Updates to CMS SOM rules on Psychosocial Issues, Deficiency Categorization, and Psychotropic Medication Use

Stephen Eide R. Ph
Oni Kinberg LCSW, MSSW
Updates to the SOM

• On March 25, 2016 CMS sent out updates to the State Operations Manuals (SOM) clarifying the area of Psychosocial Harm in Nursing Homes

• On May 27, 2016 these were forwarded by the Idaho Department of Health and Welfare Bureau of Facility Standards to all Idaho Long Term Care Facilities
Revisions to the Guidance for Psychosocial Harm in Nursing Homes

• **F329 Draft Revision:** The Centers for Medicare & Medicaid Services (CMS) has revised guidance to surveyors in Appendix PP of the SOM under F329 to enhance ease of use for surveyors and to include language related to how unnecessary use of medications may cause psychosocial harm to residents.

• **Psychosocial Outcome Severity Guide:** CMS has revised language in the Psychosocial Outcome Severity Guide in Appendix P of the SOM.

• **Revisions to Selected F tags:** CMS has added language to selected F tags to emphasize the risk of psychosocial harm associated with noncompliance with specific regulations.

• The regulatory language remains unchanged
Background

• In 2006, CMS issued the Psychosocial Outcome Severity Guide in Appendix P of the SOM. The guide provided instructions, definitions, and criteria to help surveyors determine the correct levels of negative psychosocial outcomes that developed, continued, or worsened because of a facility’s noncompliance. While surveyors currently cite instances of psychosocial harm, CMS believes these revisions will help guide surveyors to identify psychosocial harm or potential harm. The revisions also support activities or actions to improve resident safety and increase quality and reliability of care for better outcomes.
Changes to Section IV.E of Appendix P, Psychosocial Outcome Severity Guide

• There are only two areas of clarification/change under this section. One of them may be helpful to facilities when a surveyor is evaluating if psychosocial harm occurred.

• The other is clarification to the surveyor of areas to look for possible psychosocial harm
Pre-existing Conditions

• The presence of a given affect (i.e., behavioral manifestation of mood demonstrated by the resident) does not necessarily indicate a psychosocial outcome that is the direct result of noncompliance. A resident’s reactions and responses (or lack thereof) also may be affected by pre-existing psychosocial issues, illnesses, medication side effects, and/or other factors. Because many nursing home residents have sadness, anger, loss of self-esteem, etc. in reaction to normal life experiences, the survey team must have determined that the psychosocial outcome is a result of the noncompliance and not a pre-existing condition for the resident.
• Psychosocial outcomes of interest to surveyors are those caused by the facility’s noncompliance with any regulation. This also includes psychosocial outcomes resulting from facility failure to assess and develop an adequate care plan to address a resident’s pre-existing psychosocial issues, leading to continuation or worsening of the condition.
Other New Additions

- Areas where the survey team may more likely see psychosocial outcomes when citing a particular deficiency include, but are not limited to, F221/F222, Physical and Chemical Restraints; F223 Abuse; F224 Mistreatment, Neglect, Misappropriation; F225 Investigate and Report Allegations of Abuse; F226 Abuse and Neglect Policies; F241, Dignity; F246, Accommodation of Needs; F248, Activities; F279, Comprehensive Care Plans; F280, Right to Participate in Care Planning; F309, Quality of Care (pain, dementia care); F319, Treatment/Services for Mental/Psychosocial Functioning; F320, No Behavior Difficulties Unless Unavoidable; and F329, Drug Regimen is Free From Unnecessary Drugs. While the survey team may find negative psychosocial outcomes related to any of the regulations, these areas may be more susceptible to a negative psychosocial outcome or contain a psychosocial element that may be greater in severity than the physical outcome.
DEFICIENCY CATEGORIZATION (See SOM Appendix P, Part IV)

- Surveyors should be mindful of the elevated risk of psychosocial harm associated with the regulation at tags F221/222 that may lead to noncompliance, and consider this during their investigation.
- Once the team has completed their investigation, analyzed the data, reviewed the regulatory requirements, and identified any deficient practice(s) that demonstrate that noncompliance with the regulations at F221/222 exists, the team must determine the scope and severity of each deficiency, based on the resultant harm or potential for harm to the resident.
- The survey team must consider the potential for both physical and psychosocial harm when determining the scope and severity of deficiencies related to chemical and physical restraints.
- See also the Psychosocial Outcome Severity Guide and Investigative Protocol in Appendix P, Part IV, Section E for additional information on evaluating the severity of psychosocial outcomes.
Surveyors should be mindful of the elevated risk of psychosocial harm associated with the regulation at tag F241 that may lead to noncompliance, and consider this during their investigation.

Once the team has completed their investigation, analyzed the data, reviewed the regulatory requirements, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F241 exists, the team must determine the scope and severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The survey team must consider the potential for both physical and psychosocial harm when determining the scope and severity of deficiencies related to dignity.

See also the Psychosocial Outcome Severity Guide and Investigative Protocol in Appendix P, Part IV, Section E for additional information on evaluating the severity of psychosocial outcomes.
F 329 Unnecessary Drugs

• This instruction revises interpretive guidance for F329 to provide additional information to surveyors about consideration of psychosocial harm when assessing compliance related to unnecessary medications.
Overview

• These next additions look at possible unnecessary drug and other issues.
• They recognize that drug use is necessary and useful but also a possible cause of harm.
• They further stress the use of non-drug interventions.
• There is extra emphasis on stopping psychotropic after acute delirium treatment
• They stress the importance of Activities to improve quality of life, act as a non-drug intervention, and serve as a marker for the patient’s psychosocial well being.
Adverse Effects

- Adverse consequences related to medications are common enough to warrant serious attention and close monitoring. An Office of the Inspector General (OIG) report on adverse events in skilled nursing facilities (SNFs) found one in five SNF residents experienced at least one adverse event and 37 percent of these advents were related to medications. The report found 66 percent of medication-related adverse events to be preventable because the events often occurred due to substandard treatment or insufficient monitoring. Additionally, the OIG found that the use of multiple medications often complicated the determination of the primary cause of events, particularly when the primary cause was related to another medication.
Anticholinergic Side Effects

“Anticholinergic side effect” is an effect of a medication that opposes or inhibits the activity of the parasympathetic (cholinergic) nervous system to the point of causing symptoms such as dry mouth, blurred vision, tachycardia, urinary retention, constipation, confusion, delirium, hallucinations, flushing, and increased blood pressure. Types of medications that may produce anticholinergic side effects include:

- Antihistamines, antidepressants, antipsychotics, antiemetics, muscle relaxants; and
- Certain medications used to treat cardiovascular conditions, Parkinson’s disease, urinary incontinence, gastrointestinal issues and vertigo.
Distressed Behavior Definition

• “Distressed behavior” is behavior that reflects individual discomfort or emotional strain. It may present as crying, apathetic or withdrawn behavior, or as verbal or physical actions such as: pacing, cursing, hitting, kicking, pushing, scratching, tearing things, or grabbing others. Distressed behavior may be treated with medications but should also be addressed through nonpharmacological approaches. Certain medications may also cause or contribute to distressed behavior.
Addition to the Examples of Non-Drug Interventions

• Arranging staffing to optimize familiarity and consistency for a resident with symptoms of dementia
Additions to Medication Management

• Evaluation of a resident’s *physical, behavioral, and psychosocial* signs and symptoms, in order to identify the underlying cause(s), including adverse consequences of medications;
• The regulations associated with medication management include consideration of:
• Indications for use of medication (including initiation or continued use of antipsychotic medication);
• Monitoring for efficacy and adverse consequences;
• Dose (including duplicate therapy);
• Duration;
• Tapering of a medication dose/gradual dose reduction for antipsychotic medications; and,
• Prevention, identification, and response to adverse consequences.
Issues to Consider Prior to Use of Medication.

• Whether the *physical and/or psychosocial* signs, symptoms, or related causes are persistent or clinically significant enough (e.g., causing functional decline) to warrant the initiation or continuation of medication therapy;
Delirium

• (i.e., acute confusional state) is a common adverse consequence that may result from medications as well as other factors including electrolyte imbalances or infections. In many facilities, a majority of the residents have dementia. Individuals who have dementia may be more sensitive to medication effects and may be at greater risk for delirium. While delirium is not always preventable, identifying and addressing risk factors may reduce the occurrence. The presence of delirium is associated with higher morbidity and mortality. Some of the classic signs of delirium may be difficult to recognize and may be mistaken for the natural progression of dementia, particularly in the late stages of dementia.
Delirium

• Delirium often presents with symptoms of restlessness and agitation but, in older residents, may present with increased lethargy and sedation. Use of medications to treat delirium may increase confusion and exacerbate other delirium symptoms and should only be used at the lowest dose for the shortest period of time possible. Careful observation of the resident (including mental status and level of consciousness), review of the potential causes (e.g., medications, fluid and electrolyte imbalance, infections) of the mental changes and distressed behavior, and appropriate and timely management of delirium are essential.
SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS

• Additions to this area include:

• *Apathy*

• Behavioral changes, unusual behavior patterns (including increased distressed behavior, *social isolation or withdrawal*)

• *Lethargy*

• Mental status changes, (e.g., new or worsening confusion, new cognitive decline, worsening of dementia (including delirium), *inability to concentrate*)
SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS

• Psychomotor agitation (e.g., restlessness, inability to sit still, pacing, hand-wringing, or pulling or rubbing of the skin, clothing, or other objects).

• Psychomotor retardation (e.g., slowed speech, thinking, and body movements)
Possible Inadequate Indications for Medication Use

• Initiation of an antipsychotic medication to manage distressed behavior without considering a possible underlying medical cause (e.g., UTI, congestive heart failure, delirium) or environmental or psychosocial stressor.
Possible Cases of Inadequate Monitoring.

- Failure to monitor for changes in psychosocial functioning resulting from adverse consequences of medications, e.g., resident no longer participates in activities because medication causes confusion or lethargy.
Gradual Dose Reduction of Antipsychotic Medication

• Failure to attempt GDR in the absence of identified and documented clinical contraindications.
• Prolonged or indefinite antipsychotic use without attempting gradual dose reductions.
• Failure to implement behavioral interventions to enable attempts to reduce or discontinue an antipsychotic medication.
• *Failure to discontinue an antipsychotic, prescribed for acute delirium, once delirium symptoms have subsided.*
• Determine whether sedative, antipsychotic, or anti-anxiety medications are used for discipline, convenience, to subdue, or sedate rather than to treat medical symptoms. Using medications as chemical restraints may result in symptoms of withdrawal, depression, or reduced social contact.
Deficiency Categorization

• The survey team may have identified actual or potential negative physical harm, actual or potential negative psychosocial harm or both resulting from unnecessary medications.

• Negative psychosocial outcomes related to unnecessary medications may include: suicidal ideation, recurrent debilitating anxiety, extreme aggression or agitation, significant decline in former social patterns, social withdrawal, psychomotor agitation or retardation, inability to think or concentrate, and apathy. See also the Psychosocial Outcome Severity Guide in Appendix P, Section E for additional information on evaluating the severity of psychosocial outcomes.
Deficiency Categorization

• The key elements for severity determination for F329 are:

  • Presence of potential or actual harm/negative outcome(s) due to a failure related to unnecessary medications;
  • Degree of potential or actual harm/negative outcome(s) due to a failure related to unnecessary medications; and,
  • The immediacy of correction required.
Deficiency Categorization

- The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F329. First, the team must determine whether or not Severity Level 4, Immediate Jeopardy to a resident’s health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to remove the jeopardy and correct the noncompliance which allowed or caused the immediate jeopardy. (Follow the guidance in Appendix Q.)
New Examples of Possible Immediate Jeopardy

• Failure to respond appropriately to an INR level that is below the target range for treatment of atrial fibrillation, prevention of deep vein thrombosis (DVT) or pulmonary embolus, or other documented indication.

• Failure to recognize that symptoms of increased confusion and that newly developed inability to do activities of daily living resulting in hospitalization are the result of excessive doses of antipsychotic given without adequate clinical indication.
New Examples of Possible Immediate Jeopardy

- Failure to recognize that continuation of an antipsychotic, originally prescribed for acute delirium, has caused significant changes in the resident’s behavior from the resident’s baseline—the resident no longer participates in activities, has difficulty concentrating and carrying on conversations and spends most of the day in the room, sleeping in a recliner or in bed. Continuation of the antipsychotic without indication resulted in significant psychosocial harm.

- Failure to re-evaluate continuation of an antipsychotic originally prescribed for acute delirium which resulted in significant side effects from the medication— the resident stayed in bed most of the day, developed a stage III pressure ulcer, and new onset of orthostatic hypotension putting the resident at risk for falls.
New Examples of Level 3 Harm

- Facility failure to take appropriate action (e.g., suspending administration of the anticoagulant) in response to an INR greater than 4 and less than 9 for a resident who is receiving warfarin until spontaneous bruising or frank bleeding occurs, resulting in the need to transfuse or hospitalize the resident or failure to take appropriate action for an INR that is below the therapeutic level to prevent clot formation resulting in hospitalization for a DVT.

- Failure to evaluate the medication regimen as a possible cause of resident’s decline in functioning evidenced by withdrawal, crying, loss of interest in activities, and social isolation.

- Failure to evaluate a resident for a gradual dose reduction for medication originally prescribed to treat delirium. Delirium symptoms had subsided but resident was drowsy and inactive during the day as a result of the medication causing a decline in psychosocial functioning.
New Examples of Level 2 Harm

- Facility failure to monitor for response to therapy or for the emergence or presence of adverse consequences before the resident has experienced an adverse consequence or decline in function (e.g., monitoring periodically for symptoms of behavioral distress, decline in social functioning, or oversedation in someone receiving psychopharmacological medication; monitoring thyroid function at least annually in an individual receiving thyroid hormone replacement; and monitoring hydration status and basic metabolic profile for a resident receiving diuretics or ACE inhibitors, who had a change in mental status after the onset of diarrhea).

- The facility failed to initiate a gradual dose reduction for or discontinue an antipsychotic medication originally ordered for delirium symptoms. The delirium symptoms have subsided but the resident continues to receive the antipsychotic medication at the original dose.
Review whether the facility provides activities that address a resident’s needs and may permit discontinuation or reduction of psychopharmacological medications. Review also whether adverse consequences of medications interfere with a resident’s ability to participate in activities.
Questions?