

## 2025 Updates to State Operations Manual Signify Impending CMS Surveyor Focus Post-Webinar Audience Q&A

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### 1. The presentation included links to resources. Can these be provided to share with my staff?

Absolutely! Below are links for the resources referenced throughout the webinar (with their corresponding slide numbers provided in parentheses):

- [CMS Memo on Revised LTC Surveyor Guidance - Effective 3.24.25](#) (slide 8)  
Summarizes areas that have been revised, rationale for significant revisions, and a full advanced copy of Appendix PP (including revised Critical Element Pathways)
- [OIG Long-Term Trends of Psychotropic Drug Use in Nursing Homes](#) (slide 16)  
Exhibit 1: While CMS focused its efforts on reducing antipsychotic drug use, overall psychotropic drug use remained constant, and anticonvulsant drug use increased among long-stay residents aged 65 years of age and older (page 9)
- [CMS Framework for Health Equity 2022–2032](#) (slide 26)  
Provides information on addressing health equity as it relates to F867

Other resources provided as handouts include:

- [PharMerica<sup>®</sup> Compliance Cue – Pharmacy-Related Updates to SOM](#)
- [CDC Clinical Practice Guideline for Prescribing Opioids for Pain – United States, 2022](#)

### 2. What are some acceptable diagnoses for antipsychotic use that comply with SOM regulations?

An ultimate list of “acceptable diagnoses for antipsychotic use” has not been published by CMS. Instead, appropriate antipsychotic use is uniquely assessed for the individual resident, based on the clinical documentation and rationales provided in their medical record.



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In defining **Adequate Indications for Use**, the SOM states, “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.”

Based on current standards of practice, FDA-approved indications, and manufacturer recommendations for today’s marketed antipsychotics, example diagnoses would include:

- Acute agitation
- Adjunctive treatment for major depressive disorder
- Bipolar disorder and bipolar depression
- Huntington’s disease
- Nausea/vomiting
- Psychosis or psychotic mood disorder
- Schizophrenia, schizophreniform disorder, and schizoaffective disorder
- Tourette’s syndrome

SOM updates suggest an increased focus on identifying inappropriate antipsychotic use that meets the definition of an unnecessary medication, including antipsychotic use for **staff convenience** or **resident discipline**. To optimize compliance, antipsychotic prescribing policies and procedures should promote prescribing in accordance with manufacturer recommendations (i.e., product-specific prescribing guidelines as found in package inserts) and contemporary clinical practice guidelines. Target behaviors and symptoms that antipsychotics are used to treat should be outlined in resident care plans and monitoring parameters should be identified.

### 3. How many nonpharmacologic interventions need to be implemented prior to initiating a psychotropic medication? What about with STAT and PRN orders?

CMS does not provide a specific number of nonpharmacologic interventions to implement prior to initiating a psychotropic medication. Guidance solely stipulates that facilities must attempt non-pharmacologic approaches, unless clinically contraindicated to “minimize the need for psychotropics, identify the lowest effective dose, or discontinue a medication.”

Residents’ medical records should include documentation of attempted approaches as well as how effective they were at managing their symptoms. Providers should continually reassess the use of non-pharmacologic interventions to verify the need for continuing pharmacologic therapy. This documentation is essential, as without documented evidence that non-pharmacological interventions have been attempted or ruled out to treat the resident, subsequent psychotropic medications would be deemed not necessary to treat the resident, and noncompliance would be cited.

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Regarding PRN psychotropic use, CMS notes, "In certain situations, psychotropic medications may be prescribed on a PRN basis, such as while a 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." PRN psychotropic orders are typically limited to 14 days and can not be renewed until the provider reassesses the resident's condition and determines it is appropriate to continue the order.

CMS also recognizes there may be isolated situations that warrant STAT administration of a psychotropic medication, but includes guidance within the SOM stating, "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."

#### 4. For residents discharged from the hospital on antipsychotics or with a diagnosis of schizophrenia, what steps should we take for verification?

According to the SOM, "Physicians should evaluate the resident's physical, behavioral, mental, psychosocial status, and comorbid conditions, ruling out any potential physiological effects of a substance (e.g., medication or drugs) or other medical conditions, indications of distress, changes in functional status, resident complaints, behaviors, and symptoms that may have led to the new diagnosis of schizophrenia or initiation of the psychotropic medication."

Diagnoses and psychotropic medication use should be backed by documentation of symptoms and behaviors consistent with and for the required period of time in accordance with contemporary standards of practice (e.g., currently, per the Diagnostic and Statistical Manual of Mental Disorders - Fifth Edition (DSM-5)).

#### 5. Can you clarify what informed consent looks like? What type of documentation is needed and for what medications must it be obtained?

The CMS SOM does not detail explicit requirements on what informed consent must include. If there is applicable state law governing the content of an informed consent form, then facility forms must comply with those requirements.

In discussing **psychotropic** medications, in particular, CMS notes, "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**

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of a resident's consent to medication, but other types of documentation are also acceptable. If a 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."

**F552** provides residents the right to be informed, in advance, of risks, benefits, and alternatives to **all** proposed treatments. Psychotropics are **explicitly** called out (at **F605**) as requiring documentation to this effect (which **may** take the form of a written informed consent document).

When developing your facility's informed consent policies and procedures, the April 2024 memo [QSO-24-10-Hospitals Memorandum Summary](#), may provide guidance and sample language pertaining to informed consent documents (recognizing that this memo is directed at hospital facilities):

*A properly executed informed consent form contains the following minimum elements:*

- *Name of the facility where treatment is being rendered*
- *Name of the specific medical treatment for which consent is being given*
- *Name of the prescriber or responsible practitioner who is administering the medical treatment*
- *Statement that the treatment, including the anticipated benefits, risks, and alternative therapies, was explained to the patient or the patient's legal representative.*
- *Signature of the patient or the patient's legal representative*
- *Date and time the informed consent form is signed by the patient or the patient's legal representative*

Facilities are required to communicate effectively, both **verbally** and in **writing**, with residents in a language and manner they can understand. Check with state regulations on how information can be relayed to residents (i.e., if state requirements allow for verbal communication only).

Translator services must be used as appropriate and necessary. Note: many drug information resources provide medication education documents for patients in multiple languages.

## 6. Would you consider melatonin a sedative for the purposes of these regulations?

Melatonin does not fall under the requirements for psychotropic medications. Melatonin is a natural hormone that is classified as a dietary supplement by the Food and Drug Administration and, therefore, is not subject to the requirements of hypnotics under the psychotropic medication category. However, residents should still be monitored with regard to benefits, risks, and potential adverse consequences.

## 7. The presenters mentioned that psychotropics are regulated in similar fashion even for hospice residents. How do opioid regulations apply in this demographic?

When providing guidance on opioid use, CMS states, "Medication regimens for residents receiving end

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of life, palliative, or hospice care may include opioids alone or combining opioids and benzodiazepines; their use must be consistent with accepted standards of practice for this specialty of care.”

Note that the [CDC’s Opioid Prescribing Guidelines \(2022\)](#) – a gold standard clinical practice guideline – does NOT apply to patients undergoing cancer-related pain treatment, palliative care, or end-of-life care, because of the unique therapeutic goals, ethical considerations, opportunities for medical supervision, and balance of benefits and risks with opioid therapy in such care. For example, for many persons at the end of life, serious potential long-term opioid-related harms such as opioid use disorder might not be relevant.

The American Academy of Family Physicians publishes a guideline more specific to this demographic: [Pharmacologic Management of Pain at the End of Life](#).

## 8. Are there any changes to Gradual Dose Reduction (GDR) requirements? Do they only relate to psychotropic medications? What standards of practice should we refer to when conducting a GDR?

Federal requirements at §483.45(e)(2) remain unchanged. Compliance with SOM regulations at §483.45(e)(2) specifically relate to psychotropic medications. Residents who use psychotropic drugs must receive gradual dose reductions and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs. These medications have significant adverse effect profiles and the increase in surveyor focus on GDR attempts comes as CMS is trying to strengthen their message that facilities must prevent unnecessary use of psychotropic medications.

CMS’s State Operations Manual includes more information on GDRs including frequency of attempts, what constitutes a clinical contraindication, and more. The [Minimum Data Set \(MDS\) Resident Assessment Instrument \(RAI\) 3.0 User’s Manual](#) also provides great insight on GDR attempts as it outlines what surveyors may be looking for during visits (see section N0450).

When attempting GDRs, the adjective *Gradual* is imperative. Slow titrations to taper down psychotropic doses are important to determine the minimum necessary dose to manage target symptoms, while also preventing withdrawal symptoms. Manufacturer recommendations are the gold standard when approaching psychotropic dose reductions.

As CMS states, “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.”

The guidance for LTC surveyors further elaborates, “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

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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.](#)"

## 9. Are GDRs required for newer antipsychotics, such as Rexulti® or Nuplazid®?

Guidance within F605 states, "Residents who use psychotropic drugs are to receive gradual dose reductions (GDRs), **unless clinically contraindicated.**" Even newer antipsychotics, such as Rexulti® (brexpiprazole) and Nuplazid® (pimavanserin), are subject to this regulation. However, if a resident meets criteria for a clinical contraindication, supported by appropriate documentation within their medical record, a GDR attempt **may not be required.**

Clinical contraindications for GDR include:

- Worsening of resident symptoms or condition after the most recent GDR attempt
- Risk of impairment or exacerbation of underlying medical condition or psychiatric disorder
- GDR attempts are against accepted standards of care for that specific disease state or psychiatric disorder

As CMS explains, "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."

Based on this guidance, Rexulti® prescribed for chronic major depressive disorder or Nuplazid® for Parkinson's disease psychosis may be exempt from GDR requirements, assuming the medical record notes the enduring quality of these conditions, and the prescriber denotes that attempting a dose reduction is against the standard of care with the risk of exacerbating the underlying condition.

## 10. Are dose reduction attempts mandatory for drug classes other than psychotropics? What about opioids?

GDR regulations are specified as a requirement for psychotropic medications.

However, CMS regularly refers to using medications in accordance with current standards of practice. Generally, this does entail determining and using the minimum necessary medication dose, especially with respect to high-risk medications, such as opioids.

Medications used in excessive dose and/or without adequate monitoring are also subject to citation as unnecessary medications.

Therefore, prescribers should follow CDC pain management guidelines to utilize nonpharmacologic therapies and non-opioid therapies first-line, and then adjunct to opioids (as necessary for moderate to severe pain), promoting the use of minimal necessary opioid doses. Additionally, regular monitoring

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provides ongoing assessment of how a resident's pain progresses and grants opportunities to attempt dose reductions and opioid discontinuations as appropriate. Prescribers should follow guideline and manufacturer recommendations for opioid tapering.

## 11. Regarding discharge regulations, what about situations where a resident leaves AMA? Or if they leave when an appeal is still in process?

CMS defines leaving Against Medical Advice (AMA) as, "A resident who leaves the facility prior to his or her planned discharge, but **with facility knowledge** of the departure and despite facility efforts to explain the risks of leaving." Guidance surrounding resident departures via AMA state that, "These situations should be thoroughly investigated to determine if the resident or resident representative was forced, pressured, or intimidated into leaving, and documentation should show that facility staff attempted to provide other options to the resident and informed the resident of potential risks associated with departure." Facilities should also incorporate the time they became aware of the resident's desire to leave within documentation as well.

Instances where facilities determine that a premature discharge is not appropriate or necessary should have supporting documentation detailing reasons why the resident should continue to reside within the facility and risks involved with discharge. This information should be shared with the resident or resident's representative in writing and in language they understand, with an additional copy forwarded to the representative of the Office of the State Long-Term Care Ombudsman. If the resident still desires to leave, an AMA form should be signed prior to departure. A copy of the signed AMA form, with outlined risks of discharge are to be sent with the resident.

In other instances, when an appeal is pending, a facility may not transfer or discharge a resident unless the failure to transfer or discharge would endanger the health or safety of the resident or other individuals residing within the facility. Potential dangers of failed discharge or transfer must be documented within the resident's medical record.

If a resident issues an appeal while hospitalized, facilities, "must allow the resident to return pending their appeal, unless there is evidence that the facility cannot meet the resident's needs or the resident return poses danger to the health or safety of others residing within the facility." Again, appropriate documentation must be provided within the resident's medical record.

## 12. Regarding the transfer regulations, you mentioned the "physician" must sign off on documentation. Is this similar to the requirement that physicians must sign off on admission orders and NPPs are not allowed to do so?

It is true only physicians can sign off on admission orders, however, guidance within the SOM notes, "Documentation of the transfer or discharge may be completed by a non-physician practitioner (NPP) in accordance with State law."

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## 13. What changes are being made to the SOM related to infection prevention and control?

**F880 (Infection Prevention and Control)** has been revised to define **Enhanced Barrier Precautions (EBP)** and provide guidance on implementing these precautions as a preventative measure against multidrug-resistant organisms (MDROs).

For more information on changes within F880, see PharMerica's Compliance Cue [Pharmacy-Related Updates to State Operations Manual Appendix PP](#).

## 14. Where could my facility find resources such as the examples shown from the sample medication stewardship programs?

The sample medication stewardship program materials pull from freely and publicly available resources!

- The mainstay of these programs are sourced from the [CDC's Core Elements of Antibiotic Stewardship](#), which serves as a template to build analogous programs around psychotropics and opioids, as other high-risk and heavily regulated drug classes.

Other resources of interest may be found at:

- [PsychU®.org](#)  
A free community and online resource library for mental health. Keep up to date through thousands of resources on the latest mental health care developments, treatment best practice guidelines, market trends, research studies, innovative programs, decision support tools, and more.
- [Pain Management in the Post-acute and Long-Term Care Setting](#)  
A Clinical Practice Guideline (CPG) from the Society for Post-acute and Long-Term Care Medicine (AMDA)
- [AGS Recommendations on the Pharmacological Management of Persistent Pain in Older Persons](#)  
A pain management article by the American Geriatrics Society Panel
- [ICSI Assessment and Management of Chronic Pain](#)  
A healthcare guideline by the Institute for Clinical Systems Improvement
- [AAFP Opioid Conversion Table](#)  
A chronic pain management toolkit from the American Academy of Family Physicians