2025 Updates to CMS Surveyor Guidance on Psychotropic Drug Use

Ryan Carnahan, PharmD, MS, BCPP

Professor of Epidemiology

The University of Iowa College of Public Health

Acknowledgements / Disclosures

- I am supported by HRSA via the Iowa Geriatric Workforce Enhancement Program (6 U1QHP53049-01-01)

- My wife owns a psychotherapy business

- I have no relevant conflicts of interest

Goal for Today

- Describe the most significant changes to CMS surveyor guidance on psychotropic drug use in nursing home residents

- Discuss strategies coalition members are using to respond to this new guidance, particularly the requirement for consent for psychotropic drug use

Background

- CMS released a new Appendix PP, Guidance for Surveyors of Long-Term Care Facilities, with new regulations and guidance effective March 24, 2025 (with another April 25 update)
  - F605: Psychotropics as “Chemical Restraints” and “Use for Convenience of Staff”—prior psychotropic drug regulations in F758 (unnecessary drugs) moved to F605
  - Clarifies requirements for behavioral interventions before starting or increasing dose of psychotropic drugs
  - Clarifies gradual dose reduction guidance
  - New guidance explicitly requiring consent before starting or increasing dose of psychotropics
  - New requirements for use of schizophrenia as a diagnosis
  - New related guidance in F841, medical director

https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/CMS/r229soma_0.pdf

Psychotropic Drugs

- Explicitly
  - Antipsychotics
  - Antidepressants
  - Anti-anxiety agents
  - Hypnotics

- And any drug affecting CNS used for similar indications
  - E.g., valproic acid, antihistamines, anticholinergics, muscle relaxants, dextromethorphan-quinidine

F605: Psychotropic Drugs: Essentially unchanged but with new guidance

- "§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**."

F605: Chemical Restraints Guidance Highlights

- “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 convenienc**e.
- **Discipline** refers to any action, such as the administration of a medication, taken by facility staff for the purpose of punishing or penalizing residents”

Takeaways from Additional Guidance

- Need specific diagnosis and symptoms to justify medications
- Any drug with sedating effects could be seen as a chemical restraint
  - Need to carefully monitor for ADRs including sedation and document effects
- Need to assess for medical or environmental causes of symptoms
  - Guidance specifically notes that **behaviors may be "expressions or indications of distress,"** so need to rule out other causes of that
- New orders of psychotropics, e.g., from hospital or due to an emergency/acute situation, need to be carefully reviewed to determine continued need
- Behavioral interventions must be attempted and continued unless contraindicated, with goal to minimize drug use
- Per F841, the Medical Director should intervene on inappropriate use

Rationale for Psychotropic Drugs

- "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."

- If a change is made…
  - "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**."

Gradual Dose Reductions

- “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.**”

- “**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**.”

Gradual Dose Reductions

- "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"

Best Practices for GDRs

- Use GDRs at least twice in the first year if not contraindicated
  - Go slow. Rapid reductions can be problematic due to withdrawal symptoms or rapid unmasking of symptoms.
- Need clear rationale for not doing a GDR
  - There are plenty of good reasons, but “resident stable” is unlikely to be considered adequate rationale
- Assess continued need for, safety, and effectiveness of psychotropics at each MDS assessment
  - This is my interpretation of guidance to evaluate the effectiveness of the care plan at each MDS assessment, and the requirement that a prescriber be involved in that

Informed Consent for Psychotropic Drug Use

- "**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."

Schizophrenia Diagnosis Documentation

- **Schizophrenia and schizoaffective disorder do not typically arise late in life**
  - Symptoms of these conditions in someone with dementia (or delirium) are caused by other medical conditions so would not qualify
  - The same goes for bipolar disorder, though residents with bipolar disorder are not excluded from the denominator of antipsychotic quality metrics

- **Need a documented medical evaluation and symptoms demonstrating that someone has active schizophrenia to justify diagnosis**
  - PASSR should have been applied on admission, and history collected and confirmed with specific documentation of diagnostic criteria being met

- **Data are mixed on GDRs in true schizophrenia**
  - Residual symptoms without side effects may be adequate rationale for no GDR.
  - If extrapyramidal side effects are present, GDR may be beneficial.
  - **But GDRs may be catastrophic for these residents, particularly if rushed. Emphasize "gradual" if the antipsychotic dose is reduced at all.**

Discussion

- In my view, most of these regulations are not different from what has been in place for quite a while
  - These revisions mostly provide clarifying guidance to surveyors supporting what we've known to be best practices
  - Regular documentation of assessment of effectiveness and side effects of drugs, in addition to use of behavioral interventions, is clearly important
    - Sedation leading to lower quality of life for a resident is a red flag
- However, the explicit guidance requiring consent prior to initiating or increasing the dose of a psychotropic drug seems new
  - How are you handling this?
  - Is anyone using an advance consent for emergency treatment?
  - Are you using specific resources for shared decision making?
- Have you made other changes in response to the revised guidance?

Summary

- **Assess medical and environmental causes of symptoms before using a drug**
  - With documentation, and clear description of target symptoms
- **Attempting and documenting behavioral ("non-pharmacologic") interventions is required before resorting to psychotropic drugs**
  - And use should be continued unless contraindicated, regardless of drug use
- **Antipsychotics in dementia/delirium are only justified with danger to self or others**
  - Specifically due hallucinations, delusions, or aggressive behavior/severe agitation
  - Danger may include the symptom causing significant distress to resident
- **Time-limited trials with documentation of safety/effectiveness are recommended**
  - Sedation is a red flag side effect for surveyors, as are other side effects with no monitoring
- **Consent required to start or increase the dose of a psychotropic drug**
  - Including discussion of alternatives and black-box warnings

Thank you