Centers For Medicare & Medicaid Services (CMS) Guidance And Regulations: Psychotropic Medication Utilization Guidelines In The Long-Term Care Setting

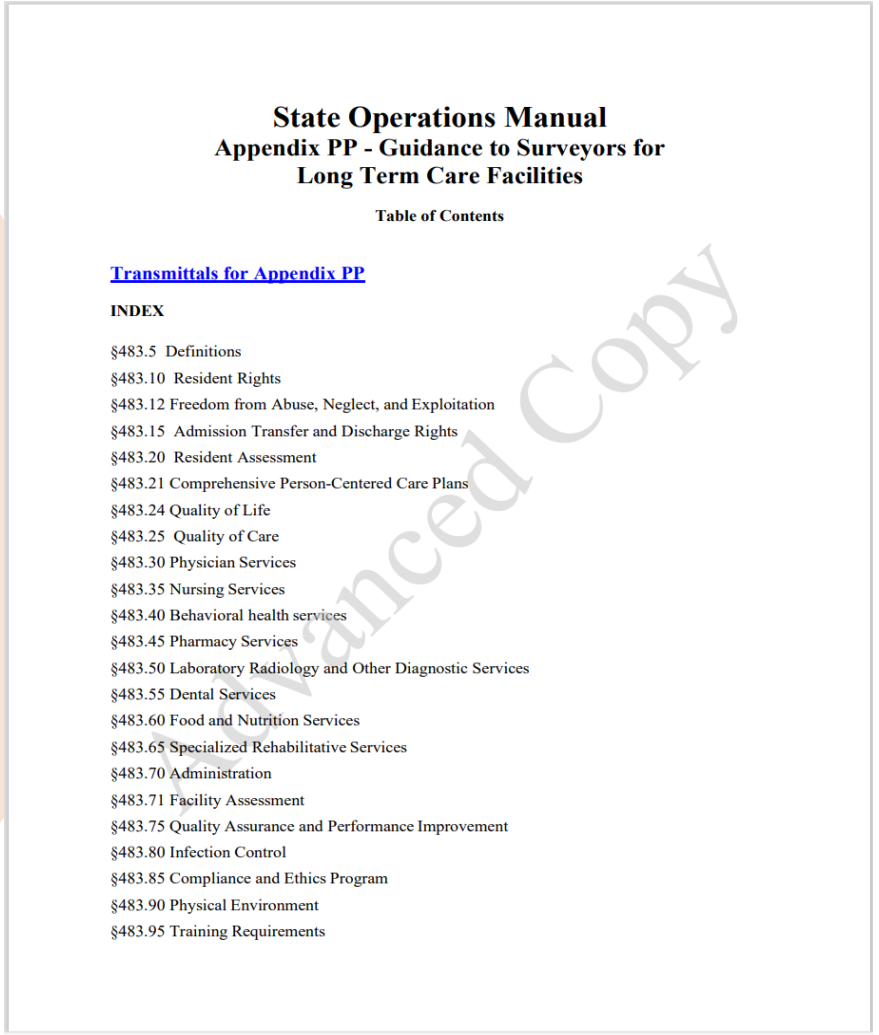
October 2025 US.PSY.D.25.00035

PsychU®
Improving mental health care... together®

This program is paid for by
Otsuka Pharmaceutical Development
& Commercialization, Inc. (OPDC).

State Operations Manual (SOM) Appendix PP Guidance To Surveyors In Long-Term Care Facilities[1]

- Document providing primary survey, certification rules, and guidance from Centers For Medicare & Medicaid Services
- Revisions are made regularly to address emerging trends nationwide



State Operations Manual
Appendix PP - Guidance to Surveyors for Long Term Care Facilities

Table of Contents

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

PsychU® Improving mental health care... together®

Medication Utilization Regulations[1]

F757 (F-Tag 757): Unnecessary Drugs

Each resident's regimen must be free from unnecessary drugs

- Excessive dose, including duplicate therapy
- Excessive duration
- Without adequate monitoring
- Without adequate indications for use
- In the presence of adverse consequences that would warrant dosage reduction or discontinuation
- Any combination of the above

Intent: Each resident's entire drug/medication regimen is managed and monitored to promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

PsychU® Improving mental health care... together®

Medication Utilization Regulations: Psychotropic Medications[1]

Preceding Guidance

In previous versions of SOM Appendix PP, guidance for unnecessary medications was described in two tags:

- F757: Unnecessary Drugs
- F758: Psychotropic Drugs

Updated Guidance 2025

- Regulations for unnecessary psychotropic medications (F758) have been incorporated into F605
- Unnecessary medications (F757) has been revised to only include guidance for non-psychotropic medications

SOM, state operations manual.

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

Purpose Of The Guidance[1]

- Medications are an integral part of the care provided to residents of nursing facilities
- Psychotropic medications have the potential to create symptoms consistent with sedation creating convenience for staff, which would be considered a chemical restraint
- In order to keep residents free from chemical restraints used for discipline or convenience and that are not required to treat the resident's medical symptoms, the facility must prevent the unnecessary use of psychotropic medications

Chemical Restraint: refers to any drug used for discipline or that makes it more convenient (ie, less effort) for staff to care for a resident, and not required to treat medical symptoms

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

Chemical Restraints Used For Convenience Or Discipline[1]

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

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

Psychotropic Medication Guidance[1]

Psychotropic drug definition:

Any drug that affects brain activities associated with mental processes and behavior

Including, <u>but not limited</u> to:

- Antipsychotic
- Antidepressant
- Antianxiety
- Hypnotic medications

Utilization of a psychotropic drug requires a comprehensive resident assessment which must ensure:

- 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
- Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs
- Not to be used as a PRN order unless specific condition is documented in clinical record

PRN, as needed.

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

Intention[1]

Intent is to ensure residents only receive psychotropic medications when other nonpharmacological interventions are clinically contraindicated

- Residents must only remain on psychotropic medications when a gradual dose reduction and behavioral interventions have been attempted and/or deemed clinically contraindicated
- Medication should only be used to treat resident's medical symptoms and not used for discipline or staff convenience, which would be deemed a chemical restraint

Not intended to supplant the judgement of the practitioner, rather to ensure psychotropic medications are only used when:

- Practitioner determines that the medication(s) is appropriate to treat a resident's specific, diagnosed, and documented condition
- The medication(s) is beneficial to the resident, as demonstrated by monitoring and documentation of the resident's response to the medication(s)

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

PsychU® Improving mental health care... together®

Assessment And Intervention Requirements[1]

Comprehensive Assessment And Behavioral (Nonpharmacological) Interventions

The use of non-pharmacological approaches must be attempted, unless clinically contraindicated, to minimize the need for psychotropic medications, use the lowest possible dose, or discontinue the medications

Initiation or change in psychotropic medication for residents' behaviors are not:

- Due to a medical condition or problem which may resolve
- Due to environmental stressors alone that can be addressed to improve the symptoms or maintain safety
- Due to psychological stressors alone that can be expected to improve or resolve as the situation is addressed.

The resident's medical record should include documentation of this evaluation and the rationale for chosen treatment options

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

Resident Rights[1]

Residents right to be informed

- 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

Compliance is met when medical record is documented that resident or resident representative informed of the proposed care, including treatment alternatives, and was able to choose the treatment option

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

Assessing The Need For Psychotropic Medications[1]

Determining the necessity to use psychotropic medications

- Guidance prohibits psychotropic drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record, and treat the resident's medical symptoms
- Diagnoses alone does not necessarily warrant use

Psychotropic drugs 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
- Gradual Dose Reduction (GDR) was attempted, but clinical symptoms returned

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

Ensuring Proper Medication Use And Administration[1]

Adequate indications of use:

- Identified, documented clinical rationale for medication administration
  - Based on assessment of resident's condition and therapeutic goals
  - After any other treatments deemed clinically contraindicated
- Psychotropic medications require documentation by the practitioner in clinical records that other treatments are clinically contraindicated

Medication administration 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

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

Gradual Dose Reduction (GDR)[1]

For any resident receiving a psychotropic medication, the facility must show evidence that a GDR has been attempted unless clinically contraindicated

Documentation should reflect date of attempted GDR, outcome, and future plan

Purpose

- Identify the optimal dose
- Determine if continued use is beneficial
- Identification of possible dangerous side effects

Indication

- Clinical condition improved or stabilized
- Underlying symptomology resolved
- Effective non-pharmacologic intervention

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

GDR Assessment Considerations[1]

Several factors may influence timing and duration of attempted GDRs, including medication regimen and pharmacology, and individual risk factors and symptomatology

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

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

GDR Assessment Considerations (Cont.)[1]

Gradual dose reduction MAY BE CONSIDERED CONTRAINDICATED if:

- Use is within current clinical standards **and**
- Physician has documented a GDR attempt would be likely to impair resident's function or exacerbate underlying medical condition or psychiatric disorder; **or**
- Most recent GDR attempt resulted in return or worsening of target symptoms, **and**
- Physician has documented the clinical rationale for why additional attempts would be likely to impair resident's function or exacerbate underlying medical condition or psychiatric disorder

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

F658

Comprehensive Care Plans[1]

Surveyors are instructed to investigate to ensure the presence of diagnosis documentation is appropriate:

- Behaviors/duration are consistent with DSM criteria
- Diagnosis was given following a comprehensive evaluation/visit
- Symptoms, disturbances, or behaviors not due to a substance or other medical condition
- Disturbance is a disruption of baseline level of function (interpersonal relationships, self-care)

CMS is aware of situations where residents are given a diagnosis of schizophrenia without sufficient supporting documentation that meets the criteria in the current version of the DSM for diagnosing schizophrenia

CMS, Centers for Medicare & Medicaid Services; DSM, Diagnostic and Statistical Manual of Mental Disorders.

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

PsychU® Improving mental health care... together®

F841

Responsibilities Of Medical Director[1]

Responsibility of the medical director to discuss and intervene with medical care inconsistent with current standard of care

- Psychotropic diagnosis and treatment is specifically discussed
- New diagnosis of schizophrenia and resulting antipsychotic order outside standard of care which was not reviewed by the medical director will warrant a deficiency
- Applies even if the diagnosis and psychotropic orders come from other physicians or practitioners

If a deficiency identified regarding resident's care, surveyors instructed to determine if medical director failed to:

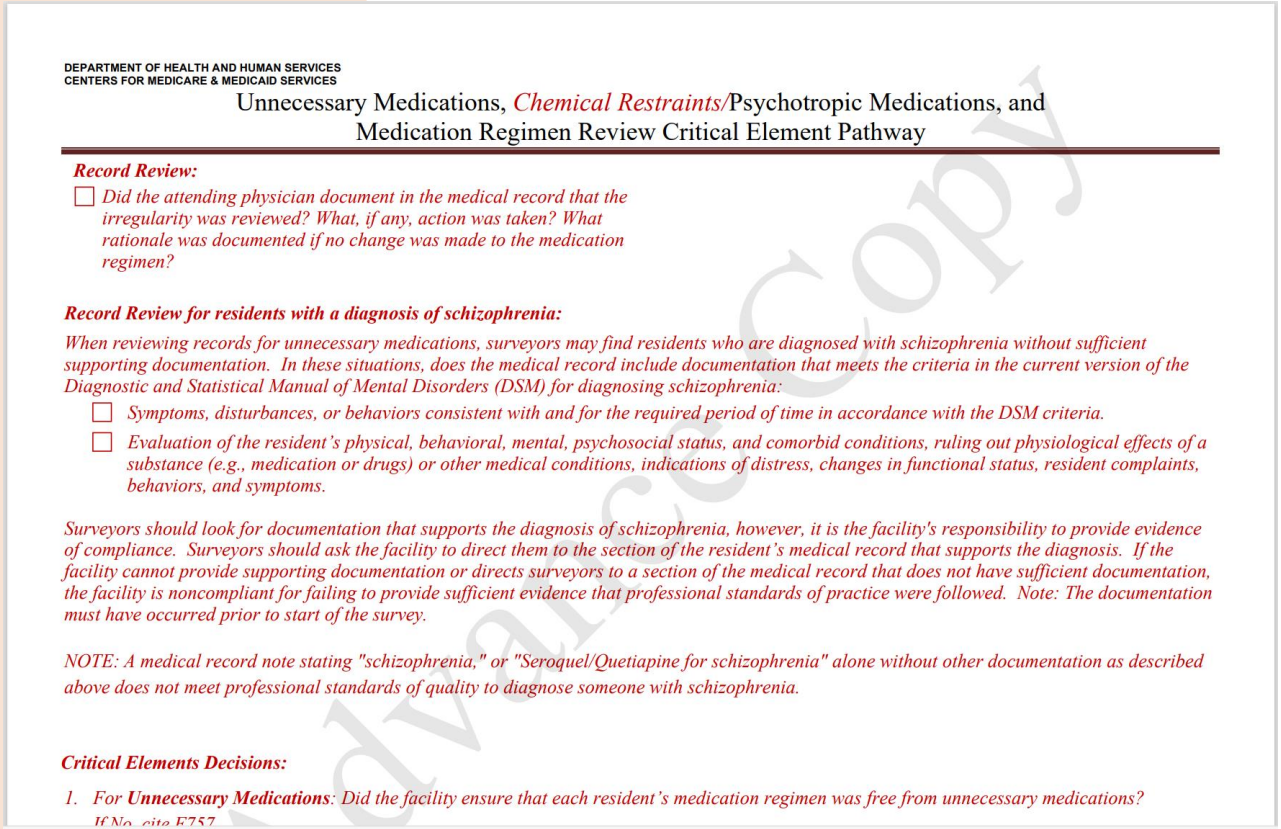
- Get involved or intercede with other physicians or practitioners to facilitate and/or coordinate medical care
- Provide guidance for resident care policies

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

Critical Element Pathways[1]

- Critical Element Pathways are a tool within SOM Appendix PP
- Structured approach to help surveyor assess potential areas of non-compliance in specific areas of care in the survey process



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Unnecessary Medications, *Chemical Restraints/*Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

Record Review:

☐ *Did the attending physician document in the medical record that the irregularity was reviewed? What, if any, action was taken? What rationale was documented if no change was made to the medication regimen?*

Record Review for residents with a diagnosis of schizophrenia:

When reviewing records for unnecessary medications, surveyors may find residents who are diagnosed with schizophrenia without sufficient supporting documentation. In these situations, does the medical record include documentation that meets the criteria in the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) for diagnosing schizophrenia:

☐ *Symptoms, disturbances, or behaviors consistent with and for the required period of time in accordance with the DSM criteria.*

☐ *Evaluation of the resident's physical, behavioral, mental, psychosocial status, and comorbid conditions, ruling out 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.*

Surveyors should look for documentation that supports the diagnosis of schizophrenia, however, it is the facility's responsibility to provide evidence of compliance. Surveyors should ask the facility to direct them to the section of the resident's medical record that supports the diagnosis. If the facility cannot provide supporting documentation or directs surveyors to a section of the medical record that does not have sufficient documentation, the facility is noncompliant for failing to provide sufficient evidence that professional standards of practice were followed. Note: The documentation must have occurred prior to start of the survey.

NOTE: A medical record note stating "schizophrenia," or "Seroquel/Quetiapine for schizophrenia" alone without other documentation as described above does not meet professional standards of quality to diagnose someone with schizophrenia.

Critical Elements Decisions:

1. *For **Unnecessary Medications**: Did the facility ensure that each resident's medication regimen was free from unnecessary medications?*
   If No, cite F757

SOM, state operations manual.

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

PsychU® Improving mental health care... together®

Facility Responsibilities[1]

For psychotropic medications, did the facility ensure that:

- The medication is necessary to treat a specific, diagnosed, and documented condition which includes symptoms that may be causing distress to the resident or others?
- The medication is not sedating the resident, but rather is treating the resident's medical symptoms?
- Alternative treatments, such as behavioral (nonpharmacological) interventions, were attempted and that these interventions have been deemed clinically contraindicated?
- A GDR was attempted and non-pharmacological approaches to care were implemented, unless clinically contraindicated?
- PRN only used if necessary to treat a specific, diagnosed, and documented condition?
- PRN orders for psychotropic medications not for antipsychotic medications are limited to 14 days, unless the attending physician/prescribing practitioner documents a rationale to extend the medication?
- PRN orders 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?

GDR, gradual dose reduction; PRN, as needed.

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

Facility Responsibilities (Cont.)[1]

Psychotropic Medications

Does the medical record show that the resident or resident representative was informed in advance of the risks and benefits of a medication, the treatment alternatives or other options, and was able to choose the option they prefer?

Did the medical director participate in implementing resident care policies by ensuring physicians and other practitioners adhere to facility policies on diagnosing and prescribing medications, and intervene with a health care practitioner regarding medical care that is inconsistent with current professional standards of care?

Reference:

1. Revised long-term care (LTC) surveyor guidance: significant revisions to enhance quality and oversight of the LTC survey process. CMS. Published November 18, 2024. Accessed August 12, 2025. https://www.cms.gov/files/document/revised-long-term-care-ltc-surveyor-guidance-significant-revisions-enhance-quality-and-oversight-ltc.pdf.

PsychU®
Improving mental health care... together®

For more information or to request a more detailed live presentation on this topic from your local Medical Science Liaison, please visit www.PsychU.org/contact

www.PsychU.org

Download The PsychU App Today!

All Of Your Resources In One Spot

- Webinars & Live Events
- Resource Library
- Psychiatric Scales Collection
- Patient & Caregiver Corner

Download the PsychU App from Google Play or from the Apple App Store!

PsychU® Improving mental health care... together®

PsychU®
Improving mental health care... together®

Thank you for attending today's live program!

Tell us what you thought by scanning the QR code and taking a quick survey. We look forward to seeing you again!

Centers For Medicare & Medicaid Services (CMS) Guidance And Regulations: Psychotropic Medication Utilization Guidelines In The Long-Term Care Setting

October 2025 US.PSY.D.25.00035