



# CMS Regulatory Updates

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BEHAVIORAL CARE SOLUTIONS

# Regulations are Changing

The Centers for Medicare and Medicaid Services (CMS) implemented several regulatory changes for skilled nursing facilities (SNFs). CMS has reiterated the definition of a psychotropic medication to be:

*“Any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the categories of antipsychotics, antidepressants, anti-anxiety, sedatives or hypnotics, anticonvulsants, cognitive enhancers, herbal supplements, and melatonin.”*

# Regulations are Changing

- The F-757 and F-758 guidelines have been revised and reorganized to include guidance for unnecessary medications, **excluding unnecessary psychotropic medications.**
- CMS moved the regulation, guidance, and surveyor procedures from F-757 and F-758 (Unnecessary Use of Psychotropics) to **F-605 (Chemical Restraint).**
- **CMS notes the purpose of this move is to streamline the survey process, increase consistency, and strengthen their message that facilities must prevent the unnecessary use of psychotropic medications. Emphasizes psychotropic medications should be the last resort for treatment.**

# Regulations are Changing

CMS has indicated that they intend to increase focus on the use of these classes of medications and we can expect that in the coming year this will be an area of emphasized survey and enforcement activity.

Of particular importance is the reorganization of the F-605 guideline “Right to be Free from Chemical Restraints” and allows up to a Level 4 Immediate Jeopardy to Resident Health and Safety Citation (I/J tag) which includes but is not limited to:

- Failure to recognize that use of an antipsychotic medication, originally prescribed for agitation, has caused significant changes in the resident’s quality of life.
- The resident no longer participates in activities they previously enjoyed.
- has difficulty concentrating and carrying on conversations.
- spends most of the day isolated in his or her room, sleeping in a recliner or in bed.
- Continued use of the antipsychotic medication without an adequate indication, GDR, and evidence of non-pharmacological approaches resulted in psychosocial harm.
- For a resident who is unable to communicate psychosocial outcomes related to medication side effects, the surveyor should make a determination of how a reasonable person would experience the changes caused by medication side effects.
- Evidence shows the medication is being used for the purpose of discipline or staff convenience.

# Stricter Surveyor Scrutiny & Accountability Measures

- **New Surveyor Training & Focus Areas:**
  - Surveyors will use updated **Critical Element Pathways** to **closely monitor medication prescribing patterns**.
  - **Increased focus on high antipsychotic use rates**, particularly for residents without a clear psychiatric diagnosis.
- **Expanded Review of Documentation:**
  - **Lack of proper documentation** or failure to attempt non-pharmacological interventions before prescribing medication **may result in citations**.
  - Surveyors will check **care plans to ensure resident-specific medication assessments** and proper risk-benefit analysis.
  - Surveyors can interview Medical Director(s) regarding patterns of use in NH.

# Regulation Focus-PRN Use

The F-605 guideline addresses Unnecessary PRN Psychotropic Medication use and indicates:

- A 14-day limitation on all PRN orders (except antipsychotics). Orders may be extended beyond 14 days if the prescribing clinician:
  - Believes it is appropriate to extend the order –and-
  - Documents clinical rationale for the extension –and-
  - Provides a specific duration of use.
- A 14-day limitation on all PRN antipsychotic orders. Order may not be extended beyond 14 days. A new order may be written if the prescribing clinician:
  - Directly examines the resident. Evaluation by facility staff is not sufficient – and-
  - Documents a clinical rationale for the new order indicating the benefit of the medication and objective indicators of improvement as a result of the PRN medication.

# Note to Clinicians

These regulation changes do NOT mean a clinician cannot use these medications or initiate a PRN in emergent situations. Guidance updates are not explicitly dictating how a clinician practices medicine but what needs to be documented in the medical record in order to do so.

Per regulation, “When a resident is experiencing an acute psychiatric emergency (e.g. the resident’s behavior or expression poses an immediate risk to self or others), medications may be required with a resident diagnosed with dementia, delirium induced psychosis or similar. As always, medications should only be used in the presence of active clinical symptoms and after non-pharmacological interventions and less restrictive measures have been attempted.” (CMS)

# Note to Clinicians

- Approved diagnosis indicated for the ongoing use of antipsychotic medications are provided below and were provided by Public Health Surveyor Team (Note these Dx differ from those indicated in the 5-Start Quality Rating System).

Schizophrenia

Delusional Disorders

Schizoaffective Disorder

Bi-Polar Disorder

Paranoid States

Depression with Psychosis

Delirium

Reactive Psychosis

- Treatment of agitation or other distressing symptoms of dementia is considered a short-term intervention once other non-pharmacological interventions have failed. Significant documentation is required to support ongoing use of this class of medications.

# Regulations are Changing- Schizophrenia Audits

- Over the last 5 years the number of residents in NH's reported as having a diagnosis of schizophrenia skyrocketed to over 20% in some cases.
- Facilities may be using this diagnosis to work around new guidelines regarding AAP use. As such, CMS has launched investigations in nursing homes aimed at verifying whether residents have been properly diagnosed with Schizophrenia.
- Nursing homes are being required to provide clear documentation supporting this diagnosis based upon standardized symptom criteria and history of disease prior to admission.
- Penalties can include impact on 5-Star Ratings and other more significant consequences.
- BCS has developed a Schizophrenia Review Protocol to assist facilities in confirming diagnosis.

# Regulations are Changing-Use of Anticonvulsants

- CMS will begin collecting data on usage of anticonvulsant medications in Section N of the MDS form effective October 1, 2024. Section N addresses “high-risk medications”.
- The trigger for this change was a November 2022 report from the U.S. Dept of Inspector General (OIG) indicating that while antipsychotic use in nursing homes declined slightly from 2011 to 2019, use of anticonvulsants increased. They attribute this change to CMS efforts to reduce antipsychotic usage.
- They also point to limited evidence of effectiveness of anticonvulsants for treating BSPD among people living with dementia based upon findings that use of anticonvulsant medications among nursing home residents with dementia has been on the rise. They commented, “Antiepileptics are commonly prescribed to nursing home residents with Alzheimer's disease and related dementias (ADRD) but there is little scientific support for their use in this population.”

# Regulations are Changing-Use of Benzodiazepines

Nursing home guidelines for use include:

- Limiting prescription trials to shorter durations (per BCS clinical leadership team recommendation).
- Increased risk of falls, hip fractures, increased confusion and sedation need to be monitored.
- Psychosocial and nonpharmacological Interventions attempted.
- Not a preplacement for other classes of regulated psychoactive medications such as antipsychotics and anticonvulsants.
- Tapering schedule longer than other medications.
- Concurrent use with opioids prohibited.
- Risk of addiction greater and use when Hx of SA prohibited.

# Practical Implications-Facilities

- **Stronger Compliance Requirements:**
  - Facilities must update policies to ensure **clear documentation of medical necessity, GDR attempts, and side effect monitoring.**
  - More rigorous **pharmacist and physician reviews** required.
- **Training & Education Requirements:**
  - **Staff must be trained** in behavioral interventions, dementia care, and CMS's new psychotropic medication guidelines.
  - Nursing staff must understand **when medications qualify as chemical restraints** and how to document appropriate use.

# Practical Implications-Facilities

- **Higher Risk of Deficiencies & Enforcement Actions:**
  - Facilities with **high psychotropic prescribing rates or improper documentation** may face **survey deficiencies, penalties, or loss of certification.**
- By excluding psychoactive medications from the F-757 and 758 unnecessary medication use guidelines and reorganizing under the F-605 chemical restraint guidelines, allows survey teams to cite up to an I/J level actual harm violation.

# Practical Implications-Clinicians

- There is no significant change from previous guidelines indicated under the F-757-758 tags regarding prescriptive and clinical practices.
- The primary change is the increased burden of documentation the clinician is required to provide to support the ongoing use of psychoactive medications.
- Treating clinicians and primary care team members may be contacted directly by Survey Teams.

# Strategies to Enhance Compliance

Behavioral Care Solutions (BCS) strives to improve behavioral health care and better ensure appropriate use of antipsychotic drugs and other psychoactive medications in the nursing home, expanded assessment for non-pharmacological interventions, and compliance with these new regulatory standards. Key aspects are detailed in the following slides.

# What do we Really Mean by Compliance?

- Compliance is about defining compassion. How we care for our most vulnerable defines who we are as a culture.
- Regulations attempt to define our view of compassion, even if they may be misguided at times. Compassion is therefore measured by compliance with these regulations.
- Compliance is the process of understanding the resident and recognizing when there is a disconnect between what is important to us and what is important to them.

# Summary Behavioral Program Checklist

- Identify Interdisciplinary Team (IDT) to lead program initiative
- Program opportunities and goals established
- Coordination of Care
- Enhancing documentation
- Behavior tracking
- Establish Behavior Committee Meeting
- Gradual Dose Reduction Considerations
- MDS Behavioral Indicators
- Staff Training
- Family Education
- Behavior Care Planning
- Activity Planning

# Enhanced Oversight of Psychotropic Medication Use

- **Stronger Justification for Use:**
  - Psychotropic medications **cannot be prescribed indefinitely without ongoing assessment**. Shorter trials are recommended by BCS Clinical Leadership Team.
  - Residents prescribed **antipsychotics, sedatives, anxiolytics, or mood stabilizers** must have a **documented clinical rationale**.
- **Increased Monitoring for Adverse Effects:**
  - Facilities **must regularly evaluate** for side effects such as **excessive sedation, falls, confusion, and diminished quality of life**.
  - Special attention is required for **residents with dementia**, as antipsychotics are linked to increased risk of stroke and mortality.

# Strengthened Requirements for Gradual Dose Reductions (GDRs)

- **Mandatory Gradual Dose Reductions (GDRs) for Psychotropics**
  - GDRs must be attempted **at least twice a year** unless a **clinical justification is documented** (e.g., severe relapse risk).
  - Updated GDR template language to reflect new standards.
  - Facilities must **document failed GDR attempts** and ensure ongoing evaluation of necessity.
- **Exception for Specific Conditions:**
  - Residents with **schizophrenia, bipolar disorder, or chronic psychiatric conditions** may be exempt if **documented evidence shows clinical need**. However, a **GDR would still be required on an annual basis**.

# Indication for Use Clearly Documented

- Behavior or mood indicators clearly identified and tracked for all psychoactive medications:
  - Antidepressants-crying, isolation, appetite, etc
  - Antianxiety-Restlessness, panic symptoms, etc.
  - Antipsychotics-delusions, hallucinations, agitated behavior (clearly defined), etc.
  - Hypnotics-Hours of sleep
- Residents prescribed antipsychotics, sedatives, anxiolytics, or mood stabilizers must have a documented clinical rationale.

Medication

Dx often seen used in EMR

More Accurate Indication for Use

Benzodiazepine	"Yelling, agitation"	Anxiety, Short term for Insomnia, Panic disorder Adjunct, N/V in chemo or hospice residents
Seroquel	"Agitation"	Tx resistant anxiety disorder, psychosis, bipolar disorder, schizophrenia
Olanzapine	'Sleep" or "mood stabilization"	Bipolar disorder, schizophrenia, MDD tx resistant, psychosis
Trazodone	"Anxiety"	Insomnia , MDD
Antidepressant - (Sertraline, Lexapro)	"Mood" or "dementia with mood concern"	Both - MDD, GAD Sertraline - Panic Disorder, OCD, PTSD, social anxiety disorder
Antidepressant - Mirtazapine	"Insomnia" or "anxiety"	MDD, appetite stimulation
Antidepressant - Duloxetine	"pain"	MDD, GAD, Neuropathic pain, Musculoskeletal Pain, Fibromyalgia
Hydroxyzine	Allergy or anxiety	Can be used for anxiety so important to add dx for this medication because if used for anxiety, needs to be reviewed for GDRs

# Documenting Potential Underlying Medical Causes have been Ruled Out

A few examples include-

- Delirium
- Neurological event
- Other neurological condition (e.g. PBA, etc.)
- Medication side effects (e.g. Akathisia, etc.)
- Drug-drug interactions
- Overuse of Anticholinergic Medications

# Tracking Behaviors - When is Behavior Monitoring Required?

- In Nursing homes, medications are prescribed to “treat behaviors.” Sometimes these behaviors are symptoms of dementia or other psychiatric conditions.
- As indicated in the previous slide, the F-tag can be cited by surveyors when medications are used without sufficient monitoring.
- When BP meds are started, readings are monitored to determine effectiveness. Similarly, when a medication is started to treat a specific behavior, we need to monitor that behavior.
- We always need to ask ourselves: How do I know a medication is working? Are there patterns of behavior that can help us determine why a behavior is occurring?
- A behavior is a reaction to a stimulus or situation. Our goal is to decide what behavior to monitor and to identify the specific behavior resulting in a medication being started.
- Operationalizing target behaviors to be tracked - Agitation is not a behavior; it is a global description of many types of behaviors (yelling, striking-out, spitting, etc.). Depression is a spectrum of behaviors such as crying, withdrawal, not eating, etc.
- It is important to define the behavior to be tracked so all staff are tracking the same thing.

# Tracking Behaviors- The Basic Care Process

The Management of all psychiatric conditions in a nursing home should follow these basic steps:

- **Assessment/Recognition-**

- The purpose of this step is to provide a rational basis for deciding if there is a need, problem or risk and what to do about it.

- **Diagnosis/Cause Identification-**

- Facility staff and team attempt to identify cause of behavior. Behavior tracking is a critical tool in this process. Most behaviors do not occur in a vacuum. Tracking allows us to determine patterns of behavior. Understanding these patterns allows us to develop interventions to treat behaviors.

- **Treatment/Management-**

- The facility's staff and team use the above information to decide how to manage a behavior, symptom or situation. Where patterns are identifiable and correctable, treatments can be determined that may include medications and other management strategies.

- **Monitoring-**

- The facility staff and team use tracking tools to monitor and evaluate the individual's progress over time in relation to a risk, need, problem, condition, or symptom, consider the effectiveness of interventions, and make a systematic determination about what to do next.

- **Without behavior tracking, there is no justification to use a medication or implement an intervention. During annual survey, this is a primary cause of violation.**

# Tracking Behaviors- Simple Tools

There are 2 primary levels of behavior tracking that staff can easily utilize:

- **Frequency Charting-**

- The handout provided demonstrates a simple charting tool that requires facility staff to indicate when a target behavior occurs and the frequency of the behavior. This allows the treatment team to easily identify simple patterns that may be present such as when the behavior occurs (more frequently in the morning, afternoon, or night) and what may be happening when the behavior occurs (mealtime, ADL's, group activity, etc.). If a pattern is detected, more complex tracking can be used.

- **Functional Analysis Tracking-**

The handout provided demonstrates an easy tracking process to better determine what may precipitate a behavior, what the behavior is, and how staff respond to a behavior. Often times, this allows the team to develop strategies that can help in managing the behavior.

- Examples of how this process can be effective.

Again, without some form of monitoring, there is no support for medication use or interventions. It is imperative and REQUIRED that tracking occurs.

# Documenting Nonpharmacological Interventions being Used

Nonpharmacological Interventions in nursing homes refer to behavioral strategies used to manage challenging behaviors in residents, and include-

- Activity engagement
- Sensory stimulation
- Structured routine planning
- Positive reinforcement
- Cognitive behavioral therapy
- Family Support

All are aimed at addressing underlying causes of behavior while promoting positive behaviors instead of relying only on medications.

# Key Aspects of Behavioral Interventions

- **Assessment and Individualized Plans**-Thorough evaluation of each resident's behavior to identify triggers and develop tailored interventions based upon their specific needs.
- **Positive Reinforcement**-Utilizing praise, rewards and positive attention to encourage desired behaviors.
- **Environmental Modifications**-Providing meaningful structured and engaging activities to redirect attention and promote social interaction, tailored to individual interests.
- **Routine Structures**-Establishing consistency in daily routines to provide predictability and reduce anxiety.

# Examples of Behavioral Interventions

- Functional Analysis Training-Understanding how to identify triggers, cues and stimuli that provoke behavior(s).
- Redirection-Distracting a resident with a calming activity when they exhibit disruptive behavior.
- Sensory Stimulation-Using music, smell, touch, or visual cues to soothe agitation or anxiety.
- Validation-Acknowledging the feelings of a resident experiencing confusion or memory loss.
- Choice-Based Activities-Providing choices to residents, however small, to participate in activities and provide a sense of control in their environment.
- Staff Training-Educating staff on how to effectively interact with residents and implement behavioral strategies consistently.

# Considerations in Behavioral Planning

- Collaboration with the healthcare team-Involving the interdisciplinary team, physicians, families, and others to develop a comprehensive intervention plan.
- Ethical considerations-Avoiding practices that may be considered restrictive or demeaning, limiting in activities, and ensuring resident dignity and autonomy.
- Monitoring, tracking, and evaluation-Initial identification and assessment of pattern of behaviors, tracking effectiveness of interventions and making adjustments as needed.

# Understanding CMS Critical Elements Care Pathways-Appendix PP

- Outlines Behavioral and Emotional Status Critical Elements
- Surveyors use this pathway to determine if the facility is providing necessary behavioral, mental, and/or emotional health care and services to each resident.
- The facility staff members must implement person-centered, nonpharmacological care to meet the individual needs of each resident.
- While there may be isolated situations where medication is required first, these situations do not negate the need for such alternative care approaches.
- See full copy of Appendix PP attached herein.



Questions  
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