Minnesota Department of Health

Psychosocial Outcomes & SOM Revisions

JUNE 20, 2016
NARRATOR TEXT

Slide 1

Today we are going to provide you with a brief summary of changes CMS is making to the State Operations Manual (SOM). Our aim today is to focus on language that CMS has revised. In the agenda for this call, however, we have provided you with a link to the complete revised regulations and guidance from CMS so that you have that available to you.

Appendix P of the SOM provides instructions for surveyors in conducting surveys. Appendix PP contains the Skilled Nursing Facility (SNF) and Nursing Facility (NF) regulations and Interpretive Guidelines (IGs). CMS does not provide page numbers for their online manuals so here is a hint for maneuvering through a CMS manual. If you use the "Find" feature on your computer or internet browser, it makes it easier for you to find what you are looking for. For instance, if you are looking for the Psychosocial Outcome Severity Guide you can use the find feature (Ctrl F on many computers). When the Find box appears, type in Psychosocial Outcome and click on the Next button. This will take you directly to the Psychosocial Outcome Severity Guide in Appendix P. In Appendix PP, if you are looking for a specific F tag, type that F number (F329, for example) in the Find box and click on the next button until you get to the F329 regulation. When CMS makes revisions, the changes are in *Red Italics*.

Slide 2

For many years, CMS has provided surveyors with guidance on determining the severity of psychosocial outcomes residents experience or could experience from identified noncompliance. In other words, if it has been determined that a facility is noncompliant with a particular regulation, how has that noncompliance affected, or could potentially affect a resident's psychosocial status?

This guidance is part of Appendix P of the State Operations Manual (SOM). CMS is now making a few changes to this Psychosocial Outcome Severity Guide. The changes are not extensive. At the same time, CMS is making some changes to the Interpretive Guidelines of specific regulations. Some of these changes are specific to reminding surveyors that noncompliance of these regulations could result in negative psychosocial outcomes for residents.

We will start today by reviewing the Psychosocial Outcome Severity Guide and the revisions CMS made with this release. We will then move on to the changes made in the interpretive guidelines of specific regulations.

Slide 3

The focus of this guide is to help surveyors determine the severity of psychosocial outcomes resulting from the identified noncompliance at a specific F tag.

Psychosocial outcomes such as mood and behavior may result from a facility's noncompliance with any regulatory component.

Psychosocial outcomes are as important as physical outcomes in determining the severity of noncompliance. Psychosocial status can be a result of noncompliance but can also be affected by pre-existing conditions and life experiences.

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CMS has added clarifying language to the Psychosocial Outcome Severity Guide by stating the survey team must determine that the psychosocial outcome is a result of the noncompliance and not a *pre-existing condition for the resident.* In other words, to determine the severity is a result of the facility's noncompliance, the surveyors need to compare the resident's behavior (e.g. their routine, activity, and responses to staff) and mood before and after the facility's noncompliance with the regulation.

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Some residents can verbally express their feelings and psychosocial reactions, other residents are unable to express themselves and responses may be non-verbal.

Survey teams may apply the "reasonable person concept" to determine psychosocial outcomes when a resident's response may not be readily determined through the investigative process.

This could occur because the resident has died, is cognitively or physically impaired, or there is insufficient documentation by the facility.

It could also happen when a resident's reaction to a deficient practice is markedly incongruent with the level of reaction the reasonable person would have to the deficient practice.

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The guide is only to be used when the survey team has established a connection between a facility's noncompliance with a regulation and a negative psychosocial outcome to the resident. The guide now contains a list of regulations where the team is more likely to see psychosocial outcomes. (See slide for tags.)

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See slide for tags.

Slide 8

The Psychosocial Outcome Severity Guide includes possible examples of negative psychosocial outcomes as a result of the facility's noncompliance at different levels of severity. For example:

Immediate Jeopardy is noncompliance that has allowed/caused/resulted in or is likely to cause/allow/result in serious injury, harm, impairment, or death to a resident: and requires immediate correction. The facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures. The guide provides some examples of negative psychosocial outcomes. Some of the examples listed are:

- Suicidal ideation (with a plan) or suicidal attempt.
- Engaging in self-injurious behavior that is likely to cause serious injury.
- Expressions of anger at an intense and sustained level that has caused or is likely to cause serious injury, harm, impairment, or death to self or others.

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Actual Harm that is not Immediate Jeopardy is noncompliance that results in actual harm, and can include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being. The guide provides some Actual Harm examples. Some of the listed examples are:

- Persistent depressed mood that may be manifested by verbal and nonverbal symptoms.
- Significant decline in former social patterns that does not rise to a level of immediate jeopardy.
- Ongoing, persistent feeling and/or expression of dehumanization or humiliation that persists regardless of whether the precipitating, dehumanizing event(s) or situation(s) has ceased.

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No Actual Harm with Potential for More than Minimal Harm that is Not Immediate Jeopardy indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her

highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided. The guide provides some examples. Some of the listed examples are:

- Intermittent sadness, as reflected in facial expression and/or demeanor, tearfulness, crying, or verbal/vocal agitation (e.g., repeated requests for help, moaning, and sighing.)
- Feeling of shame or embarrassment without a loss of interest in the environment and the self.
- Complaints of boredom and/or reports that there is nothing to do, accompanied by expressions of periodic distress that do not result in maladaptive behaviors (e.g., verbal or physical aggression).

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The Interpretive Guidelines in Appendix PP serve to interpret and clarify the Conditions (or Requirements) for Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs). The IG's merely define or explain the relevant statute and regulation and do not impose any requirements that are not in statute or regulation.

With this release, CMS is modifying the IG's of some regulations. The new language directs surveyors to be mindful of the risk of psychosocial harm when considering deficiency categorization for these regulations and then directs surveyors to refer back to the Psychosocial Outcome Severity Guide that we just summarized.

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The new language on this slide has been added to the IG's for several regulations. It directs surveyors to consider the potential for both physical and psychosocial harm when considering scope and severity of noncompliance of those regulations. It then refers surveyors to the Psychosocial Outcome Severity Guide in Appendix PP. This language has been added to the regulations listed on the following two slides.

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F221/222, Physical and Chemical Restraints; F241, Dignity; F242, Self-Determination and Participation; F246, Accommodation of Needs; F248, Activities; F250, Social Services

Slide 14

F310, Activities of Daily Living; F320, Mental and Psychosocial Adjustment; and F353, Nursing Services

Slide 15

F329 Unnecessary Drugs. Appendix PP. The Interpretive Guidelines for this regulation received extensive revisions in 2007. At that time, MDH provided training for surveyors and providers. With this year's release, CMS revised several portions of this regulation and added some information about psychosocial outcomes. Today we are going to review only the 2016 revisions made to the IG's for F329, Unnecessary drugs.

The IG's for this regulation contains a section of definitions. CMS made some additions to the definitions section.

"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 and hallucinations. CMS added *"flushing and increased blood pressure"* to the previously listed side effects. In addition, CMS added language as to which types of drugs might result in anticholinergic side effects. This is probably not new information for many or even most health care professionals, but it is a good review. The list includes:

> *Antihistamines, antidepressants, antipsychotics, antiemetics, muscle relaxants; and*
>
> *Certain medications used to treat cardiovascular conditions, Parkinson's disease, urinary incontinence, gastrointestinal issues and vertigo.*

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Under the definition of, "Distressed behavior," additional language has been added. *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.*

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In the OVERVIEW section of these IG's it indicates it is important for the interdisciplinary team to consider non-pharmacological approaches in addition to medications. CMS has added a possible non-pharmacological intervention to the list of examples, *"Arranging staffing to optimize familiarity and consistency for a resident with symptoms of dementia."*

These materials are for reference only. For complete information, refer to Appendix P and Appendix PP of the State Operations Manual.

CMS has also added some additional websites to the clinical standards of practice and guidelines list.

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Under the MEDICATION MANAGEMENT section, the revised language clarifies that "signs and symptoms" include "*physical, behavioral, and psychosocial"* signs and symptoms. This clarifies that signs and symptoms are not always just physical signs and symptoms.

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.

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The language referencing monitoring medications for efficacy and adverse consequences indicates that adverse consequences related to medications are common enough to warrant serious attention and close monitoring. Additional language in this section references, "*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 adverse events 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."*

> *U.S. Department of Health and Human Services, Office of Inspector General. (2014, February). Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries. (Publication No. OEI-06-11-00370). Retrieved from http://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf.*

This is why both providers and surveyors are concerned about Medication Management!

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As part of monitoring for Adverse Consequences, delirium needs to be considered. The revised language for F329 includes clarifications of delirium. 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.

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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.

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MDH would like to remind you that MDS items C1300 and C1600 address possible symptoms of delirium and acute mental status changes. These items are found on both the comprehensive and quarterly MDS's. There is also a Delirium Care Area Assessment (CAA). There will be some revisions to these areas on the MDS with the new, updated RAI Manual scheduled to be released in October of this year.

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The Investigative Protocol for F329 includes observation, record review, and interviews. You can expect the surveyors to do more than just a paper review when they are looking at the residents' medications.

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There is a table included in the IG's as part of the Investigative Protocol. Included in the table are symptoms, signs, and conditions that may be associated with medications. Some additional

signs and symptoms that might be associated with medications have been added to the table. These include: *apathy; social isolation or withdrawal; lethargy; inability to concentrate; psychomotor agitation (e.g. restlessness, inability to sit still, pacing, hand-wringing, or pulling or rubbing of the skin, clothing, or other objects); and psychomotor retardation (e.g. slowed speech, thinking, and body movements).*

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Under noncompliance related to Inadequate Indications for Use, the guidance now includes *delirium* as a possible cause for distressed behavior for which antipsychotic medication might be prescribed to manage the behavior.

Under noncompliance related to Inadequate Monitoring, the guidance now includes the *failure* by the facility *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.*

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Under noncompliance related to Antipsychotic Medications without Gradual Dose Reduction, the guidance now includes noncompliance due to a *failure to discontinue an antipsychotic prescribed for acute delirium, once delirium symptoms have subsided.*

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The Investigative Protocol for Unnecessary Drugs includes additional tags that surveyors should also consider. The guidance now includes two additional tags that should be considered.

F222, Restraints, to 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.

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F248, Activities, 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.

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Deficiency Categorization is the process of determining the scope and severity of a deficiency. Instructions for determining the Severity noncompliance for F329 have some revisions included in this transmittal. The guidance stresses that *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.*

The Guidance then reminds surveyors *to See the Psychosocial Outcome Severity Guide for additional information on evaluating the severity of psychosocial outcomes.* We summarized the Psychosocial Outcome Severity Guide at the beginning of this section of the call today.

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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.

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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 facility is required to implement specific actions to remove the jeopardy and correct the noncompliance which allowed or caused the immediate jeopardy.

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The guidance now includes some additional examples for Severity Level 4.

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.

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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.

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Failure to re-evaluate continuation of an antipsychotic originally prescribed for acute delirium which resulted in significant side effects from the medication.

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Level 3 is noncompliance that results in a negative outcome that has compromised the resident's ability to maintain and/or reach his/her highest practicable physical, mental and psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. This does not include a deficient practice that only could or has caused limited consequence to the resident.

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Additional examples have been included under Severity Level 3, Actual Harm that is Not Immediate Jeopardy.

In addition to not responding to an elevated INR, the guidance now indicates that Severity Level 3 could be assigned for *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.

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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.

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Level 2 is noncompliance that results in no more than minimal physical, mental and/or psychosocial discomfort to the resident and/or has the potential (not yet realized) to compromise the resident's ability to maintain and/or reach his/her highest practicable physical, mental and/or psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services.

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Additional examples have been included under Severity Level 2, No Actual Harm with Potential for More than Minimal Harm that is Not Immediate Jeopardy.

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 (examples now include *a decline in social functioning or* oversedation in someone receiving psychopharmacological medications.)

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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.

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For several years the IGs for F329 have included two tables with information about medications commonly used in long term care facilities. CMS has removed these tables from the IGs and replaced them with several websites. It was difficult for CMS to assure the tables were current.

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Thank you for your attention today. Remember to review all of the information you were given today as our slides were only a summary of the information.

These materials are for reference only. For complete information, refer to Appendix P and Appendix PP of the State Operations Manual.