prescribing practitioner provided a rationale. Without a rationale, the use of the medication(s) may be unnecessary and therefore, noncompliant.*

*The surveyor must review documentation to confirm that residents are being adequately monitored and re-evaluated for adverse consequences and the need for tapering. Adverse consequences related to medications are common enough to warrant serious attention and close monitoring, and can range from minimal harm to functional decline, hospitalization, permanent injury, and death.*

*Specifically, antipsychotic medications have serious side effects and can be especially dangerous for elderly residents, as described in the article Antipsychotic Medications, https://www.ncbi.nlm.nih.gov/books/NBK519503/. 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.*

*One of the existing mechanisms to warn prescribers about risks associated with medications is the Food and Drug Administration (FDA) requirement that manufacturers include 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 place statements about serious problems or contraindications in a prominently displayed box ("black box") in the medication labelling. The boxed warning is reserved for prescription drugs that pose a significant risk of*

*serious or life-threatening adverse effects, based on medical studies. 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. This tool and other resources are available on the CMS Adverse Events in Nursing Homes website, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Adverse-Events-NHs. 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.*

**PRN Medication Use**

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. For acute or emergency situations where the symptoms have stabilized, the staff and prescriber should consider whether medications are still relevant. 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)(3-5).

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 rationale 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 believes it is appropriate to write a new order for the PRN antipsychotic, the attending physician or prescribing practitioner must first evaluate the resident to determine if the new order for the PRN |

| Type of PRN order | Time Limitation | Exception | Required Actions |
|---|---|---|---|
| | | | 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 because 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.

***INVESTIGATIVE PROCEDURES***

*Use the Unnecessary Medications, Chemical Restraints/Psychotropic Medications, and Medication Regimen Review Critical Element (CE) Pathway along with the interpretive guidance when investigating concerns and determining if the facility meets the requirements.*

*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:<br><br>• Anorexia and/or unplanned weight loss, or weight gain<br>• Apathy<br>• Behavioral changes, unusual patterns (including increased expressions or indications of distress, social isolation or withdrawal)<br>• Bleeding or bruising, spontaneous or unexplained<br>• Bowel dysfunction including diarrhea, constipation and impaction<br>• Dehydration, fluid/electrolyte imbalance | 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:<br><br>• Clinical indications for use of the medication<br>• Implementation of person-centered, non-pharmacological approaches to care<br>• Dose, including excessive dose and duplicate therapy<br>• Duration, including excessive duration |

| SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS | REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT |
|---|---|
| • Depression, mood disturbance<br>• Dysphagia, swallowing difficulty<br>• Falls, dizziness, or evidence of impaired coordination<br>• Gastrointestinal bleeding<br>• Headaches, muscle pain, generalized or nonspecific aching or pain<br>• Lethargy<br>• Mental status changes, (e.g., new or worsening confusion, new cognitive decline, worsening of dementia (including delirium), inability to concentrate)<br>• Psychomotor agitation (e.g., restlessness, inability to sit still, pacing, hand-wringing, or pulling or rubbing of the skin, clothing, or other objects).<br>• Psychomotor retardation (e.g., slowed speech, thinking, and body movements)<br>• Rash, pruritus<br>• Respiratory difficulty or changes<br>• Sedation (excessive), insomnia, or sleep disturbance<br>• Seizure activity<br>• Urinary retention or incontinence<br><br>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. | • Consideration of potential for tapering/GDR or rationale for clinical contraindication<br>• Monitoring for and reporting of:<br>o Response to medications and progress toward therapeutic goals and resident's goals<br>o Emergence of medication-related adverse consequences<br>• Adverse consequences, if present and potentially medication-related, note if there was:<br>o Recognition, evaluation, reporting, and management by the IDT<br>o Physician action regarding potential medication-related adverse consequences<br>• The resident's 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 facility. 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 in the resident's condition 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. 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.*

***POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION***

- *F552, Right to be Informed/Make Treatment Decisions*
- *F553, Right to Participate Planning Care*
- *F580, Notification of Changes*
- *F656, Develop/Implement Comprehensive Care Plan*
- *F679, Activities*
- *F725 and F726, Sufficient and Competent Staff*
- *F710, Physician Supervision*
- *F740, Behavioral Health Services*
- *F742, Treatment/Svc for Mental/Psychosocial Concerns*
- *F756, Drug Regimen Review*
- *F841, Medical Director*

***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 Level 4, immediate jeopardy to resident health and safety include, but are not limited to**:*

- *The resident was admitted to the facility and was independent in mobility and ambulation and did not require assistance to eat. The resident experienced episodes of wandering into other residents' rooms and became argumentative when redirected. Staff reported difficulty monitoring the resident while taking care of other residents and requested a psychotropic medication from the physician to reduce the resident's wandering behavior. During the survey, the resident was observed sleeping, was difficult to arouse, and required assistance with many activities of daily living, including eating. Medical records showed no attempts with non-pharmacological interventions and no other underlying medical reason for the resident's decline and sedation.*
- *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 their room, sleeping in a recliner or in bed. The antipsychotic medication was continued without an adequate clinical rationale and evidence of non-pharmacological approaches documented in the medical record, resulting in serious psychosocial harm.*
- *After initiating use of a psychotropic medication, a GDR was not attempted and there was no documented rationale of the clinical contraindication. Further, there was no evidence of monitoring for drug interactions or adverse events. This indicates a likelihood of serious harm due to continued use of the psychotropic medication along with other failures to protect the resident's health.*

- *A PRN antipsychotic medication initiated more than 14 days ago, originally prescribed for acute delirium, continued to be administered daily without re-evaluation, and with no evidence of monitoring for adverse consequences. The failures to monitor for adverse consequences and re-evaluate the appropriateness of giving the medication created a likelihood for serious harm from adverse consequences and a significant decline in functioning.*

***Examples of Level 3, actual harm that are not immediate jeopardy include, but are not limited to:***

- *Failure to evaluate and monitor the resident and discontinue a psychotropic medication originally prescribed to treat a resident's delirium. Delirium symptoms subsided but the resident remained drowsy from continued administration of the medication. While the resident remains independent with ADLs, the resident has missed some group activities due to the drowsiness.*
- *A resident has an order for a PRN psychotropic medication that the resident can take for anxiety. However, staff regularly administer the PRN psychotropic medication to the resident with no documented indication but during an interview, staff explained the medication helps the resident sleep, so they've been giving it nightly even though the resident did not request it. Since receiving the medication, the resident has been sleeping through breakfast and has experienced significant weight loss.*

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

- *A resident has been receiving a psychotropic medication for several months to treat symptoms documented in the medical record. The resident is being monitored for side effects from the medication and the target symptoms have decreased. However, there is no evidence of a GDR attempt or documentation of a clinical contraindication for not attempting a GDR.*

- *A resident was prescribed a PRN psychotropic medication for episodes of anxiety which can have a sedating effect. The resident is no longer experiencing anxiety and has not requested the medication for over a week. Although the medication has not been administered recently, the PRN order has been in place for more than 14 days and there is no documented rationale for extending the order for the medication.*

***Severity Level 1:***
*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.,