

Regulatory Update: Compliance Cue

Guidance for Psychotropic Medication Pharmacy-related F-Tags

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With new surveyor guidance effective October 24, 2022, psychotropic use remains a continued focus of CMS. F758 of the CMS State Operations Manual (SOM) Appendix PP provides guidance to surveyors for long-term care (LTC) facilities regarding psychotropics, including language to address situations where CMS has identified residents potentially misdiagnosed with a condition for which antipsychotics are an approved use (such as a new diagnosis of schizophrenia).



What's Required

Per CMS

§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." CMS is aware of situations where practitioners have potentially misdiagnosed residents with a condition for which antipsychotics are an approved use (e.g., new diagnosis of schizophrenia) which would then exclude the resident from the long-stay antipsychotic quality measure. For these situations, surveyors are instructed to refer to the following regulations: Á

- §483.20(g), F641, to determine if the facility completed an assessment which accurately reflects the resident's status.
- §483.21(b)(3)(i), F658, to determine if the practitioner's diagnostic practices meet professional standards.

Why the increased focus on misdiagnosis?

Erroneous diagnoses attributed to antipsychotics could incorrectly exclude the resident from the long-stay antipsychotic quality measure (QM – one of three domains of the Nursing Home Compare Five-Star Quality Rating System – which does not include residents diagnosed with schizophrenia, Huntington's disease, or Tourette syndrome). This additional survey scrutiny is supported by a 2022 OIG study – [Long-Term Trends of Psychotropic Drug Use in Nursing Homes](#) – that found increasing numbers of unsupported schizophrenia diagnoses (residents reported as having schizophrenia per MDS, but lacking corresponding diagnoses in Medicare claims and encounter data). CMS has taken a further step, announcing per a 1-18-2023 [memorandum](#) that CMS will begin conducting off-site audits to assess facilities' MDS data accuracy – specifically the evidence for appropriately documenting, assessing, and coding a schizophrenia diagnosis in their MDS data.

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F758 – Misdiagnosis Related to Antipsychotics



Steps to Facility Compliance

- Engage stakeholders (psychiatric providers, medical directors, consultant pharmacists) to ensure implementation of appropriate professional standards and processes for diagnosing individuals with schizophrenia.
- Contact supporting [Quality Improvement Organizations](#) for additional resources, assistance, and tools.
- Review current Policies and Procedures for alignment with regulations per SOM Appendix PP.
- Evaluate staff practices for compliance with the regulation as detailed above.
- Leverage your PharMerica pharmacist to educate staff as needed.



How PharMerica Can Help

- Utilize psychotropic timeouts to evaluate resident-specific psychotropic medications for documented diagnosis/clinical indication to ensure accuracy and alignment with accepted clinical standards of practice per §483.45(d)(4)*.
- Respond to facility requests for retrospective audits to assess facility compliance with updated regulations and provide feedback on opportunities for improvement.
- Attend behavioral meetings, participating in collaborative discussion with the facility care team and educating as needed.

*See [CMS State Operations Manual Appendix PP](#) pages 556-587 for full text.