

COMPLIANCE CUE

F605

Free from Chemical Restraints

BACKGROUND

On January 15, 2025, CMS released memo [QSO-25-12-NH](#), announcing major updates to surveyor guidance on several F-tags in the State Operations Manual (SOM) Appendix PP, effective March 24, 2025.

F605 (Free from Chemical Restraints) is one such tag featuring extensive revisions, as **F758** (Free from Unnecessary Psychotropic Meds/PRN Use) has been removed entirely, and regulations and guidance from that section have been incorporated and will now be cited under F605.

REQUIREMENT: CHEMICAL RESTRAINTS

§483.12(a)(2) “[The facility must] 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.”

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 to make care more convenient for staff, or could indicate that while the facility did not intend to sedate or subdue a resident, an unnecessary medication is being administered that has that effect.

A medication used for staff **convenience** or to **discipline**, and which 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
- Decline in physical functioning, including an increased dependence in activities of daily living

INTENT

The intent of this requirement is to ensure residents only receive psychotropic medications as indicated, and allow residents to maintain their highest practicable well-being in an environment that prohibits the use of chemical restraints:

- For discipline or convenience; and
- Which are not required to treat a resident’s medical symptoms.

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If psychotropic medication administration is warranted, guidance under **F605** reminds surveyors of resident's rights under **F552** (Right to be Informed/Make Treatment Decisions). Under regulations set forth through **F552**, prior to initiating or increasing doses of psychotropic medications, residents must be informed of the risks, benefits, and alternative medications. It is within the resident's rights to then either accept or decline the initiation or increase of a psychotropic medication.

To reflect the revisions made to **F605**, CMS has taken a further step by renaming the Critical Elements Pathway, which outlines investigative procedures for surveyors, to now be called the [Unnecessary Medications, Chemical Restraints/Psychotropic Medications, and Medication Regimen Review Critical Element Pathway](#) (Form CMS – 20082; pg 884).

QUESTION

Can the facility be cited for both **F605** and **F757** for a medication being used 'unnecessarily' as a chemical restraint?

No, if the survey team identifies an unnecessary medication that is acting as a chemical restraint (sedating or subduing a resident), the noncompliance is cited at **F605** (Chemical Restraints) and not cited at **F757** (Unnecessary Medications). Both tags shall not be cited for the same noncompliance. **F757** explicitly excludes psychotropic medications and is applicable to all other classes of medications when use is deemed unnecessary.

REQUIREMENT: UNNECESSARY PSYCHOTROPIC MEDICATIONS

§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

Remember, medications outside these four traditional classes may be subject to psychotropic regulations when they are used in a manner to affect mental processes/behaviors in place of one of these traditionally held psychotropics (e.g., an anticonvulsant used for agitation).

§483.45(d) "Each resident's drug regimen must be free from unnecessary drugs."

An unnecessary drug is any drug when used:

- In excessive dose (including duplicate drug therapy); or

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

INTENT

The intent of this requirement aims to ensure residents are only prescribed psychotropic medications for adequate indications after non-pharmacologic interventions are considered and deemed insufficient and/or clinically contraindicated.

“Adequate Indications for Use” refers to administration of a medication as directed according to the manufacturer’s recommendations, clinical practice guidelines, standards of care, or clinical medication references.

Facility providers and consultant pharmacists are to continually review resident medication regimens to ensure psychotropic medications are being prescribed at the lowest effective dose and for the shortest duration possible, as deemed appropriate by clinical guidelines.

QUESTION

A medication regimen review reveals an older adult was started on “quetiapine for schizophrenia” while in the hospital. This medication was continued for the resident upon discharge to a SNF. Does this count for an adequate indication for use?

Not necessarily. To continue this medication upon admission into the long-term care facility, the individual should have appropriate documentation within their medical record validating an established diagnosis of schizophrenia according to criteria set forth by contemporary standards of practice (e.g., per the DSM-5 Manual). CMS has increased scrutiny around erroneous schizophrenia diagnoses in particular. Clinicians should investigate whether this diagnosis was established prior to the acute hospital stay, to avoid circumstances where, for example, an older adult was truly prescribed an antipsychotic for acute hospital-associated delirium.

REQUIREMENT: GRADUAL DOSE REDUCTIONS

§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.”

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“**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.

“**Psychotropic drugs**” refers to medications that affect brain activity, thought process, or behavior. These may include, but are not limited to antipsychotics, antidepressants, anxiolytics, and hypnotics.

- Drugs that are used in a similar fashion to psychotropics and also affect brain activity (e.g., anticonvulsants), are also subject to the same regulations as psychotropic medications.

INTENT

This intent of this requirement is to ensure residents are not prescribed psychotropics for indefinite use, unless dose reductions are clinically contraindicated, such as when used for **enduring conditions**, including chronic depression, Parkinson’s disease psychosis, or recurrent seizures.

CMS notes that 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. For example, compliance with the requirement to perform a GDR may be met if, 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).

QUESTION

What constitutes a “clinical contraindication” to a GDR attempt?

A GDR may be considered clinically contraindicated for reasons that include, but that are not limited to, the following:

1. Risk of exacerbation of an underlying medical condition or psychiatric disorder with a GDR attempt
2. Worsening of target symptoms or condition after the most recent GDR attempt
3. A GDR attempt would contradict relevant current standards of practice

Note: even when a contraindication is historically noted, it is essential that clinicians continually assess and document whether a GDR continues to be inappropriate or if an attempt should be made. For example, if a change in underlying condition or the appearance of treatment-emergent side effects occur that alter the determination.

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REQUIREMENT: PRN PSYCHOTROPICS AND TREATMENT DURATIONS

§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."

§483.45(e)(4) "PRN orders for psychotropic drugs are limited to 14 days. Except 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 antipsychotic 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."

Note: PRN antipsychotic orders are limited to 14 days, with no exceptions. If the prescriber wishes to renew an order beyond that time frame, this regulation requires that they personally evaluate the resident before a new order is initiated (i.e., nursing progress notes solely stating the prescriber's wishes to continue an antipsychotic have historically failed surveys).

INTENT

The intent of this requirement is to ensure prescribed medications remain beneficial, safe, and appropriate for the resident, as demonstrated by continued monitoring and documentation of the resident's response.

Even if a medication was initially added to treat a symptom as needed, the continued administration of the medication in the absence of the symptoms, especially those with sedating effects, will cause surveyors to deem that the medication is acting as a chemical restraint.

QUESTION

Can nursing reports of the resident's condition be used by the attending physician to extend or renew a PRN antipsychotic order?

Yes, BUT nursing reports cannot function as the sole evaluation of the residents condition. Attending physicians must still personally examine the resident's current condition and progress prior to extending or renewing an antipsychotic PRN order. Documentation should reflect this evaluation and comment on the need to extend or renew the order.

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FACILITY COMPLIANCE

LEADERSHIP TO...

- ✓ Increase focus on care planning and establishing goals of care, including Gradual Dosage Reductions, behavior monitoring, and adverse event monitoring.
- ✓ Review current policies and procedures for alignment with regulations per SOM Appendix PP.
- ✓ Review the Unnecessary Medications, Chemical Restraints/Psychotropic Medications, and Medication Regimen Review Critical Element Pathway with relevant staff.
- ✓ Ensure accurate diagnoses are captured at resident admission, with emphasis on supporting documentation for use of psychotropics and 'other' medications used with psychotropic intent.
- ✓ Leverage your PharMerica pharmacist to educate staff as needed.

PHARMERICA COMPLIANCE

CONSULTANT PHARMACISTS TO...

- ✓ Provide education on psychotropic adverse event profiles, monitoring parameters, alternative and adjunctive therapies, etc., with the goal of improving health outcomes.
- ✓ Provide routine Gradual Dose Reduction recommendations when appropriate – collaborating with facility staff/caregivers to ensure optimal dosing.
- ✓ Attend behavior and QAPI meetings – participating in collaborative discussion with facility care team.
- ✓ Remain cognizant of warning signs for over sedation (i.e., unintentional weight loss, cognitive decline, lethargy, withdrawal) during routine MRRs and nursing note reviews – to report and provide corrective action plans when chemical restraint potential is identified.