CMS Updates State Operations Manual

In a March 25, 2016 Survey and Certification Memorandum, CMS released a draft revision of F329 Unnecessary Drugs and several other F-Tags that include new "guidance ... to enhance ease of use for surveyors and to include language related to how unnecessary use of medications may cause psychosocial harm to residents." New language for F329 Unnecessary Drugs addresses actual or potential negative physical or psychosocial harm or both resulting from unnecessary medications. The following was added to the F329 Unnecessary Drugs Investigative Protocol to help surveyors determine scope and severity by providing new examples to the existing list:

- Severity Level Four Considerations: Immediate Jeopardy to Resident Health or Safety
  - *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.*
  - *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.*
- Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy
  - *Failure to take appropriate action for an INR that is below the therapeutic level to*
  - *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.*
- Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy
  - *Decline in social functioning, or over sedation in someone receiving psychopharmacological medication*
  - *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.*

Other F-Tags that include new draft language are F221 Physical Restraints, F222 Chemical Restraints, F241 Dignity, F242 Self-Determination and Participation, F246 Accommodation of Need, F248 Activities, F250 Social Services, F310 Activities of Daily Living, F320 No Behavior Difficulties Unless Unavoidable, and F353 Nursing Services. These new draft instructions remind surveyors of the following: *Surveyors should be mindful of the elevated risk of psychosocial harm associated with the regulation at tags* [see above list] *that may lead to noncompliance, and consider this during their investigation.*

To obtain the CMS Memorandum and complete text for the F-Tags referenced in this article, visit https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-15.pdf