

COMPLIANCE CUE

F758

Free from Unnecessary Psychotropic Meds/PRN Use

BACKGROUND

F758 of the CMS State Operations Manual Appendix PP provides guidance to Long Term Care Facility (LTCF) surveyors regarding **Unnecessary Psychotropic Medications/PRN Use**.

Last month's Compliance Cue covered [F757 – Unnecessary Medications](#). The existence of this separate tag dedicated exclusively to psychotropics demonstrates the heightened level of survey scrutiny applied to this drug class. The most recent surveyor guidance, issued through the October 2022 Phase 3 updates to the CMS State Operations Manual, includes several focused elements related to F758 and the management of psychotropic drugs:

- [Expanding the very definition of psychotropics to include medications beyond the conventionally included drug classes](#)
- [Increasing surveillance for misdiagnoses related to antipsychotics](#)
- [Guidance on Gradual Dose Reductions \(GDRs\) for psychotropics](#)

Click on the links to read PharMerica's Compliance Cues on each of those specific areas of F758 survey focus!

REQUIREMENTS

§483.45(c) Drug Regimen Review

(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 –

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

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- (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
- (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.
- (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.

PharMerica's Consultant Pharmacists note the following as commonly encountered knowledge gaps resulting in survey action:

- Hospice patients are NOT exempt from the PRN psychotropic regulations.
- Per CMS: "**Other 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, 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.**
 - Commonly encountered medications that can fall into this psychotropic classification include **valproic acid, oxcarbazepine, diphenhydramine, and hydroxyzine**.
- Just as medications conventionally classified as non-psychotropic are subject to psychotropic medication requirements when used in substitution for a psychotropic drug (rather than for the original or approved indication), medications pharmacologically classified as psychotropic used for "other" indications are also still subject to the psychotropic regulations.
 - e.g.: **Prochlorperazine**, used for nausea/vomiting, is still considered a psychotropic (due to its pharmacological classification as an antipsychotic).

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KEY QUESTIONS FOR SURVEYORS

For Unnecessary Medications: Did the facility ensure that each resident's medication regimen was free from unnecessary medications? (Note: if the unnecessary medication in question is a psychotropic medication, surveyors may cite F758).

For Psychotropic Medications, did the facility ensure that:

- they are used only to treat a specific, diagnosed, and documented condition;
- a GDR was attempted and non-pharmacological approaches to care were implemented, unless clinically contraindicated;
- a duration was included for PRN anxiolytics used for seizures (Lorazepam) per federal regulations;
- PRN use is only if necessary to treat a specific, diagnosed, and documented condition;
- PRN orders for psychotropic medications which **are not** for antipsychotic medications are limited to 14 days, unless the attending physician/prescribing practitioner documents a rationale to extend the medication;
- PRN orders which **are** for antipsychotic medications are limited to 14 days, without exception and the attending physician/prescribing practitioner did not renew the order without first evaluating the resident?

If 'No' to any of these, surveyors may cite **F758**.

NONCOMPLIANCE DEFICIENCY EXAMPLES

- 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 use 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.

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STEPS TO FACILITY COMPLIANCE

- ✓ Review (1) this **Compliance Cue**, (2) the **Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element (CE) Pathway**, and (3) the **CMS SOM section on F758** with all relevant staff
- ✓ Review facility policies and procedures for alignment with regulations per these resources, including:
 - Training staff on the expanded scope of the psychotropic regulations, with application beyond the traditionally help drug class, as outlined in this [PharMerica CC on the expanded psychotropic definition](#)
 - Maintaining appropriate professional standards of practice and processes for diagnosing individuals with schizophrenia, as outlined in this [PharMerica CC on misdiagnoses related to antipsychotics](#)
 - Ensuring staff is trained on executing and documenting GDR attempts, as outlined in this [PharMerica CC on GDRs](#)
- ✓ Contact supporting [Quality Improvement Organizations](#) for additional resources, assistance, and tools.
- ✓ Leverage your PharMerica pharmacist to educate staff as needed.

HOW PHARMERICA CAN HELP

- ✓ Experienced and knowledgeable consultant pharmacists available to provide MRRs to evaluate for unnecessary psychotropic drugs.
 - Utilize psychotropic timeouts to evaluate psychotropic drugs for documented clinical indication consistent with accepted clinical standards of practice and in accordance with §483.45(d)(4).
 - Identify and ensure documentation of GDR opportunities, attempts, and nonpharmacological interventions in the resident's care plan.
 - Attend behavioral meetings, participating in collaborative discussion with facility care team and educating as needed.
- ✓ In-service facility staff on the **PharMerica Model Psychotropic Stewardship Program**, available to support nursing homes in optimizing psychotropic use and navigating these regulations.

RESOURCES

Be aware that surveyors are encouraged to use the [Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway](#) [LTC Survey Pathways ⇨CMS-20082] when investigating concerns related to Unnecessary Psychotropic Medications/PRN Use Drugs.