Alabama Nursing Home Association
Important Information and Websites

1. OBRA PASSR Screening Information: https://apps.mh.alabama.gov/pasrr/

2. Nursing Home Critical Pathways: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes

    a. Discharge Critical Element Pathway
    b. Preadmission Screening and Resident Review Critical Element Pathway
    c. Behavioral and Emotional Critical Element Pathway
    d. Abuse Critical Element Pathway
    e. Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

3. Federal Regulatory Groups

4. State Operations Manual – Appendix PP: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Appendix-PP-State-Operations-Manual.pdf

5. F600 Resident to Resident Abuse of Any Type

6. Reporting of Abuse

7. Immediate Jeopardy Template

8. SBAR – Situation, Background, Assessment, Request

9. F757 & F758 – Unnecessary Drugs, Psychotropic Drugs

Discharge Critical Element Pathway

Discharge Critical Element Pathway

Use this pathway for a resident that has been or is planning to be discharged to determine if facility practices are in place to ensure the resident's discharge plan meets the needs of the resident.

Review the Following in Advance to Guide Observations and Interviews:

- ☐ Review the most current comprehensive and most recent quarterly (if the comprehensive isn't the most recent) MDS/CAAs for Sections A – Discharge Status (A2100), C – Cognitive Patterns, G – Functional Status, and Q – Participation in Assessment and Goal Setting.
- ☐ Physician's orders (e.g., medications, treatments, labs or other diagnostics, and the discharge order – planned or emergent).
- ☐ Pertinent diagnoses.
- ☐ Care plan (high risk diagnoses, behavioral concerns, history of falls, injuries, medical errors, discharge planning to meet the resident's needs including but not limited to resident education and rehabilitation, and caregiver support and education).

Observations:

- ☐ Does staff provide care for the resident as listed in the discharge plan? If not, what is different?
- ☐ How are staff providing education regarding care and treatments in the care plan?
- ☐ How does the resident perform tasks or demonstrate understanding after staff provides education?

Resident, Resident Representative, or Family Interview:

- ☐ What are your discharge plans?
- ☐ What has the facility discussed with you about returning to the community or transitioning to another care setting?
- ☐ Were you asked about your interest in receiving information regarding returning to the community? If not, are you interested in receiving information?
- ☐ What was your involvement in the development of your discharge plan?
- ☐ What has the facility talked to you about regarding post-discharge care?
- ☐ Ask about any discrepancies between the resident's discharge plan and the facility's discharge plan.
- ☐ If discharge is planned:
  - How did the facility involve you in selecting the new location? Did you have a trial visit, if feasible? How did it go;
  - How were your goals, choices, and treatment preferences taken into consideration;
  - What are your plans for post-discharge care (e.g., self-care, caregiver assistance);
  - What information did the facility give you regarding your discharge (e.g., notice, final discharge plan)? When was it given? Was the information understandable; and
  - What discharge instructions (e.g., medications, rehab, durable medical equipment needs, labs, contact info for home health, wound treatments) has the facility discussed with you? Were you given a copy of the discharge instructions? If applicable, did the facility have you demonstrate how to perform a specific procedure so that you can do it at home?

Discharge Critical Element Pathway

Staff Interviews (Nurses, DON, Social Worker and Attending Practitioner):

- ☐ What is the process for determining whether a resident can be discharged back to the community? How do you involve the resident or resident representative in the discharge planning? Do you make referrals to the Local Contact Agency when the resident expresses an interest in being discharged?
- ☐ How often are the discharge needs of the resident evaluated and is the post-discharge plan of care updated?
- ☐ What is the resident's discharge plan, including post-discharge care?
- ☐ Why is the resident being discharged (i.e., for the resident's welfare and the resident's needs cannot be met in the facility, because the resident no longer required services provided by the facility, because the health or safety of the individual was endangered, or due to non-payment)?
- ☐ For residents being discharged to another healthcare provider: What did the facility do to try and provide necessary care and services to meet the resident's needs prior to discharge? What does the new facility offer that can meet the resident's needs that you could not offer?
- ☐ Where is the resident being discharged to? How was the resident involved in selecting the new location? Was a trial visit feasible?
- ☐ What, when and how is a resident's discharge summary, and other necessary healthcare information shared with staff at a new location?
- ☐ For discharge summary concerns are noted, interview staff responsible for the discharge summary.
- ☐ How does the facility provide education to the resident or care provider regarding care and treatments that will be needed post-discharge?

Record Review:

- ☐ Did the facility ask the resident about their interest in receiving information regarding returning to the community? If not, why not?
- ☐ If the resident wants to return to the community, was there a referral to the local contact agency or other appropriate entities?
- ☐ If referrals were made, did the facility update the discharge plan in response to information received?
- ☐ If the resident cannot return to the community, who made the determination and why?
- ☐ Did the facility identify the resident's discharge needs and regularly re-evaluate those discharge needs?
- ☐ Does the care plan adequately address the resident's discharge planning? Does it address identified needs, measureable goals, resident and/or resident representative involvement, treatment preferences, education, and post-discharge care? Has the care plan been revised to reflect any changes in discharge planning?
- ☐ Who from the IDT was involved in the ongoing process of developing the discharge plan?
- ☐ What are the circumstances and basis for the discharge? Was the discharge necessary? Was the reason for the discharge documented by a physician, as appropriate?
- ☐ Is there documentation of the specific needs that could not be met, the attempts the facility made to meet the resident's needs, and the specific services the new facility will provide to meet the resident's needs?

Discharge Critical Element Pathway

- ☐ If the resident went to a SNF, HHA, IRF, or LTCH, did the facility assist the resident and the resident representative in selecting a post-acute care provider by using data that includes, but is not limited to SNF, HHA, IRF, or LTCH available standardized patient assessment data, data on quality measures, and data on resource use to the extent the data is available that is relevant and applicable to the resident's goals of care and treatment preferences.
- ☐ If this was a facility-initiated discharge, was advance notice given (either 30 days or, as soon as practicable, depending on the reason for the discharge) to the resident, resident representative, and a copy to the ombudsman:
  - o Did the notice include all the required components (reason, effective date, location, appeal rights, Ombudsman, ID and MI info as needed) and was it presented in a manner that could be understood; and
  - o If changes were made to the notice, were recipients of the notice updated?
- ☐ Did the facility provide a discharge summary to the receiving provider, which includes all required components at F661?
- ☐ Does the discharge summary include a recapitulation of the resident's stay, a final summary of the resident's status, and reconciliation of all pre- and post-discharge medications? If not, describe what is missing.
- ☐ For residents discharged to the community, does the medical record have evidence that written discharge instructions were given to the resident and if applicable the resident representative?

Critical Element Decisions:

1) Did the facility:
   - o Involve the IDT, resident and/or resident representative in developing a discharge plan that reflects the resident's current discharge needs, goals, and treatment preferences while considering caregiver support;
   - o Document that the resident was asked about their interest in receiving information about returning to the community;
   - o Assist the resident and/or resident representatives in selecting a post-acute care provider if the resident went to another SNF (skilled nursing facility), NH (nursing home), HHA (home health agency), IRF (inpatient rehab facility), or LTCH (LTC hospital); and/or

   If No, cite F660

2) Did the facility:
   a. Develop a discharge summary which includes a recapitulation of the resident's stay, a final summary of the resident's status, and reconciliation of all pre- and post-discharge medications?
   b. Develop a post-discharge plan of care, including discharge instructions?

   If No, cite F661

Discharge Critical Element Pathway

3) Does the resident's discharge meet the requirements at 483.15(c)(1) (i.e., for the resident's welfare, the resident's needs could not be met in the facility, the resident no longer required services provided by the facility, the health or safety of the individuals in the facility was endangered, non-payment, or the facility no longer operates)?
If No, cite F622

4) Was required discharge information documented in the resident's record and communicated to the receiving facility?
If No, cite F622

5) If this was a facility-initiated discharge, was the resident and resident representative notified of the discharge in writing and in a manner they understood at least 30 days in advance of the discharge? Did the notice meet all requirements at 483.15(c)(3) through (6) and (c)(8)?
If No, cite F623

Other Tags, Care Areas (CA) and Tasks (Task) to Consider: Participate in Care Plan F553, Notification of Change F580, Professional Standards F658, Medically Related Social Services F745, Resident Records F842, QAA/QAPI (Task), Orientation for Transfer or Discharge F624.

Preadmission Screening and Resident Review Critical Element Pathway

Preadmission Screening and Resident Review Critical Element Pathway

Use this pathway for a resident who has or may have a serious Mental Disorder (MD), Intellectual Disability (ID) or a Related Condition to determine if facility practices are in place to identify residents with one of these conditions and to determine if Level I PASARR screening has been conducted and referrals have been made to the appropriate state-designated authority for Level II PASARR evaluation and determination.

Review the following to Guide Observations and Interviews:

- ☐ Review the most current comprehensive MDS and CAAs for Sections A – PASARR and conditions (A1500-A1580), I – Active Diagnoses - psychiatric/mood disorders (I5700-I6100), N – Medications (N0410), and O – Special Treatment/Proc/Prog – psychological therapy (O0400).
- ☐ Physician's orders (e.g., psychoactive medications).
- ☐ Pertinent diagnoses/conditions.
- ☐ Level I PASARR screening results and Level II PASARR evaluation and determination, if appropriate.

Resident, Representative, or Family Interview:

- ☐ Can you tell me about your current diagnosis/condition (e.g., MD, ID, or mood concerns)?
- ☐ Did you have this diagnosis/condition prior to your admission to this facility?
- ☐ Do you receive any specialized services to help with your mental health or disability concerns? If not, why not? If so, describe.
- ☐ What are they doing to address your mental health or disability concerns (e.g., behavior management plan, ID interventions, meds, level II recommended interventions)?

Staff Interviews (Nurses, DON, Social Worker):

- ☐ What is the facility's process for identifying residents with a possible MD, ID or a related condition prior to admission to the facility?
- ☐ How does the facility identify residents with newly evident or possible serious MD, ID or a related condition after admission to the facility?
- ☐ Who is responsible for making the referral to the appropriate state-designated authority when a resident is identified as having an evident or possible MD, ID or related condition?
- ☐ If a resident is identified as having newly-evident or possible MD, ID or a related condition after admission, what is the facility's process for referring the resident to the appropriate state-designated authority?
- ☐ If the resident was identified as having evident or possible MD, ID or a related condition, and a referral to the appropriate state-authority was not made, ask why.

Preadmission Screening and Resident Review Critical Element Pathway

Record Review:

- ☐ Did the resident have an MD, ID or related condition at the time of admission or was the condition identified after admission?
- ☐ Was a Level I screen for possible MD, ID or a related condition completed prior to admission OR if the resident was expected to be in the facility less than 30 days and remained in the facility more than 30 days (as allowed by the State) was a Level 1 screen performed?
- ☐ If the Level I screening process identified evident or possible MD, ID or a related condition, was a referral made to appropriate state-designated authority for Level II PASARR evaluation and determination?
- ☐ Review facility policies and procedures regarding Level I screening (e.g., the criteria that would require a Level II evaluation) and referral for Level II PASARR evaluation and determination.
- ☐ If a Level II evaluation should have been done but wasn't, what mental health or disability services are being provided (e.g., social service interactions or counseling)? [If concerns are identified, initiate the Behavior pathway.]
- ☐ Was there a "significant change" in the resident's condition (i.e., a decline in the resident's status that will not normally resolve itself without intervention by staff or by implementing standard disease-related clinical interventions, is not self-limiting, and impacts more than one area of health and requires IDT review, and/or revision of the care plan)?
- ☐ If yes, was a significant change in status assessment conducted within 14 days of determining the change was significant?
- ☐ If the significant change in status was related to a new or possible MD, ID or related condition, did the facility notify the state-designated mental health or ID authority timely?
- ☐ Did the facility incorporate the recommendations from the PASARR Level II determination and evaluation report into the resident's assessment and care plan?

Critical Elements Decisions:

1) Is there evidence of Level I pre-screening of the resident to determine if the newly admitted resident had or may have had a MD, ID or a related condition prior to admission to the facility?
   If No, cite F645
   NA, the resident entered the facility as an exception (an exempted hospital discharge), in accordance with the State PASARR process, and has been in the facility less than 30 days.

2) If pre-admission screening of residents expected to be in the facility 30 days or less is not performed, in accordance with the State PASARR process, and the presumed short-stay resident was not screened prior to admission to the facility and remained in the facility longer than 30 days, did the facility screen the resident to determine if the resident had or may have had an MD, ID or a related condition?
   If No, cite F645
   NA, Level I pre-screening of the resident was performed prior to admission to the facility or the resident was in the facility less than 30 days.

Preadmission Screening and Resident Review Critical Element Pathway

3) If the Level I pre-screening of the resident, either prior to admission or within 30 days, in accordance with the state PASARR process, identified that the resident had or may have had an MD, ID or related condition, did the facility refer the resident to the appropriate state-designated authority for Level II PASARR evaluation and determination?
If No, cite F645

4) For a resident who had a negative Level I pre-screen, who was later identified with newly evident or possible serious MD, ID or a related condition, did the facility refer the resident to the appropriate state-designated authority for Level II PASARR evaluation and determination?
If No, cite F644
NA, the resident was not later identified with newly evident or possible serious MD, ID or a related condition.

5) For a resident with a Level II, did the facility coordinate assessments with the PASARR program by incorporating the recommendations from the PASARR level II determination and the PASARR evaluation report into the resident's assessment, care planning, and transitions of care?
If No, cite F644
NA, the resident did not have a Level II.

6) If the resident's significant change in status was related to newly evident or possible MD, ID or related condition, did the facility notify the appropriate state-designated mental health or ID authority for a Level II evaluation as soon as the criteria indicative of a significant change in status was evident?
If No, cite F644
NA, the resident did not have a signicant change in status related to newly evident or possible MD, ID or related condition.

7) Did the facility notify the state mental health authority or state intellectual disability authority, as applicable, promptly after a significant change in the mental or physical condition of a resident who has a mental disorder or intellectual disability for a review?
If No, cite F646
NA, the resident did not have a signicant change in mental or physical condition.

8) For the newly admitted residents and if applicable based on the concern under investigation, did the facility develop and implement a baseline care plan within 48 hours of admission that included the minimum healthcare information necessary to properly care for the immediate needs of the resident? Did the resident and resident representative receive a written summary of the baseline care plan that he/she was able to understand?
If No, cite F655
NA, the resident did not have an admission since the previous survey OR the care or service was not necessary to be included in a baseline care plan.

Preadmission Screening and Resident Review Critical Element Pathway

9) If the condition or risks were present at the time of the required comprehensive assessment, did the facility comprehensively assess the resident's physical, mental, and psychosocial needs to identify the risks and/or to determine underlying causes, to the extent possible, and the impact upon the resident's function, mood, and cognition?
   If No, cite F636
   NA, condition/risks were identified after completion of the required comprehensive assessment and did not meet the criteria for a significant change MDS OR the resident was recently admitted and the comprehensive assessment was not yet required.

10) If there was a significant change in the resident's status, did the facility complete a significant change in status assessment within 14 days of determining the status change was significant?
   If No, cite F637
   NA, the initial comprehensive assessment had not yet been completed; therefore, a significant change in status assessment is not required OR the resident did not have a significant change in status.

11) Did staff who have the skills and qualifications to assess relevant care areas and who are knowledgeable about the resident's status, needs, strengths and areas of decline, accurately complete the resident assessment (i.e., comprehensive, quarterly, significant change in status)?
   If No, cite F641

12) Did the facility develop and implement a comprehensive person-centered care plan that includes measureable objectives and timeframes to meet the resident's medical, nursing, mental, and psychosocial needs and includes the resident's goals, desired outcomes, and preferences?
   If No, cite F656
   NA, the comprehensive assessment was not completed.

13) Did the facility reassess the effectiveness of the interventions and review and revise the resident's care plan (with input from the resident or resident representative, to the extent possible), if necessary, to meet the resident's needs?
   If No, cite F657
   NA, the comprehensive assessment was not completed OR the care plan was not developed OR the care plan did not have to be revised.

Other Tags, Care Areas (CA), and Tasks (Task) to Consider: QOL F675, Behavior and Emotional (CA), Social Services F745, Rehab and Restorative (CA), Rehab Services Qualified Staff F826, Qualification of Social Worker F850, Facility Assessment F838, Resident Record F842, QAA/QAPI (Task).

Behavioral and Emotional Critical Element Pathway

Behavioral and Emotional Status Critical Element Pathway

Use this pathway to determine if the facility is providing necessary behavioral, mental, and/or emotional health care and services to each resident. Similarly, the facility staff members must implement person-centered, non-pharmacological approaches to care to meet the individual needs of each resident. While there may be isolated situations where pharmacological intervention is required first, these situations do not negate the obligation of the facility to develop and implement non-pharmacological approaches. Refer to the Dementia Care pathway to determine if the facility is providing the necessary care and services necessary.

Review the Following in Advance to Guide Observations and Interviews:

- ☐ Review the most current comprehensive and most recent quarterly (if the comprehensive isn't the most recent) MDS/CAAs for Sections A – PASARR and Conditions (A1500 – A1580), C – Cognitive Patterns, D – Mood, E – Behavior, G – Functional Status, I – Active Diagnoses – Psychiatric/Mood Disorders (I5700 – I6100), N – Medications, and O – Special Treatment/Proc/Prog – Psychological Therapy (O0400D).
- ☐ Physician orders.
- ☐ Pertinent diagnoses.
- ☐ Care plan (e.g., states concerns related to a resident's expressions or indications of distress in behavioral and/or functional terms as they relate specifically to the resident, potential cause or risk factors for the resident's behavior or mood, person-centered non-pharmacological and pharmacological interventions to support the resident and lessen distress, if pharmacological interventions are in place how staff track, monitor, and assess the interventions, and alternative means if the resident declines treatment).

Observations Across Various Shifts:

- ☐ If the resident is exhibiting expressions or indications of distress (e.g., anxiety, striking out, self-isolating) how does staff address these indications?
- ☐ Are staff implementing care planned interventions to ensure the resident's behavioral health care and service needs are being met? If not, describe.
- ☐ Focus on staff interactions with residents who have a mental or psychosocial disorder to determine whether staff consistently apply accepted quality care principles.
- ☐ Is there sufficient, competent staff to ensure resident safety and meet the resident's behavioral health care needs?
- ☐ What non-pharmacological interventions (e.g., meaningful activities, music or art therapy, massage, aromatherapy, reminiscing, diversional activities, consistent caregiver assignments, adjusting the environment) does staff use and do these approaches to care reflect resident choices and preferences?
- ☐ How does staff monitor the effectiveness of the resident's care plan interventions?
- ☐ How does staff demonstrate their knowledge of the resident's current behavioral and emotional needs? Does staff demonstrate competent interactions when addressing the resident's behavioral health care needs?
- ☐ Is the resident's distress caused by facility practices which do not accommodate resident preferences (e.g., ADL care, daily routines, activities, etc.)?

Behavioral and Emotional Status Critical Element Pathway

Resident, Family and/or Resident Representative Interview:

- ☐ Awareness of current conditions or history of conditions or diagnoses.
- ☐ How does the facility involve you/the resident in the development of the care plan, including implementation of non-pharmacological interventions and goals?
- ☐ How does the facility ensure approaches to care reflect your/the resident's choices and preferences?
- ☐ How effective have the interventions been? If not effective, what type of alternative approaches has the facility tried?
- ☐ How are the resident's individual needs being met through person-centered approaches to care?
- ☐ What are your or the resident's concerns, if any, regarding the resident's mood?
- ☐ Have you or the resident had a change in mood? If so, please describe.
- ☐ What interventions is the resident receiving for the resident's mood? Are the interventions effective? If not, describe.
- ☐ What other non-pharmacological approaches to care are used to help with the resident's mood? Are they effective? If not, describe.

Staff Interviews (Interdisciplinary team (IDT) members) across Various Shifts:

- ☐ What are the underlying causes of the resident's behavioral expressions or indications of distress, specifically included in the care plan?
- ☐ What specific approaches to care, both non-pharmacological and pharmacological, have been developed and implemented to support the behavioral health needs of the resident, including facility-specific guidelines/protocols? What is the rational for each intervention?
- ☐ How are the interventions monitored?
- ☐ How do you ensure care is provided that is consistent with the care plan?
- ☐ How, what, when, and to whom do you report changes in condition?
- ☐ What types of behavioral health training have you completed?
- ☐ Ask about any other related concerns the surveyor has identified.
- ☐ How do you monitor for the implementation of the care plan and changes in the resident's condition?
- ☐ How are changes in both the care plan and condition communicated to the staff?
- ☐ How often does the IDT meet to discuss the resident's behavioral expressions or indications of distress, the effectiveness of interventions, and changes in the resident's condition?

Note: If care plan concerns are noted, interview staff responsible for care plan development to determine the rationale for the current care plan.

Behavioral and Emotional Status Critical Element Pathway

Record Review:

- ☐ Review therapy notes and other progress notes that may have information regarding the assessment of expressions or indications of distress, mental or psychosocial needs, and resident responsiveness to care approaches.
- ☐ Determine whether the assessment information accurately and comprehensively reflects the condition of the resident.
- ☐ What is the time, duration, and severity of the resident's expressions or indications of distress?
- ☐ What are the underlying causes, risks, and potential triggers for the resident's expressions or indications of distress, such as decline in cognitive functioning, the result of an illness or injury, or prolonged environmental factors (e.g., noise, bright lights, etc.)?
- ☐ What non-pharmacological approaches to care are used to support the resident and lessen their distress?
- ☐ What PASARR Level II services or psychosocial services are provided, as applicable?
- ☐ Does the facility ensure residents with substance use disorders have access to counseling programs (e.g., 12 step groups)?
- ☐ Is the care plan comprehensive? Is it consistent with the resident's specific conditions, risks, needs, expressions or indications of distress and includes measurable goals and timetables? How did the resident respond to care-planned interventions? If interventions were ineffective, was the care plan revised and were these actions documented in the resident's medical record?
- ☐ Was there a "significant change" in the resident's condition (i.e., will not resolve itself without intervention by staff or by implementing standard disease-related clinical interventions; impacts more than one area of health; requires IDT review or revision of the care plan)? If so, was a significant change comprehensive assessment conducted within 14 days?
- ☐ Was behavioral health training provided to staff?

Critical Element Decisions:

1) Did the facility provide the necessary behavioral health care and services to attain or maintain the highest practical physical, mental, and psychosocial well-being in accordance with the comprehensive assessment and plan of care?
If No, cite F740

2) Does the facility have sufficient and competent direct care staff to provide nursing and related services and implement non-pharmacological interventions to meet the behavioral health care needs of the resident, as determined by resident assessments, care plans, and facility assessment?
If No, cite F741

Behavioral and Emotional Status Critical Element Pathway

3) Did the facility provide appropriate treatment and services to correct the assessed problem for a resident who displays or is diagnosed with a mental disorder or psychosocial adjustment difficulty, or who has a history of trauma and/or post-traumatic stress disorder (PTSD)?

   If No, cite F742

   NA, the resident does not display or is not diagnosed with a mental or psychosocial adjustment difficulty, or does not have a history of trauma and/or PTSD.

4) Did the facility ensure that the resident whose assessment did not reveal or who does not have a diagnosis of a mental or psychosocial adjustment difficulty, or a documented history of trauma and/or PTSD does not display a pattern of decreased social interaction and/or increased withdrawal, anger, or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern is unavoidable?

   If No, cite F743

   NA, the resident's assessment revealed or the resident has a diagnosis of a mental disorder or psychosocial adjustment difficulty, or a documented history of trauma and/or PTSD.

5) For newly admitted residents and if applicable based on the concern under investigation, did the facility develop and implement a baseline care plan within 48 hours of admission that included the minimum healthcare information necessary to properly care for the immediate needs of the resident? Did the resident and resident representative receive a written summary of the baseline care plan that he/she was able to understand?

   If No, cite F655

   NA, the resident did not have an admission since the previous survey OR the care or service was not necessary to be included in a baseline care plan.

6) If the condition or risks were present at the time of the required comprehensive assessment, did the facility comprehensively assess the resident's physical, mental, and psychosocial needs to identify the risks and/or to determine underlying causes, to the extent possible, and the impact upon the resident's function, mood, and cognition?

   If No, cite F636

   NA, condition/risks were identified after completion of the required comprehensive assessment and did not meet the criteria for a significant change MDS OR the resident was recently admitted and the comprehensive assessment was not yet required.

7) If there was a significant change in the resident's status, did the facility complete a significant change assessment within 14 days of determining the status change was significant?

   If No, cite F637

   NA, the initial comprehensive assessment had not yet been completed; therefore, a significant change in status assessment is not required OR the resident did not have a significant change in status.

Behavioral and Emotional Status Critical Element Pathway

8) Did staff who have the skills and qualifications to assess relevant care areas and who are knowledgeable about the resident's status, needs, strengths, and areas of decline accurately complete the resident assessment (i.e., comprehensive, quarterly, significant change in status)?
If No, cite F641

9) Did the facility develop and implement a comprehensive person-centered care plan that includes measureable objectives and timeframes to meet the resident's medical, nursing, mental, and psychosocial needs and includes the resident's goals, desired outcomes, and preferences?
If No, cite F656
NA, the comprehensive assessment was not completed.

10) Did the facility reassess the effectiveness of the interventions and, review and revise the resident's care plan (with input from the resident, or resident representative, to the extent possible), if necessary to meet the resident's needs?
If No, cite F657
NA, the comprehensive assessment was not completed OR the care plan was not developed OR the care plan did not have to be revised.

Other Tags, Care Areas (CA), and Tasks (Task) to Consider: Resident Rights F550, Abuse (CA), Admission Orders F635, Professional Standards F658, Qualified Staff F659, PASARR (CA), Sufficient and Competent Staff (Task), Social Services F745, Unnecessary/Psychotropic Medications (CA), Resident Records F842.

Abuse Critical Element Pathway

Abuse Critical Element Pathway

Use this pathway for investigating an alleged violation of abuse to a resident. This would include allegations where a resident was deprived of goods or services by an individual, necessary to attain or maintain physical, mental and psychosocial well-being. If photographic documentation is obtained during the survey, refer to S&C-06-33. In addition, for investigating other concerns:

- Refer to the Investigative Protocol found at F603 for concerns related to involuntary seclusion;
- Refer to the Neglect CE Pathway to investigate concerns about structures or processes leading to a resident(s) with an outcome, for example, unrelieved pain, avoidable pressure ulcers/injuries, poor grooming, avoidable dehydration, lack of continence care, or malnourishment; or
- Refer to the Investigative Protocol for F608-Reporting Reasonable Suspicion of a Crime, if a covered individual did not report a reasonable suspicion of a crime or for an allegation of retaliation.

NOTE: If you witness an act of abuse or receive an unreported allegation of abuse, you must immediately report it to the facility administrator, or his/her designated representative if the administrator is not present. The survey team would then determine whether the facility takes appropriate action in accordance with the requirements at F608, F609 and F610, including implementing safeguards to prevent further potential abuse. If you witness an act of abuse, you must document who committed the abusive act, the nature of the abuse, where and when it occurred, and potential witnesses.

Review the following in Advance to Guide Observations and Interviews:

☐ Information related to an alleged violation of abuse, such as:

- Date, time, and location (e.g., unit, room, floor) where alleged abuse occurred;
- Name of alleged victim(s), alleged perpetrator(s) and witnesses, if any;
- Narrative/specifics of the alleged abuse(s) including frequency and pervasiveness of the allegation; and
- Whether the allegation was reported by the facility and/or to other agencies, such as Adult Protective Services or law enforcement.

☐ Sources for this information may include:

- Resident, representative, or family interviews, observations or record review;
- Reports from the long-term care ombudsman or other State Agencies;
- Deficiencies related to abuse (CASPER 3 Report); and
- Complaints and facility-reported allegations of abuse, including any facility investigation reports, received since the last standard survey.

☐ Facility's abuse prohibition policies and procedures provided during the Entrance Conference (review only those components necessary during the investigation to determine if staff are implementing the policies as written). Refer to F607.

Abuse Critical Element Pathway

Observation across Various Shifts:. Request staff assistance to make observations, as needed. Only if you are a licensed nurse or practitioner can you observe the resident's private areas.

- ☐ Observe whether the alleged perpetrator (staff, other resident, or visitor) is present in the facility. What access does the alleged perpetrator have to the alleged victim and other residents?
- ☐ Describe the alleged victim's reaction, if any, when the alleged perpetrator, or a specific resident(s) or staff person(s) is present:
  - o Avoids or withdraws from conversations or activities;
  - o Displays fear of, or shies away from being touched; and/or
  - o Exhibits behaviors such as angry outbursts, tearfulness, or stress (agitation, trembling, cowering)?
- ☐ Describe physical injuries, if any, related to the alleged abuse, such as:
  - o Fractures, sprains or dislocations;
  - o Burns, blisters, or scalds;
  - o Bite marks, scratches, skin tears, and lacerations with or without bleeding, including those that would be unlikely to result from an accident;
  - o Bruises, including those forming shapes (e.g., finger imprints) or found in unusual locations such as the head, neck, lateral locations on the arms, posterior torso and trunk, inner thigh, genital area and/or breasts; and/or
  - o Facial injuries, including but not limited to, broken or missing teeth, facial fractures, black eye(s), bruising, bleeding or swelling of the mouth or cheeks.
- ☐ Observe and describe:
  - o If the alleged perpetrator is a resident, whether he/she displays symptoms, such as
    - ▪ Verbally aggressive behavior, such as screaming, cursing, bossing around/demanding, insulting to race or ethnic group, intimidating;
    - ▪ Physically aggressive behavior, such as hitting, kicking, grabbing, scratching, pushing/shoving, biting, spitting, threatening gestures, throwing objects;
    - ▪ Sexually aggressive behavior such as saying sexual things, inappropriate touching/grabbing;
    - ▪ Taking, touching, or rummaging through other's property;
    - ▪ Wandering into other's rooms/space; or
    - ▪ Resistive to care and services.
  - o If the alleged perpetrator is staff, whether he/she displays rough handling of residents, appears rushed, dismisses requests for assistance, expresses anxiety, or frustration regarding work and lack of staffing.
- ☐ Observe for possible environmental factors related to the alleged abuse, such as:
  - o If in a resident's room, the room configuration, presence of privacy curtains, and the availability of a working call light/call bell;
  - o Lighting levels; or
  - o Location in relation to the nurse's station, staff lounges, or outside access such as windows, doors, or hallways.
- ☐ For an allegation that a resident was deprived of goods or services by staff, observe for physical/psychosocial outcomes related to care deficits.

Abuse Critical Element Pathway

Interviews: Be impartial, use discretion, and non-judgmental language. Use an interpreter as needed to obtain as accurate information as possible. Attempt to interview the alleged victim and witnesses as soon as possible.

Alleged Victim or Representative and Witness(es) Interview: Conduct private interviews unless the alleged victim requests the presence of another person. Observe the alleged victim's emotions and tone, as well as any nonverbal expressions or gesturing to a particular body area, in response to the questions. Maintain the confidentiality of witnesses and the person who reported the allegation (e.g., change the order of the interviews, location or time), to the extent possible. During the interview with the witnesses, the surveyor may ask him/her to re-create or re-enact the alleged incident, to better understand the sequence of events.

☐ For the **alleged victim/resident representative/witness**, ask, as applicable:

- What occurred prior to, during, and immediately following the alleged abuse?
- When and where did the alleged abuse occur?
- Could he/she identify the alleged perpetrator and any witnesses? Who?
- What was said? What was the tone of the alleged perpetrator's voice or volume?
- Did you report the alleged abuse? Who did you report it to? What was their response? If not reported, what prevented you from reporting the alleged abuse?
- Did you report the alleged abuse to any external entities (e.g., police, physician, ombudsman, and other state agencies)? Who did you report it to? What was their response?
- Do you think retaliation has occurred since you reported the alleged abuse? If so, what actions were taken?

☐ For the **alleged victim/resident representative**, document as applicable:

- Did you suffer any injuries (e.g., bruises, cuts, fractures) from the alleged abuse? Please describe, including the alleged victim's response to the injuries (e.g., pain, new difficulty sitting or walking).
- Did you go to the hospital or physician's clinic for evaluation and treatment? When and which facility?
- Do you feel safe?
- Have there been past encounters with the alleged perpetrator?
- Have there been past instances of abuse?

☐ For the **resident's representative**, ask, as applicable:

- Have you observed any changes in the alleged victim's behavior, and if so, describe?

☐ For an **allegation that a resident was deprived of goods or services by staff, for the alleged victim/resident representative**, ask, as applicable:

- How do staff respond to your requests for assistance? If staff do not respond, what happens?
- Do you have any concerns about the manner in which care is provided to you? If so, describe. Did you report this to anyone? If so, to whom, when, and what was the response?
- Do you feel that you have had any negative changes (e.g., weight loss, pressure ulcers) because of the failure to receive the care that you need?
- Have you had any changes in medication (e.g., antipsychotics) that may be impacting the care you receive?

Abuse Critical Element Pathway

Alleged Perpetrator Interview: If the alleged perpetrator is a staff member, the staff member may have been suspended or re-assigned until the facility's investigation is completed and in some situations, the facility may have terminated the employment of the individual. In some cases the alleged perpetrator may not be in the facility or may refuse to be interviewed. If possible, interview the alleged perpetrator in person or by phone even if the alleged perpetrator is no longer working in the facility. In addition, the alleged perpetrator may be a resident or visitor. Interview the alleged perpetrator to determine the following, to the extent possible, and include information regarding inability, if any, to conduct the interview:

- ☐ What information can you provide regarding the alleged abuse?
- ☐ Were you present in the facility at the time of the alleged abuse? If so, where were you at?
- ☐ What is your relationship, if any, to the alleged victim?
- ☐ For an allegation that a resident was **deprived of goods or services**, ask the staff member:
  - How do you respond to the resident's requests for assistance;
  - Have you had any concerns when you have been assigned to this resident? If so, describe. Did you report this to anyone? If so, to whom, when, and what was the response?
  - Have you noticed any negative changes (e.g., weight loss, pressure ulcers) with this resident? If so, describe; and
  - Has the resident had any behavioral symptoms (e.g. combative behavior, frequent requests for assistance, calling out, grabbing) that may be impacting the care that they receive? If so, have you reported this? If reported, to whom, when, and what was the response?
- ☐ If the **alleged perpetrator is a staff member**:
  - What is your position?
  - Describe any contact that you have with the alleged victim.
  - Do you continue to have access to the alleged victim? If not, why?
  - How long have you worked in the facility?
  - What type of orientation, training, work assignments, and supervision did you receive?
  - What training have you received related to abuse prevention, reporting abuse, and the facility's abuse policy and procedures?
- ☐ Do you have any other information you wish to share in regard to the investigation?

Abuse Critical Element Pathway

Staff Interviews: Interview the most appropriate direct care staff member. Review staff schedules from all departments to determine who was working at the time of the alleged abuse and who may have had contact with the alleged perpetrator or alleged victim. Interview the most appropriate direct care staff member:

- ☐ Did you have knowledge of the alleged abuse? If so, describe.
- ☐ What actions, if any, did you take in response to the allegation?
- ☐ If you're familiar with the alleged victim, have you noticed any changes in the alleged victim's behavior as a result of the alleged abuse? If so, describe.
- ☐ How did the alleged perpetrator and victim act towards one another prior to and after the incident?
- ☐ Did the alleged perpetrator and/or victim exhibit any behaviors that would provoke one another? If so, what actions were taken to address this?
- ☐ If the alleged perpetrator was staff, had the alleged perpetrator exhibited inappropriate behaviors to the alleged victim or other residents in the past, such as using derogatory language, rough handling, or ignoring residents while giving care?
- ☐ If the alleged perpetrator was a visitor, did the visitor exhibit any inappropriate behaviors in the past or have any indication of risk to the resident(s)?
- ☐ Did you report the alleged abuse to any supervisors/administration? Who did you report it to? What was their response?
  - o If reported, do you think retaliation has occurred since you reported the alleged abuse? If so, describe. Do you fear retaliation?
  - o If not reported, what prevented you from reporting the alleged abuse?
- ☐ Did you report the alleged abuse to any external entities (e.g., police, physician, ombudsman, and other state agencies)? Who did you report it to? What was their response?
- ☐ Have you received training on abuse identification, prevention, and reporting requirements?
- ☐ For an allegation that a resident was **deprived of goods or services** by staff, ask:
  - o How do staff respond to the resident's requests for assistance? If staff do not respond, what do they say;
  - o Do you have any concerns about the manner in which care is provided to the resident? If yes, describe. Did you report this to anyone? If so, to whom, when, and what was the response;
  - o Has the resident had any negative changes (e.g., weight loss, pressure ulcers) because of the failure to receive the care that he/she needs;
  - o Has the resident had any changes in medication (e.g., antipsychotics) that may be impacting the care that they receive? Note: Determine if the resident may have received unnecessary medications such as chemical restraints.

Abuse Critical Element Pathway

Other Healthcare Professionals (DON, Social Worker, Attending Practitioner) Interviews, as Appropriate Ask the appropriate personnel:

- ☐ Do you have knowledge of the alleged abuse? If so, describe.
- ☐ When and by whom were you notified of the alleged abuse?
- ☐ Did you conduct an assessment of the alleged victim for potential injuries or a change in mental status? What interventions or treatment (e.g., counseling) were provided, if any?
- ☐ Was the alleged victim assessed and/or treated at a hospital after the alleged incident? NOTE: Attempt to interview the practitioner from the hospital who examined the alleged victim to determine physical findings and mental status at the time.
- ☐ Do you know if the alleged victim's representative and attending practitioner were notified of the alleged abuse? If so, when and what were the responses?
- ☐ If there are discrepancies in injuries based on the alleged victim's description, how was this investigated?
- ☐ Did the alleged perpetrator and/or victim exhibit any behaviors that would provoke one another? If so, what actions were taken to address this?
- ☐ Did you report the alleged abuse to administration? Who did you report it to? What was their response? If not reported, what prevented you from reporting the alleged abuse? Did you report the alleged abuse to anyone else (e.g., resident representative, attending practitioner)?
- ☐ Were any external entities (e.g., APS or law enforcement) contacted? If so, who made the report, to whom, and when?
- ☐ If the **alleged perpetrator was a resident**:
  - Did you conduct any interviews related to the alleged abuse and identify the circumstances of what occurred prior to, during and after the alleged abuse?
  - Does the care plan identify interventions to address any behaviors of the alleged perpetrator?
  - Was the care plan implemented?
- ☐ If the **alleged perpetrator is a visitor**:
  - Was there any indication of a prior history of abuse, aggression, or other inappropriate behaviors?
  - Was there any indication of a physical or psychosocial change in the alleged victim after a visit with the alleged perpetrator, whether onsite or outside of the facility?
  - Did you interview the alleged perpetrator and identify the circumstances of what occurred prior to, during and after the alleged abuse? If so, describe?
  - Were visits from the alleged perpetrator supervised? When and where did visits usually occur?
  - Is access to the alleged victim currently allowed? If so, under what circumstances?
  - What protections have been put in place (e.g., supervision of visits while the investigation is being conducted); and/or
  - Has access to other residents been limited? If so, how?
- ☐ For an allegation that a resident was **deprived of goods or services** by staff, ask:
  - Have you noticed any negative changes (e.g., weight loss, pressure ulcers) with this resident? If so, please describe.
  - How do staff respond to the resident's requests for assistance? If staff do not respond, what do they say;
  - Do you have any concerns about the manner in which care is provided to the resident? If yes, describe. Has staff report this concern to you? If so, when and what did you do;
  - Has the resident had any behavioral symptoms (e.g., combative behavior, frequent requests for assistance, calling out, grabbing) that may be impacting care they receive? If so, did staff report this to you? If reported, when and what was your response;
  - Has the resident had any changes in medication (e.g., antipsychotics) that may be impacting the care that they receive? Note: Determine if the resident may have received unnecessary medications such as chemical restraints; and/or

Abuse Critical Element Pathway

- If the interventions were not effective in reducing the behaviors, were they revised and if so, what was changed?
- Did the revised interventions provide the needed protections?
- What protections have been put in place at this time?
- Has access to other residents at risk been limited? If so, how?

☐ If the **alleged perpetrator was staff**, ask:

- Did the alleged perpetrator exhibited inappropriate behaviors to the alleged victim or other residents in the past (e.g., using derogatory language, rough handling, or ignoring residents while giving care)? If yes, describe.
- Was there a history of resident/family grievances or problems identified with care delivery or services provided? If so, what was the result of the investigation of the concerns, and describe any disciplinary actions and/or training provided related to the complaints/concerns.
- Did annual performance reviews identify issues with the provision of care, treatment, or other concerns? If so, what was provided to address the concerns.
- How is monitoring and supervision provided regarding the delivery of care and services by the alleged perpetrator?
- Who is responsible for supervising and monitoring the delivery of care at the bedside?

Facility Investigator Interview: If the facility investigated the alleged abuse, interview the staff member responsible for the initial reporting and the overall investigation of the alleged abuse. For some facilities, the Administrator may be the Facility Investigator.

☐ When (date and time) were you notified of the alleged abuse and by whom?

☐ What information was reported to you related to the alleged abuse?

☐ When and what actions were taken to protect the alleged victim from further abuse while the investigation was in process?

☐ Describe medical interventions, if any, taken in relation to the alleged abuse, (e.g., hospitalization, transfer to ER, onsite visit by attending practitioner).

☐ What steps were taken to investigate the allegation? Can you provide me a timeline of events that occurred?

☐ Describe interviews conducted, such with the alleged victim/resident representative, witnesses, alleged perpetrator, and practitioner and what information was obtained.

☐ Describe record reviews conducted related to the alleged abuse and what information was obtained.

☐ Were there any photographs or videos obtained related to the alleged abuse? If yes, describe.

☐ When and who received results of the investigation?

Abuse Critical Element Pathway

- ☐ Describe any mental assessments that were conducted pertaining the alleged abuse, and any interventions taken to assist the resident (e.g., counseling).
- ☐ If the allegation relates to sexual abuse, describe the immediate actions of the staff, including preserving evidence, providing medical intervention (e.g., transfer to hospital for sexual assault for rape kit), conducting a physical assessment, and reporting.
- ☐ Who did you notify and when (date/time) of the alleged abuse? Was an outside entity informed about the alleged abuse, and if so, when (date and time)? NOTE: If a suspected crime, note the date and time reported. Obtain copies of the outside entities investigations, if available.
- ☐ What actions were taken as a result of the investigation (e.g., for the alleged victim, the alleged perpetrator, other staff, training, policy revisions)?
- ☐ Is there any related information regarding the allegation that may not be included in the investigation report?

Administrator Interview:

- ☐ When (date and time) were you notified of the allegation and by whom?
- ☐ When (date and time) was the initial report reported to required agencies and law enforcement, as applicable?
- ☐ Who was/is responsible for the investigation? Is the investigation completed or ongoing? If completed, what was the outcome? (if the administrator is the facility investigator, use the questions above to determine how the investigation was conducted.)
- ☐ When (date and time)were the results of the investigation reported to you and to the required agencies?
- ☐ When and what actions were taken to protect the alleged victim and residents at risk from further abuse while the investigation was in process?
- ☐ What happened as a result of the investigation?
- ☐ How do you monitor for potential or actual reported allegations of abuse?
- ☐ If the alleged perpetrator is an employee, were there previous warnings or incidents at the facility? If the alleged abuse was verified, describe actions that were taken.
- ☐ How do you assure retaliation does not occur when staff or a resident reports an allegation of abuse?
- ☐ For an allegation that a resident was **deprived of goods or services**, ask:
  - o Have staff reported any concerns to you about the manner in which care is provided to the resident? If yes, when, what did they report, and what did you do; and
  - o Who is responsible for supervising and monitoring the delivery of care at the bedside?

QAA Responsible Person Interview:

- ☐ How do you monitor reported allegations of abuse?
- ☐ When did the QAA Committee receive the results of the investigation for the allegation of abuse?
- ☐ Did the QAA Committee make any recommendations based on the results of the investigation, such as policy revisions or training to prevent abuse?

Abuse Critical Element Pathway

Review the Alleged Victim's Record:

- ☐ Was the alleged victim was assessed at risk for abuse (e.g., as indicated in the RAI, care plan, progress notes from nurses, social services, practitioners)? If so, how did the facility implement interventions to mitigate risks?
- ☐ When (date/time) did the allegation occur? When was it discovered and by whom?
- ☐ When was the resident's representative, practitioner and other required entities notified?
- ☐ Were physical injuries noted related to the alleged abuse?
- ☐ Are there changes in the alleged victim's mood or demeanor before and after the alleged abuse (e.g., distrust, fear, angry outburst, cowering, tearfulness, agitation, panic attacks, withdrawal, difficulty sleeping, and PTSD symptoms)?
- ☐ Are there potential indicators of sexual abuse (e.g., STD, vaginal or anal bleeding, pain or irritation in genital area, bruising/lacerations on breasts or inner thighs, or recent difficulty with sitting or walking)?
- ☐ Was the resident assessed and the care plan revised as needed? What interventions (e.g., first aid, hospitalization) occurred to address any physical injuries or changes in mental status? (Note: If the resident required medical treatment, you may need to contact the hospital and/or practitioner to obtain related medical records for review.)
- ☐ For an allegation that a resident was **deprived of goods or service**:
  - Does the record reflect any negative changes (e.g., weight loss, pressure ulcers);
  - Has the alleged victim had any behavioral symptoms (e.g., combative behavior, frequent requests for assistance, calling out, grabbing) that may be impacting the care that they receive? If so, describe; and/or
  - Determine if the alleged victim may have received unnecessary medications such as chemical restraints and if this impacted the care received.

Review the Alleged Perpetrator's Record, if a Resident:

- ☐ What circumstances are documented (date/time) before, during and after the alleged abuse?
- ☐ Is there a previous history of exhibiting any behaviors that would provoke others? If so: Does the care plan address behaviors, if any, of the alleged perpetrator, and include interventions (e.g., monitoring, staff supervision, redirection?
  - Were care plan interventions implemented?
  - If the interventions were not effective in reducing the behaviors, were they revised and if so, what was changed?
- ☐ After the alleged abuse, did staff separate the alleged victim and other residents at risk?
- ☐ What are the plans to monitor and supervise the resident?
- ☐ If interventions were unsuccessful, was the physician notified? Were new interventions implemented?

- Did the revised interventions provide the needed protections?
- What protections are currently in place?
- Does the alleged perpetrator have limited access to other residents at risk? If so, how?

Review the Alleged Perpetrator's Personnel File, if Staff:

- ☐ Is there any information related to the alleged abuse? If so, describe.
- ☐ Is there a history of other allegations?
- ☐ Were adverse personnel actions taken? If so, describe.
- ☐ Is there information related to any finding of abuse/neglect/exploitation/misappropriation of property/mistreatment?
- ☐ If a nurse aide:
  - Was training and orientation provided related to dementia management, abuse and neglect prevention?
  - Were annual performance reviews conducted? Was there a history of competency concerns? If so, what disciplinary actions and/or training was provided related to performance deficits?

Investigative Report from Other Investigatory Agencies (APS, Professional Licensing Boards, Law Enforcement):

- ☐ Review a copy of the report if another investigatory agency (e.g., APS, Professional Licensing Board, and Law Enforcement) conducted an investigation.
- ☐ What did the other investigatory agency find? Note: deficient practice is not determined based on another agency's investigation.

Critical Element Decisions:

1) Did the facility protect a resident's right to be free from any type of abuse that results in, or has the likelihood to result in physical harm, pain, or mental anguish?
   If No, cite F600

2) Did the facility hire or engage staff who have:
   - Not been found guilty of abuse, neglect, exploitation, misappropriation of property, or mistreatment by a court of law?
   - Not had a finding entered into the State nurse aide registry concerning abuse, neglect, exploitation, mistreatment of residents, or misappropriation of resident property?
   - Not had a disciplinary action taken by a state professional licensure body as a result of a finding of abuse, neglect, exploitation, mistreatment of residents, or misappropriation of resident property?
   - Not had a successful appeal of their disqualification from employment?

AND/OR

Did the facility report to the State nurse aide registry or licensing authorities any knowledge of actions taken by a court of law that would indicate unfitness as a staff member of a nursing home?
If No, cite F606
NA, the alleged perpetrator was not staff

3) Did the facility develop and implement written policies and procedures that prohibit and prevent abuse, establish policies and procedures to investigate any such allegations, and include training as required at paragraph §483.95?
If No, cite F607

4) Did the facility develop, implement, and maintain an effective training program for all new and existing staff that includes training on activities that constitute abuse; procedures for reporting incidents of abuse; and dementia management and resident abuse prevention?
If No, cite F943

5) Does the facility's in-service training for nurse aides include resident abuse prevention?
If No, cite F947

6) Did the facility develop and implement written policies and procedures to ensure reporting of suspected crimes within mandated timeframes, annual notification of covered individuals of reporting obligations, posting of signage stating employee rights related to retaliation against the employee for reporting a suspected crime, and prohibition and prevention of retaliation?
If No, cite F608

7) For alleged violations of abuse, did the facility:
   - Identify the situation as an alleged violation involving abuse, including injuries of unknown source?
   - Immediately report the allegation to the administrator and to other officials, including to the State survey and certification agency, and APS in accordance with State law?
   - Report the results of all investigations within five working days to the administrator or his/her designated representative and to other officials in accordance with State law (including to the State survey and certification agency)?

   If No to any of the above, cite F609

8) For alleged violations of abuse, did the facility:
   - Prevent further potential abuse while the investigation is in progress?
   - Initiate and complete a thorough investigation of the alleged violation?
   - Maintain documentation that the alleged violation was thoroughly investigated?

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- Take corrective action following the investigation, if the allegation is verified?

If No to any of the above, cite F610

Other Tags, Care Areas (CA), and Tasks (Task) to Consider: Dignity (CA), Visitors F563/F564, Notice of Rights and Rules F572, Privacy (CA), Grievances F585, Reporting Reasonable Suspicion of a Crime F608, Accidents (CA), Social Services F745, Behavioral-Emotional Status (CA), Sufficient and Competent Staffing (Task), QAA/QAPI (Task).

Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

Use for a resident who has potentially unnecessary medications, is prescribed psychotropic medications or has the potential for an adverse outcome to determine whether facility practices are in place to identify, evaluate, and intervene for potential or actual unnecessary medications. Use also to evaluate the medication regimen review (MRR) process.

NOTE: If the resident has a diagnosis of dementia and is receiving any psychotropic medications (including but not limited to antipsychotic medications) the surveyor should refer to the Dementia Care Critical Element Pathway as a guide to determine the facility's compliance at F744.

Review the Following in Advance to Guide Observations and Interviews:

☐ Review the most current comprehensive and most recent quarterly (if the comprehensive isn't the most recent assessment) MDS/CAAs for areas pertinent to the medications ordered such as adverse consequences and behaviors.

☐ Review all medications currently ordered or discontinued going back to the most recent signed recapitulation. Determine if the facility:

✓ **Documents an acceptable clinical indication for use.**
- Medication is prescribed for a diagnosed condition and not being used for convenience or discipline.
- Medication is clinically indicated to manage a resident's symptoms or condition where other causes have been ruled out.
- 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.
- Intended or actual benefit is sufficient to justify the potential risk(s) or adverse consequences associated with the medication, dose, and duration.

✓ **Demonstrates use of written protocols or resources to guide antibiotic use.**
- The use of infection assessment tools for antibiotic use for one or more infections (e.g., use of a Situation, Background, Assessment and Recommendation (SBAR) communication tool for UTI assessment, application of the Loeb minimum criteria for initiation of antibiotics).

✓ **Demonstrates monitoring for each medication as appropriate.**
- The following medications pose a high risk for adverse consequences and should be monitored:
  - **Opioids** – assess pain, implement bowel program.
  - **Anticoagulant** – bleeding/bruising, protime/international normalized ratio (PT/INR), interaction with other medications, facility must have policies around monitoring, lab work, communication of lab values, implementation of new orders in response to lab values and/or symptoms.
  - **Diuretics** – edema, potassium level, signs of electrolyte imbalance.
  - **Insulin** – monitoring of blood glucose levels, hemoglobin A1c (HbA1c), and symptoms of hyper/hypoglycemia.
  - **Antibiotics** – interactions with other medications (e.g., warfarin), adverse events (e.g., rash, diarrhea); prescriptions must include documentation of indication, dose, route and duration and be reviewed 2-3 days after antibiotic initiation to assess response and labs, and prescriber should reassess antibiotic selection as appropriate.

- **All psychotropics** – monitor behavioral expressions or indications of distress.
- Facility staff, along with the pharmacist and prescribing practitioner recognize and evaluate the onset or worsening of signs or symptoms, or a change in condition to determine whether these potentially may be related to the medication regimen; and follow up as necessary upon identifying adverse consequences.
- Facility staff monitor the effectiveness of each medication and make changes to the pharmacological intervention, when necessary.

✓ **Demonstrates appropriate dosing for each medication.**
- Is there documentation of a rationale for any medication that exceeds the manufacturer's recommendations, clinical practice guidelines, evidence based guidelines or standards of practice?

✓ **Documents duration for each medication.**
- Medications are not used for an excessive duration.

✓ **Documents clinical rationale for continued use for the medications, as required.**
- Tapering when clinically indicated in an effort to discontinue or reduce the dose.
- Concomitant use of two or more medications in the same pharmacological class.
- Potential incompatibilities between medications.

✓ **Demonstrates a system that monitors and addresses the presence of or potential for adverse consequences.**
- A clear clinical rationale from the attending physician/prescribing practitioner for continuing a medication that may be causing an adverse consequence, including risks and benefits.

✓ **Demonstrates a system for and documents gradual dose reduction (GDR) for psychotropic medications, unless contraindicated.**
- Within the first year in which a resident is admitted on a psychotropic medication or after the facility has initiated a psychotropic medication:
  - GDR attempts in two separate quarters with at least one month between the attempts.
  - The GDR must be attempted annually thereafter unless clinically contraindicated.
  - Non-pharmacological approaches must be attempted and documented instead of using psychotropic medications, along with use of psychotropic medications, and while GDR is attempted.

✓ **Demonstrates adherence to requirements for as needed (PRN) psychotropic and antipsychotic medications.**
- Residents do not receive PRN psychotropic medications unless necessary to treat a diagnosed specific condition which must be documented in the record.
- PRN orders for psychotropic medications which **are not** antipsychotic medications are limited to 14 days. The attending physician/prescriber may extend the order beyond 14 days if he or she believes it is appropriate. If the attending physician extends the PRN for the psychotropic medication, the medical record must contain a documented rationale and determined duration.
- PRN orders for psychotropic medications which **are** antipsychotic medications are limited to 14 days. A PRN order for an antipsychotic cannot be renewed unless the attending physician/prescriber evaluates the resident to determine if it is appropriate to write a new PRN order for the antipsychotic medication. The evaluation entails direct evaluation of the resident and assessment of the

resident's current conditions and progress to determine if the PRN antipsychotic medication is still needed. Attending physician/prescribing practitioner documentation of the evaluation should address:
- o Whether the antipsychotic medication is still needed on a PRN basis?
- o What is the benefit of the medication to the resident?
- o Have the resident's expressions or indications of distress improved as a result of the PRN antipsychotic medication?

☐ Review the care plan for medications, especially high risk medications, and individualized approaches to care, including non-pharmacological interventions.

Observations:

☐ Are care planned interventions implemented for medications that pose a high risk for adverse consequences?

☐ What non-pharmacological approaches to care are used? Are they effective?

☐ What pharmacological interventions are used? Why was the medication used and was it effective (e.g., pain is relieved, distress is addressed)?

☐ How does staff respond and interact with the resident?

☐ Does the resident continue to show expressions or indications of distress? If so, how does staff respond?

☐ Are staff using a medication for convenience or discipline? If so, describe. (For concerns related to a medication that involves an inadequate indication for use and evidence shows the medication is also being used for the purpose of discipline or convenience rather than to treat the resident's medical symptoms, surveyors should assess compliance with §483.10(e)(1) and §483.12(a)(2), F605, Right to Be Free From Chemical Restraints.)

☐ Does the resident have psychosocial, behavioral, mental, or physical adverse consequences that may be related to a medication:
- o Anorexia/unplanned weight changes, edema;
- o Decline in physical functioning (e.g., mobility or activities of daily living (ADLs));
- o Rash, pruritus;
- o Bleeding or bruising, spontaneous or unexplained;
- o Respiratory changes;
- o Bowel dysfunction (e.g., cramping abdominal pain);
- o Urinary retention, incontinence;
- o Dehydration or swallowing difficulty;
- o Falls, dizziness, or headaches;
- o Muscle/nonspecific pain or unexplained abnormal movement;
- o Psychomotor agitation (restlessness, pacing, hand wringing);
- o Psychomotor retardation (slowed speech, thinking, movement);
- o Subdued, sedated, lethargic, or withdrawn;
- o Insomnia or sleep disturbances;
- o Mental status changes;
- o Behavioral changes or unusual behavior patterns; or
- o Depression, apathy or mood disturbance.

Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

Resident, Family or Resident Representative Interview:

- ☐ What medications do you get and why do you need to take them?
- ☐ What are your goals for your medications?
- ☐ What information on the risk, benefits and potential side effects of medications were you provided?
- ☐ What changes in your medications have occurred, including gradual dose reductions for psychotropic medications?

  NOTE: Permission given by or a request made by the resident and/or representative does not serve as a sole justification for the medication itself.
- ☐ What alternatives to taking some of the medications, including non-pharmacological approaches, has staff told you about?
- ☐ Do you think the medication has helped (e.g., pain control, improvements in function, decrease in edema, mood)? If not, why?
- ☐ What side effects have you had from the medication (ask about specific medications)? Have you experienced any changes in what you are able to do since starting or changing a medication(s)? Do you have allergies to any medication(s)?
- ☐ Have you participated in discussions and/or care plan meetings about your medications?

Staff Interviews (Nursing Aides, Nurse, Director of Nursing (DON), Social Services):

- ☐ What, when, and to whom do you report changes in the resident's status (e.g., indications of distress or pain)?
- ☐ How do you learn what the resident's daily care needs are?
- ☐ What non-pharmacological approaches are used?
- ☐ What is the clinical indication for the medication?
- ☐ How does the facility monitor the medication?
  - o What monitoring tools or systems are used?
  - o How did the interdisciplinary team (IDT) determine what should be monitored?
  - o For psychotropic medications, how did you determine what behavior to monitor?
  - o How do you assure orders for medication monitoring are implemented (e.g., HbA1c, PT/INR)?
  - o How do you communicate relevant information regarding medication monitoring for this resident to other team members?
- ☐ How do you assess whether each medication is effective?
- ☐ Why does the resident have two medications in the same class?
- ☐ How does the IDT determine what dose and duration is clinically indicated?
- ☐ If the amount of any medication exceeds the manufacturer's recommendations, clinical or evidence-based practice guidelines, or standards of practice, what is the rationale?
- ☐ How do you monitor for significant adverse consequences?
- ☐ Has the resident had a change in condition, diet, weight loss, dehydration, or acute illness? If so, what was done to assess the possible complications for these changes due to medications?
- ☐ Has the resident had an adverse reaction? If so, what and how was the adverse reaction addressed?
- ☐ How do you evaluate whether medications should be initiated, continued, reduced, discontinued, or otherwise modified? How often is the evaluation for modification conducted?

Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

- ☐ How does the facility ensure a review of medications for GDRs?
- ☐ If the resident is on a psychotropic medication: When did you attempt to reduce the medication in the last year and what were the results?
- ☐ If the practitioner denied a GDR: Did the practitioner provide a risk-benefit statement describing the contraindications for a GDR?
- ☐ How do you monitor staff to ensure they are implementing care planned approaches?
- ☐ What was the rationale for the practitioner's decisions in managing the resident's medications or medication-related concerns?
- ☐ How did you involve the resident in decisions regarding medications?
- ☐ How often is the MRR conducted and are medical charts included in this review?
- ☐ Under what circumstances is the MRR conducted more often than monthly?
- ☐ Are there policies and procedures in place to address issues which include the different steps in the MRR process and steps to take when an identified irregularity requires immediate action?
- ☐ How are medication-related issues communicated to other staff, the attending practitioner or prescribing practitioner, and resident and, if appropriate, resident representative?
- ☐ How is the MRR process conducted for short-stay residents?
- ☐ Has there been a change in the resident's overall function and mood that potentially may indicate unnecessary medications or adverse reactions? If so, describe.
- ☐ If the resident is receiving PRN psychotropic or antipsychotic medication(s): How is this medication monitored and how does the IDT determine if the PRN medication is clinically indicated and ensure the PRN orders are consistent with PRN requirements for psychotropic and antipsychotic medications?
- ☐ Ask about any other related concerns the surveyor has identified.

Pharmacist Interview:

- ☐ Do you perform a monthly MRR (or more frequently if needed)?
- ☐ Do you include each resident's medical record in this monthly review?
- ☐ How do you evaluate PRN medications, specifically PRN psychotropic and antipsychotic medications?
- ☐ What are you reviewing (e.g., adequate indication, dose, continued need, and adverse consequences)?
- ☐ Did you identify and report to the attending physician, medical director, and DON any irregularities with this resident's medication regimen? Did you use a separate, written report?
- ☐ If the pharmacist didn't identify a specific issue, ask why the issue was not identified as an irregularity on the MRR.
- ☐ What is the MRR process for short-stay residents?
- ☐ What protocols to do you have in place (e.g., lab to monitor for adverse events and drug interactions related to use of antibiotics and other high-risk medications)?
- ☐ Are you part of the IDT who reviews this resident's medication?
- ☐ What steps do you take when an irregularity requires immediate action? Are these steps part of facility policy?

Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

Attending Practitioner, Medical Director, and DON Interviews:

- ☐ Did you receive a written report of irregularities identified during the MRR?
- ☐ Did you make a change in the resident's medication in response to the identified irregularity(ies) or document a rationale if you didn't make a change in the medication regimen?
- ☐ What is the rationale behind why the medication is being used (e.g., antipsychotic for dementia or other high risk medications)?
- ☐ What other approaches were attempted prior to the use of a psychotropic medication and/or while attempting a GDR?
- ☐ When was a GDR last completed? What was the result?
- ☐ Are you included in the IDT meeting for this resident?

Record Review:

- ☐ Was the underlying cause (medical, environmental, or psychosocial stressors) of the conditions or symptoms requiring the medication identified?
- ☐ If a medication was discontinued, was there evidence of a GDR, if applicable (e.g., for psychotropic and antipsychotic medications)?
- ☐ Did the pharmacist conduct an MRR for the resident at least once a month that included a review of the resident's medical record?
- ☐ Did the pharmacist identify and report all medication irregularities to the attending physician, medical director, and DON? Were the irregularities documented on a separate, written report? Were the reports acted upon?
- ☐ 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?
- ☐ If the resident had a change in condition such as, dehydration or acute illness, was the medication regimen reviewed? Did the pharmacist complete a MRR?
- ☐ Is there evidence of actual or potential adverse events, such as allergic reactions, inadequate monitoring? (Refer to the CMS Adverse Drug Event Trigger Tool).
- ☐ Was there a "significant change" in the resident's condition (i.e., will not resolve itself without intervention by staff or by implementing standard disease-related clinical interventions; impacts more than one area of health; requires IDT review or revision of the care plan)? If so, was a significant change comprehensive assessment conducted within 14 days?
- ☐ Is the MAR accurate, complete and followed according to standards of practice?
- ☐ For antibiotics: Are signs or symptoms of infection documented? Have appropriate diagnostic tests been obtained to inform antibiotic selection and continuation?
- ☐ What is the facility response when monitoring indicates a lack of progress toward the therapeutic goal?
- ☐ What individualized, non-pharmacological approaches were documented, specifically for residents who receive psychotropic medications?
- ☐ Review the facility's policies regarding psychotropic medications and MRR. Are they updated and maintained? Does the policy include timeframes for the steps in the process? Does the policy include the steps the licensed pharmacist must take for a medication irregularity that requires urgent action?

Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

Critical Elements Decisions:

1. For the **Medication Regimen Review (MRR)**:
   A. Did the licensed pharmacist:
      - Conduct an MRR, at least monthly, that included a review of the resident's medical record;
      - Conduct an MRR more frequently, as needed; and
      - Report irregularities to the attending physician, medical director, and the DON?

   B. Did the attending physician document:
      - Review of identified irregularity(ies);
      - The action, if any, taken;
      - A rationale if no action is taken?

   C. Has the facility developed and implemented MRR policies and procedures?
      - Do they address, at a minimum:
        - Time frames for steps in the MRR process;
        - Steps the pharmacist must take when an irregularity requires urgent action.

   If No to any of the above, cite F756

2. For **Unnecessary Medications**: Did the facility ensure that each resident's medication regimen was free from unnecessary medications? (Note: If the unnecessary medication is a psychotropic medication, cite F758)
   If No, cite F757

Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

3. For **Psychotropic Medications**, did the facility ensure that:
   - they are used only to treat a specific, diagnosed, and documented condition;
   - a GDR was attempted, unless clinically contraindicated, and non-pharmacological approaches to care were implemented;
   - PRN use is only if necessary to treat a specific, diagnosed, and documented condition;
   - PRN orders for psychotropic medications which **are not** for antipsychotic medications are limited to 14 days,unless the attending physician/prescribing practitioner documents a rationale to extend the medication;
   - PRN orders which **are** 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?

   If No to any of the above, cite F758
   NA, the resident was not prescribed psychotropic medications.

4. Did the facility conduct ongoing review for antibiotic stewardship?
   If No, cite F881

5. For newly admitted residents and if applicable based on the concern under investigation, did the facility develop and implement a baseline care plan within 48 hours of admission that included the minimum healthcare information necessary to properly care for the immediate needs of the resident? Did the resident and resident representative receive a written summary of the baseline care plan that he/she was able to understand?
   If No, cite F655.
   NA, the resident did not have an admission since the previous survey OR the care or service was not necessary to be included in a baseline care plan.

6. If the condition or risks related to medications were present at the time of the required comprehensive assessment, did the facility comprehensively assess the resident's physical, mental, and psychosocial needs to identify the risks and/or to determine underlying causes, to the extent possible, and the impact upon the resident's function, mood, and cognition?
   If No, cite F636
   NA, condition/risks were identified after completion of the required comprehensive assessment and did not meet the criteria for a significant change MDS OR the resident was recently admitted and the comprehensive assessment was not yet required.

7. If there was a significant change in the resident's status, did the facility complete a significant change assessment within 14 days of determining the status change was significant?
   If No, cite F637
   NA, the initial comprehensive assessment had not yet been completed therefore a significant change in status assessment is not required OR the resident did not have a significant change in status.

8. Did staff who have the skills and qualifications to assess relevant care areas and who are knowledgeable about the resident's status, needs, strengths and areas of decline, accurately complete the resident assessment (i.e., comprehensive, quarterly, significant change in status)?
   If No, cite F641

9. Did the facility develop and implement a comprehensive person-centered care plan that includes measureable objectives and timeframes to meet a resident's medical, nursing, mental, and psychosocial needs and includes the resident's goals, desired outcomes, and preferences?
   If No, cite F656
   NA, the comprehensive assessment was not completed.

10. Did the facility reassess the effectiveness of the approaches and review and revise the resident's care plan (with input from the resident and, if appropriate, the resident representative) to meet the resident's needs?
    If No, cite F657
    NA, the comprehensive assessment was not completed OR the care plan was not developed OR the care plan did not have to be revised.

Other Tags, Care Areas (CA), and Tasks (Task) to Consider: Right to be Informed and Participate F552, F553, Notification of Change F580, Chemical Restraints F605, Choices (CA), Social Services F745, Admission Orders F635, Professional Standards F658, Pain (CA), General Pathway (CA) for Diabetic Management, Dementia Care (CA), ADLs (CA), Urinary Incontinence (CA), Behavioral-Emotional Status (CA), Nutrition (CA), Hydration (CA), Sufficient and Competent Staffing (Task), Physician Services F710, F711, Pharmacy Services F755, QAA/QAPI (Task).

Federal Regulatory Groups

Federal Regulatory Groups for Long Term Care Facilities

*** Substandard quality of care = one or more deficiencies with s/s levels of F, H, I, J, K, or L in Red**

F540 Definitions

483.10 Resident Rights

F550 *Resident Rights/Exercise of Rights
F551 Rights Exercised by Representative
F552 Right to be Informed/Make Treatment Decisions
F553 Right to Participate in Planning Care
F554 Resident Self-Admin Meds-Clinically Appropriate
F555 Right to Choose/Be Informed of Attending Physician
F557 Respect, Dignity/Right to have Personal Property
F558 *Reasonable Accommodations of Needs/Preferences
F559 *Choose/Be Notified of Room/Roommate Change
F560 Right to Refuse Certain Transfers
F561 *Self Determination
F562 Immediate Access to Resident
F563 Right to Receive/Deny Visitors
F564 Inform of Visitation Rights/Equal Visitation Privileges
F565 *Resident/Family Group and Response
F566 Right to Perform Facility Services or Refuse
F567 Protection/Management of Personal Funds
F568 Accounting and Records of Personal Funds
F569 Notice and Conveyance of Personal Funds
F570 Surety Bond - Security of Personal Funds
F571 Limitations on Charges to Personal Funds
F572 Notice of Rights and Rules
F573 Right to Access/Purchase Copies of Records
F574 Required Notices and Contact Information
F575 Required Postings
F576 Right to Forms of Communication with Privacy
F577 Right to Survey Results/Advocate Agency Info
F578 Request/Refuse/Discontinue Treatment;Formulate Adv Di
F579 Posting/Notice of Medicare/Medicaid on Admission
F580 Notify of Changes (Injury/Decline/Room, Etc.)
F582 Medicaid/Medicare Coverage/Liability Notice
F583 Personal Privacy/Confidentiality of Records
F584 *Safe/Clean/Comfortable/Homelike Environment
F585 Grievances
F586 Resident Contact with External Entities

483.12 Freedom from Abuse, Neglect, and Exploitation

F600 *Free from Abuse and Neglect
F602 *Free from Misappropriation/Exploitation
F603 *Free from Involuntary Seclusion
F604 *Right to be Free from Physical Restraints
F605 *Right to be Free from Chemical Restraints
F606 *Not Employ/Engage Staff with Adverse Actions
F607 *Develop/Implement Abuse/Neglect, etc. Policies
F608 *Reporting of Reasonable Suspicion of a Crime
F609 *Reporting of Alleged Violations
F610 *Investigate/Prevent/Correct Alleged Violation

483.15 Admission, Transfer, and Discharge

F620 Admissions Policy
F621 Equal Practices Regardless of Payment Source
F622 Transfer and Discharge Requirements
F623 Notice Requirements Before Transfer/Discharge
F624 Preparation for Safe/Orderly Transfer/Discharge
F625 Notice of Bed Hold Policy Before/Upon Transfer
F626 Permitting Residents to Return to Facility

483.20 Resident Assessments

F635 Admission Physician Orders for Immediate Care
F636 Comprehensive Assessments & Timing
F637 Comprehensive Assmt After Significant Change
F638 Quarterly Assessment At Least Every 3 Months
F639 Maintain 15 Months of Resident Assessments
F640 Encoding/Transmitting Resident Assessment
F641 Accuracy of Assessments
F642 Coordination/Certification of Assessment
F644 Coordination of PASARR and Assessments
F645 PASARR Screening for MD & ID
F646 MD/ID Significant Change Notification

483.21 Comprehensive Resident Centered Care Plans

F655 Baseline Care Plan
F656 Develop/Implement Comprehensive Care Plan
F657 Care Plan Timing and Revision
F658 Services Provided Meet Professional Standards
F659 Qualified Persons
F660 Discharge Planning Process
F661 Discharge Summary

483.24 Quality of Life

F675 *Quality of Life
F676 *Activities of Daily Living (ADLs)/ Maintain Abilities
F677 *ADL Care Provided for Dependent Residents
F678 *Cardio-Pulmonary Resuscitation (CPR)
F679 *Activities Meet Interest/Needs of Each Resident
F680 *Qualifications of Activity Professional

483.25 Quality of Care

F684 *Quality of Care
F685 *Treatment/Devices to Maintain Hearing/Vision
F686 *Treatment/Svcs to Prevent/Heal Pressure Ulcers
F687 *Foot Care
F688 *Increase/Prevent Decrease in ROM/Mobility
F689 *Free of Accident Hazards/Supervision/Devices
F690 *Bowel/Bladder Incontinence, Catheter, UTI
F691 *Colostomy, Urostomy, or Ileostomy Care
F692 *Nutrition/Hydration Status Maintenance
F693 *Tube Feeding Management/Restore Eating Skills
F694 *Parenteral/IV Fluids
F695 *Respiratory/Tracheostomy care and Suctioning
F696 *Prostheses
F697 *Pain Management
F698 *Dialysis
F699 *{PHASE-3} Trauma Informed Care
F700 *Bedrails

483.30 Physician Services

F710 Resident's Care Supervised by a Physician
F711 Physician Visits- Review Care/Notes/Order
F712 Physician Visits-Frequency/Timeliness/Alternate NPPs
F713 Physician for Emergency Care, Available 24 Hours
F714 Physician Delegation of Tasks to NPP
F715 Physician Delegation to Dietitian/Therapist

483.35 Nursing Services

F725 Sufficient Nursing Staff
F726 Competent Nursing Staff
F727 RN 8 Hrs/7 days/Wk, Full Time DON
F728 Facility Hiring and Use of Nurse
F729 Nurse Aide Registry Verification, Retraining

Federal Regulatory Groups for Long Term Care Facilities

*** Substandard quality of care = one or more deficiencies with s/s levels of F, H, I, J, K, or L in Red**

F730 Nurse Aide Perform Review – 12Hr/Year In- service
F731 Waiver-Licensed Nurses 24Hr/Day and RN Coverage
F732 Posted Nurse Staffing Information

483.40 Behavioral Health Services

F740 Behavioral Health Services
F741 Sufficient/Competent Staff-Behav Health Needs
F742 *Treatment/Svc for Mental/Psychosocial Concerns
F743 *No Pattern of Behavioral Difficulties Unless Unavoidable
F744 *Treatment /Service for Dementia
F745 *Provision of Medically Related Social Services

483.45 Pharmacy Services

F755 Pharmacy Svcs/Procedures/Pharmacist/Records
F756 Drug Regimen Review, Report Irregular, Act On
F757 *Drug Regimen is Free From Unnecessary Drugs
F758 *Free from Unnec Psychotropic Meds/PRN Use
F759 *Free of Medication Error Ratesof 5% or More
F760 *Residents Are Free of Significant Med Errors
F761 Label/Store Drugs & Biologicals

483.50 Laboratory, Radiology, and Other Diagnostic Se

F770 Laboratory Services
F771 Blood Blank and Transfusion Services
F772 Lab Services Not Provided On-Site
F773 Lab Svs Physician Order/Notify of Results
F774 Assist with Transport Arrangements to Lab Svcs
F775 Lab Reports in Record-LabName/Address
F776 Radiology/Other Diagnostic Services
F777 Radiology/Diag. Svcs Ordered/Notify Results
F778 Assist with Transport Arrangements to Radiology
F779 X-Ray/Diagnostic Report in Record-Sign/Dated

483.55 Dental Services

F790 Routine/Emergency Dental Services in SNFs
F791 Routine/Emergency Dental Services in NFs

483.60 Food and Nutrition Services

F800 Provided Diet Meets Needs of Each Resident
F801 Qualified Dietary Staff
F802 Sufficient Dietary Support Personnel
F803 Menus Meet Res Needs/Prep in Advance/Followed
F804 Nutritive Value/Appear ,Palatable/Prefer Temp
F805 Food in Form to Meet Individual Needs
F806 Resident Allergies, Preferences and Substitutes
F807 Drinks Avail to Meet Needs/Preferences/ Hydration
F808 Therapeutic Diet Prescribed by Physician
F809 Frequency of Meals/Snacks at Bedtime
F810 Assistive Devices - Eating Equipment/Utensils
F811 Feeding Asst -Training/Supervision/Resident
F812 Food Procurement, Store/Prepare/Serve - Sanitary
F813 Personal Food Policy
F814 Dispose Garbage & Refuse Properly

483.65 Specialized Rehabilitative Services

F825 Provide/Obtain Specialized Rehab Services
F826 Rehab Services- Physician Order/Qualified Person

483.70 Administration

F835 Administration
F836 License/Comply w/Fed/State/Local Law/Prof Std
F837 Governing Body
F838 Facility Assessment
F839 Staff Qualifications
F840 Use of Outside Resources
F841 Responsibilities of Medical Director
F842 Resident Records - Identifiable Information
F843 Transfer Agreement
F844 Disclosure of Ownership Requirements
F845 Facility closure-Administrator
F846 Facility closure
F849 Hospice Services
F850 *Qualifications of Social Worker >120 Beds
F851 Payroll Based Journal

483.75 Quality Assurance and Performance Improvem

F865 QAPI Program/Plan, Disclosure/Good Faith Attempt
F866 {PHASE-3} QAPI/QAA Data Collection and Monitoring
F867 QAPI/QAA Improvement Activities
F868 QAA Committee

483.80 Infection Control

F880 Infection Prevention & Control
F881 Antibiotic Stewardship Program
F882 {PHASE-3} Infection Preventionist Qualifications/Role
F883 *Influenza and Pneumococcal Immunizations

483.85 {PHASE-3} Compliance and Ethics Program

F895 {PHASE-3} Compliance and Ethics Program

483.90 Physical Environment

F906 Emergency Electrical Power System
F907 Space and Equipment
F908 Essential Equipment, Safe Operating Condition
F909 Resident Bed
F910 Resident Room
F911 Bedroom Number of Residents
F912 Bedrooms Measure at Least 80 Square Ft/Resident
F913 Bedrooms Have Direct Access to Exit Corridor
F914 Bedrooms Assure Full Visual Privacy
F915 Resident Room Window
F916 Resident Room Floor Above Grade
F917 Resident Room Bed/Furniture/Closet
F918 Bedrooms Equipped/Near Lavatory/Toilet
F919 Resident Call System
F920 Requirements for Dining and Activity Rooms
F921 Safe/Functional/Sanitary/Comfortable Environment
F922 Procedures to Ensure Water Availability
F923 Ventilation
F924 Corridors Have Firmly Secured Handrails
F925 Maintains Effective Pest Control Program
F926 Smoking Policies

483.95 Training Requirements

F940 {PHASE-3} Training Requirements - General
F941 {PHASE-3} Communication Training
F942 {PHASE-3} Resident's Rights Training
F943 Abuse, Neglect, and Exploitation Training
F944 {PHASE-3} QAPI Training
F945 {PHASE-3} Infection Control Training
F946 {PHASE-3} Compliance and Ethics Training
F947 Required In-Service Training for Nurse Aides
F948 Training for Feeding Assistants
F949 {PHASE-3} Behavioral Health Training

F600 Resident to Resident Abuse of Any Type

F600

Resident to Resident Abuse of Any Type A resident to resident altercation should be reviewed as a potential situation of abuse. When investigating an allegation of abuse between residents, the surveyor should not automatically assume that abuse did not occur, especially in cases where either or both residents have a cognitive impairment or mental disorder. Having a mental disorder or cognitive impairment does not automatically preclude a resident from engaging in deliberate or non-accidental actions. In determining whether F600-Free from Abuse and Neglect should be cited in these situations, it is important to remember that abuse includes the term "willful". The word "willful" means that the individual's action was deliberate (not inadvertent or accidental), regardless of whether the individual intended to inflict injury or harm. An example of a deliberate ("willful") action would be a cognitively impaired resident who strikes out at a resident within his/her reach, as opposed to a resident with a neurological disease who has involuntary movements (e.g., muscle spasms, twitching, jerking, writhing movements) and his/her body movements impact a resident who is nearby. If it is determined that the action was not willful (a deliberate action), the surveyor must investigate whether the facility is in compliance with the requirement to maintain an environment as free of accident hazards as possible, and that each resident receives adequate supervision (See F689).

The facility may provide evidence that it completed a resident assessment and provided care planning interventions to address a resident's distressed behaviors such as physical, sexual or verbal aggression. However, based on the presence of resident to resident altercations, if the facility did not evaluate the effectiveness of the interventions and staff did not provide immediate interventions to assure the safety of residents, then the facility did not provide sufficient protection to prevent resident to resident abuse. For example, redirection alone is not a sufficiently protective response to a resident who will not be deterred from targeting other residents for abuse once he/she has been redirected.

Staff should monitor for any behaviors that may provoke a reaction by residents or others, which include, but are not limited to: • Verbally aggressive behavior, such as screaming, cursing, bossing around/demanding, insulting to race or ethnic group, intimidating; • Physically aggressive behavior, such as hitting, kicking, grabbing, scratching, pushing/shoving, biting, spitting, threatening gestures, throwing objects; • Sexually aggressive behavior such as saying sexual things, inappropriate touching/grabbing; • Taking, touching, or rummaging through other's property; and • Wandering into other's rooms/space.

Also, resident to resident abuse could involve a resident who has had no prior history of aggressive behaviors, since a resident's behavior could quickly escalate into an instance of abuse. For example, a resident pushes away or strikes another resident who is rummaging through his/her possessions.

TYPES OF ABUSE Identified facility characteristics 1,2 that could increase the risk for abuse include, but are not limited to: • Unsympathetic or negative attitudes toward residents; • Chronic staffing problems; • Lack of administrative oversight, staff burnout, and stressful working conditions; • Poor or inadequate preparation or training for care giving responsibilities; • Deficiencies of the physical environment; and • Facility policies operate in the interests of the institution rather than the residents.

In addition, the risk for abuse may increase when a resident exhibits a behavior(s) that may provoke a reaction by staff, residents, or others, such as 3: • Verbally aggressive behavior, such as screaming, cursing, bossing around/demanding, insulting to race or ethnic group, intimidating; • Physically aggressive behavior, such as hitting, kicking, grabbing, scratching, pushing/shoving, biting, spitting, threatening gestures, throwing objects; • Sexually aggressive behavior such as saying sexual things, inappropriate touching/grabbing; • Taking, touching, or rummaging through other's property; • Wandering into other's rooms/space; and • Resistive to care and services.

Some situations of abuse do not result in an observable physical injury or the psychosocial effects of abuse may not be immediately apparent. In addition, the alleged victim may not report abuse due to shame, fear, or retaliation. Other residents may not be able to speak due to a medical condition and/or cognitive impairment (e.g., stroke, coma, Alzheimer's disease), cannot recall what has occurred, or may not express outward signs of physical harm, pain, or mental anguish. Neither physical marks on the body nor the ability to respond and/or verbalize is needed to conclude that abuse has occurred.

Abuse may result in psychological, behavioral, or psychosocial outcomes including, but not limited to, the following: • Fear of a person or place, of being left alone, of being in the dark, and/or disturbed sleep and nightmares; • Extreme changes in behavior, including aggressive or disruptive behavior toward a specific person; and • Running away, withdrawal, isolating self, feelings of guilt and shame, depression, crying, talk of suicide or attempts.

The guidance below identifies some characteristics of specific types of abuse.

Physical Abuse Physical abuse includes, but is not limited to, hitting, slapping, punching, biting, and kicking.

Possible indicators of physical abuse include an injury that is suspicious because the source of the injury is not observed, the extent or location of the injury is unusual, or because of the number of injuries either at a single point in time or over time.

Examples of injuries that could indicate abuse include, but are not limited to: • Injuries that are non-accidental or unexplained; • Fractures, sprains or dislocations; • Burns, blisters, or scalds on the hands or torso; • Bite marks, scratches, skin tears, and lacerations with or without bleeding, including those that are in locations that would unlikely result from an accident; • Bruises, including those found in unusual locations such as the head, neck, lateral locations on the arms, or posterior torso and trunk, or bruises in shapes (e.g., finger imprints); and • Facial injuries, including but not limited to, broken or missing teeth, facial fractures, black eye(s), bruising, bleeding or swelling of the mouth or cheeks.

Mental and Verbal Abuse Mental abuse is the use of verbal or nonverbal conduct which causes or has the potential to cause the resident to experience humiliation, intimidation, fear, shame, agitation, or degradation.

Verbal abuse may be considered to be a type of mental abuse. Verbal abuse includes the use of oral, written, or gestured communication, or sounds, to residents within hearing distance, regardless of age, ability to comprehend, or disability. Examples of mental and verbal abuse include, but are not limited to: • Harassing a resident; • Mocking, insulting, ridiculing; • Yelling or hovering over a resident, with the intent to intimidate; • Threatening residents, including but limited to, depriving a resident of care or withholding a resident from contact with family and friends; and • Isolating a resident from social interaction or activities.
NOTE: Although a finding of mental abuse indicates that a facility is not promoting an environment that enhances a resident's dignity, surveyors must cite a finding of mental abuse at F600 at the appropriate severity level with consideration of the psychosocial outcome to residents.

Mental abuse includes abuse that is facilitated or enabled through the use of technology, such as smartphones and other personal electronic devices. This would include keeping and/or distributing demeaning or humiliating photographs and recordings through social media or multimedia messaging. If a photograph or recording of a resident, or the manner that it is used, demeans or humiliates a resident(s), regardless of whether the resident provided consent and regardless of the resident's cognitive status, the surveyor must consider non-compliance related to abuse at this tag. This would include, but is not limited to, photographs and recordings of residents that contain nudity, sexual and intimate relations, bathing, showering, using the bathroom, providing perineal care such as after an incontinence episode, agitating a resident to solicit a response, derogatory statements directed to the resident, showing a body part such as breasts or buttocks without the resident's face, labeling resident's pictures and/or providing comments in a demeaning manner, directing a resident to use inappropriate language, and showing the resident in a compromised position. Depending on what was photographed or recorded, physical and/or sexual abuse may also be identified.

Allegations of Resident To Resident Sexual Abuse Studies show that a considerable amount of unwanted sexual contact in nursing homes may be initiated by a resident who is sexually aggressive as a result of disease processes such as brain injuries or dementia. In addition, a resident may have a pre-occupation for sexual activity, or have had a prior history of sexual abuse. The resident who is sexually aggressive may target a resident who is unable to protect him/herself, and may involve various types of sexual aggression such as fondling both over and under clothing, masturbation in the presence of another resident and is unwanted by that other resident, forcing oral sex, or sexual intercourse.

If there is an allegation that a resident did not wish to engage in sexual activity with another resident or may not have the capacity to consent, the facility must respond to it as an alleged violation of sexual abuse.

Reporting of Abuse

New Abuse Reporting Requirements - Effective November 28, 2016

On October 4, 2016, the Centers for Medicare and Medicaid Services (CMS) released the final rules regarding the requirements of participation for skilled nursing facilities. One of the most significant changes to the regulations is the new abuse reporting requirements. Pursuant to 42 CFR 483.12, skilled nursing facilities must report any allegation of abuse within two hours of the allegation. Additionally, any neglect, mistreatment, exploitation or injuries of unknown source that results in serious bodily injury must also be reported within two hours to ADPH. Although serious bodily injury is not defined by the new rules, this term was used in the Elder Justice Act and was defined as "[i]njury involving extreme physical pain; involving substantial risk of death; involving protracted loss or impairment of the function of a bodily member, organ, or mental faculty; or requiring medical intervention such as surgery, hospitalization, or physical rehabilitation." All other allegations of neglect, mistreatment, exploitation or misappropriation of resident property must be reported within 24 hours. There was no change to the submission of the results of the investigation within five working days.

This requirement went into effect on November 28, 2016.

Type of Allegation	2 hour reporting	24 hour reporting
Abuse without serious bodily injury	X	
Abuse with serious bodily injury	X	
Neglect without serious bodily injury		X
Neglect with serious bodily injury	X	
Mistreatment without serious bodily injury		X
Mistreatment with serious bodily injury (likely rises to abuse)	X	
Exploitation without serious bodily injury		X
Exploitation with serious bodily injury (likely considered abuse)	X	
Injuries of unknown source without serious bodily injury		X
Injuries of unknown source with serious bodily injury	X	
Misappropriation of resident property		X

Editor's Note: ANHA Associate Member Burr Forman contributed this article.

Immediate Jeopardy Template

Immediate Jeopardy Template

Survey teams must use the Immediate Jeopardy (IJ) Template to document evidence of each component of IJ; and if IJ is confirmed, the IJ Template will be used to convey information to the entity. Any information presented on this template is subject to change and does not reflect an official finding against a Medicare provider or supplier. Form CMS-2567 is the only form that contains official survey findings.

Instructions: The survey team must use evidence gathered from observations, interviews, and record reviews to carefully consider each component of IJ outlined in the left-hand column of this template. In order for IJ to exist, the survey team must answer "Yes" to all three components and provide a preliminary fact analysis in the right hand column to support their determination. If IJ is confirmed by the survey team and SA Supervisor, provide this IJ Template to the entity and note the date and time that it was provided at the top of page 2. Use one IJ template for each tag being considered at IJ level.

For the purpose of completing this template, the following definitions apply:

Likely/Likelihood means the nature and/or extent of the identified noncompliance creates a reasonable expectation that an adverse outcome resulting in serious injury, harm, impairment, or death will occur if not corrected.

Noncompliance means failure to meet one or more federal health, safety, and/or quality regulations.

Recipient at Risk is a recipient who, as a result of noncompliance, and in consideration of the recipient's physical, mental, psychosocial or health needs, and/or vulnerabilities, is likely to experience a serious adverse outcome.

Serious injury, serious harm, serious impairment or death are adverse outcomes which result in, or are likely to result in:

- death; or
- a significant decline in physical, mental, or psychosocial functioning, (that is not solely due to the normal progression of a disease or aging process); or
- loss of limb, or disfigurement; or
- avoidable pain that is excruciating, and more than transient; or
- other serious harm that creates life-threatening complications/conditions.

***NOTE: IJ does not require serious injury, harm, impairment or death to occur. It is sufficient that non-compliance makes serious injury, harm, impairment or death likely to occur to one or more recipients.**

Date/Time IJ Template provided to entity: _____

IJ Component	Yes/No	Preliminary fact analysis which demonstrates whether key component exists.
Noncompliance: Has the entity failed to meet one or more federal health, safety, and/or quality regulations? If yes, in the blank space, identify the tag and briefly summarize the issues that lead to the determination that the entity is in noncompliance with the identified requirement. This includes the action(s), error(s), or lack of action, and the extent of the noncompliance (for example, number of cases). Use one IJ template for each tag being considered at IJ level.	Yes/No	
AND		
Serious injury, serious harm, serious impairment or death: Is there evidence that a serious adverse outcome occurred, or a serious adverse outcome is likely as a result of the identified noncompliance? If Yes, in the blank space, briefly summarize the serious adverse outcome, or likely serious adverse outcome to the recipient.	Yes/No	
AND		
Need for Immediate Action: Does the entity need to take immediate action to correct noncompliance that has caused or is likely to cause serious injury, serious harm, serious impairment, or death? If yes, in the blank space, briefly explain why.	Yes/No	

Disclaimer: The findings on this IJ Template are preliminary and do not represent an official finding against a Medicare provider or supplier. Form CMS-2567 is the only form that contains official survey findings.

SBAR – Situation, Background, Assessment, Request

SBAR

Physician/NP/PA Communication and Progress Note
To Discuss Possible Drug Reduction for an Individual Already Receiving an Antipsychotic Drug for Off-Label Use

Patient Name:
Date of Birth:
Medical record #:

Before Calling the MD/NP/PA:

__ Evaluate the patient and complete the SBAR form
__ Check VS: BP, pulse, respiratory rate, neurological check, lung sound, temperature, pain level
__ Review chart for:

- psychiatric conditions and/or hospitalizations
- recent physician or psychologist progress notes
- pharmacist medication regimen review notes
- abnormal clinical and laboratory findings
- notes on possible drug side-effects

__ Be prepared to report on dosing changes, changes in target symptoms and potential side effects
__ Have relevant information available when reporting (medication list including doses, method and time(s) of administration)
__ Be prepared to have a list of all medications, including PRNs, and the individual's medical record

Situation

The drug and behavior (if problematic) I am calling about is _____
Date drug started ___/___/___
Date of last dose adjustment and dosage change made ___/___/___
Individual's symptoms has gotten worse/better/stayed the same since the drug started _____
Have any potential side effects been noticed? __No __Yes (If yes describe) _____
_____
Things that make the symptoms worse _____
_____
Things that make the symptoms better (non-pharmacological approach) _____
_____
Other things that have occurred related to this symptom and treatment _____
_____

Background

Primary diagnosis and/or reason person is at the nursing home _____
_____
Pertinent mental health history _____
_____
Behavioral concerns identified by family _____
Vital signs BP_____/_____ HR_____ RR_____ Temp_____
Individual is on a scheduled pain management program ___Yes ___No
If yes, what medication interventions is the individual receiving? _____
Conditions (check all those that apply)

- ☐ orthostatic hypotension
- ☐ weight gain
- ☐ increase glucose level
- ☐ urinary retention
- ☐ constipation
- ☐ sedation
- ☐ restlessness
- ☐ pacing
- ☐ drooling
- ☐ tremors
- ☐ rigidity
- ☐ slowness of movement
- ☐ jerk body responses
- ☐ lip smacking/ chewing/abnormal tongue movement
- ☐ involuntary movement of extremities
- ☐ worsening confusion/delirium
- ☐ fall

Other _____

Signature_____ RN/LPN Date___/___/___ Time___/___AM/PM

Patient Name:
Date of Birth:
Medical record #:

Medication changes or new orders in the last two weeks _____
Recent Labs _____
Allergies _____
Any other data _____

Assessment (RN) or Appearance (LPN)
(For RNs): The individual's symptoms appear (better/worse/same) _____
I think the symptoms may be related to _____
Do you believe the individual has achieved a therapeutic dose? ___ No ___Yes If yes: Do you believe dose reduction may be needed? _____
(For LPNs): The individual's symptom(s) appear (better/worse/same) _____

Request
I suggest or request (check all that applies):

- ☐ Other (start/change non-pharmacological approach)
- ☐ Change in/stop current med order(s)
- ☐ Provider visit (MD/NP/PA)
- ☐ Continued monitoring
- ☐ Lab work

Staff name _____ **RN/LPN** _____
Reported to: Name _____ (MD/NP/PA) **Date**___/___/___ **Time**____ AM/PM
If to MD/NP/PA, communicated via: _____ Phone (____) ____ - _____ In-person

Progress Note (complete and place SBAR/progress note in medical record)

_____
_____
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_____

__ Family or health care proxy notified
Return call/new orders from MD/NP/PA Date___/___/___ Time___/___AM/PM

_____
_____

Signature_____ RN/LPN Date___/___/___ Time___/___AM/PM

This SBAR is developed specifically for antipsychotic, off-label use. Facilities are encouraged to modify/adapt changes to the SBAR as needed.

F757 & F758

F757
(Rev. 173, Issued: 11-22-17, Effective: 11-28-17, Implementation: 11-28-17)

§483.45(d) Unnecessary Drugs—General.
Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—

§483.45(d)(1) In excessive dose (including duplicate drug therapy); or

§483.45(d)(2) For excessive duration; or

§483.45(d)(3) Without adequate monitoring; or

§483.45(d)(4) Without adequate indications for its use; or

§483.45(d)(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or

§483.45(d)(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.

F758
(Rev. 173, Issued: 11-22-17, Effective: 11-28-17, Implementation: 11-28-17)

§483.45(c)(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:
(i) Anti-psychotic;

(ii) Anti-depressant;
(iii) Anti-anxiety; and
(iv) Hypnotic

§483.45(e) Psychotropic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that--

§483.45(e)(1) 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;

§483.45(e)(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;

§483.45(e)(3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and

§483.45(e)(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in §483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.

§483.45(e)(5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.

INTENT: §483.45(d) Unnecessary drugs and §483.45(c)(3) and (e) Psychotropic Drugs
The intent of this requirement is that:

- *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;*
- *the facility implements gradual dose reductions(GDR) and non-pharmacological interventions, unless contraindicated, prior to initiating or instead of continuing psychotropic medication; and*
- *PRN orders for psychotropic medications are only used when the medication is necessary and PRN use is limited.*

NOTE: For concerns related to unnecessary medications, excluding psychotropic medications, surveyors should assess compliance with §483.45(d), F757.

For concerns related to psychotropic medications only, including the unnecessary medication requirements, surveyors should assess compliance with §483.45(c) and (e), F758.

The Guidance for these two tags is combined to avoid unnecessary duplication.

Although the regulatory language refers to "drugs," the guidance in this document generally will refer to "medications," except in those situations where the term "drug" has become part of an established pharmaceutical term (e.g., adverse drug event, and adverse drug reaction or consequence).

For purposes of this guidance, references to "the pharmacist" mean the facility's licensed pharmacist, whether employed directly by the facility or through arrangement.

The surveyor's review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents.

DEFINITIONS §483.45(d) Unnecessary drugs and §483.45(c)(3) and (e) Psychotropic Drugs
Definitions are provided to clarify terminology related to medications and to the evaluation and treatment of residents.

***"Adverse consequence"** is a broad term referring to unwanted, uncomfortable, or dangerous effects that a drug may have, such as impairment or decline in an individual's mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease) (adapted from The Merck Manual Professional Version, http://www.merckmanuals.com/professional/clinical-pharmacology/adverse-drug-reactions/adverse-drug-reactions.)*

NOTE: *Adverse drug reaction (ADR) is a form of adverse consequences. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or treatment. The term "side effect" is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.*

***"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, anti-psychotics, antiemetics, muscle relaxants; and*
- *Certain medications used to treat cardiovascular conditions, Parkinson's disease, urinary incontinence, gastrointestinal issues and vertigo.*

*"**Behavioral interventions**" are individualized, non-pharmacological approaches to care that are provided as part of a supportive physical and psychosocial environment, directed toward understanding, preventing, relieving, and/or accommodating a resident's distress or loss of abilities, as well as maintaining or improving a resident's mental, physical or psychosocial well-being.*

*"**Clinically significant**" refers to effects, results, or consequences that materially affect or are likely to affect an individual's mental, physical, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.*
*"**Expressions or indications of distress**" refers to a person's attempt to communicate unmet needs, discomfort, or thoughts that he or she may not be able to articulate. The expressions may present as crying, apathy, or withdrawal, or as verbal or physical actions such as: pacing, cursing, hitting, kicking, pushing, scratching, tearing things, or grabbing others.*

*"**Dose**" is the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.*

*"**Excessive dose**" means the total amount of any medication (including duplicate therapy) given at one time or over a period of time that is greater than the amount recommended by the manufacturer's label, package insert, and accepted standards of practice for a resident's age and condition.*

*"**Duplicate therapy**" refers to multiple medications of the same pharmacological class/category or any medication therapy that substantially duplicates a particular effect of another medication that the individual is taking.*

*"**Extrapyramidal symptoms (EPS)**" are neurological side effects that can occur at any time from the first few days of treatment with antipsychotic medication to years later. EPS includes various syndromes such as:*

- *Akathisia, which refers to a distressing feeling of internal restlessness that may appear as constant motion, the inability to sit still, fidgeting, pacing, or rocking.*
- *Medication-induced Parkinsonism, which refers to a syndrome of Parkinson-like symptoms including tremors, shuffling gait, slowness of movement, expressionless face, drooling, postural unsteadiness and rigidity of muscles in the limbs, neck and trunk.*
- *Dystonia, which refers to an acute, painful, spastic contraction of muscle groups (commonly the neck, eyes and trunk) that often occurs soon after initiating treatment and is more common in younger individuals.*

*"**Gradual Dose Reduction (GDR)**" is the stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued.*

*"**Indications for use**" is the identified, documented clinical rationale for administering a medication that is based upon an assessment of the resident's condition and therapeutic goals and 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.*

*"**Neuroleptic Malignant Syndrome (NMS)**" is a syndrome related to the use of medications, mainly antipsychotics, that typically presents with a sudden onset of diffuse muscle rigidity, high fever, labile blood pressure, tremor, and notable cognitive dysfunction. It is potentially fatal if not treated immediately, including stopping the offending medications.*

*"**Psychotropic drug**" is defined in the regulations at §483.45(c)(3), as "any drug that affects brain activities associated with mental processes and behavior." Psychotropic drugs include, but are not limited to the following categories: anti-psychotics, anti-depressants, anti-anxiety, and hypnotics.*

*"**Serotonin Syndrome**" is a potentially serious clinical condition resulting from overstimulation of serotonin receptors. It is commonly related to the use of multiple serotonin-stimulating medications (e.g., SSRIs, SNRIs, triptans, certain antibiotics). Symptoms may include restlessness, hallucinations, confusion, loss of coordination, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting and diarrhea.*

*"**Tardive dyskinesia**" refers to abnormal, recurrent, involuntary movements that may be irreversible and typically present as lateral movements of the tongue or jaw, tongue thrusting, chewing, frequent blinking, brow arching, grimacing, and lip smacking, although the trunk or other parts of the body may also be affected.*

GUIDANCE §483.45(d) Unnecessary drugs and §483.45(c)(3) and (e) Psychotropic Drugs

Medications are an integral part of the care provided to residents of nursing facilities. They are administered to try to achieve various outcomes, such as curing an illness, arresting or slowing a disease process, reducing or eliminating symptoms, or as part of diagnosing or preventing a disease or symptom.

Proper medication selection and prescribing (including dose, duration, and type of medication(s)) may help stabilize or improve a resident's outcome, quality of life and functional capacity. Any medication or combination of medications—or the use of a medication without adequate indications, in excessive dose, for an excessive duration, or without adequate monitoring—may increase the risk of a broad range of adverse consequences such as medication interactions, depression, confusion, immobility, falls, hip fractures, and death. The Beers Criteria for Potentially Inappropriate Medication Use in Older Adults provides information on safely prescribing medications for older adults, http://www.healthinaging.org/medications-older-adults/.

***NOTE:** References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.*

Intrinsic factors including physiological changes accompanying the aging process, multiple comorbidities, and certain medical conditions may affect the absorption, distribution, metabolism or elimination of medications from the body and may also increase an individual's risk of adverse consequences.

While assuring that only those medications required to treat the resident's assessed condition are being used, reducing the need for and maximizing the effectiveness of medications are important considerations for all residents. Therefore, as part of all medication management (especially psychotropic medications), it is important for the IDT to implement non-pharmacological approaches designed to meet the individual needs of each resident. Educating facility staff and providers about the importance of implementing individualized, non-pharmacological approaches to care prior to the use of medications may minimize the need for medications or reduce the dose and duration of those medications. Additional information as well as examples of non-pharmacological interventions may be found in other guidance for regulations at §483.40, Behavioral Health Services and §483.25, Quality of Care and Quality of Life.

The indications for initiating, withdrawing, or withholding medication(s), as well as the use of non-pharmacological approaches, are determined by assessing the resident's underlying condition, current signs, symptoms, and expressions, and preferences and goals for treatment. This includes, where possible, the identification of the underlying cause(s), since a diagnosis alone may not warrant treatment with medication. Orders from multiple prescribers or providers can increase the resident's chances of receiving unnecessary medications.

Staff and practitioner access to current medication references and pertinent clinical protocols helps to promote safe administration and monitoring of medications. One of the existing mechanisms to warn prescribers about risks associated with medications is the Food and Drug Administration (FDA) requirement that manufacturers include within the medication labeling warnings about adverse reactions and potential safety hazards identified both before and after approval of a medication, and what to do if they occur (Visit:http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/). Manufacturers are required to update labels to warn about newly identified safety hazards—regardless of whether causation has been proven and whether the medication is prescribed for a disease or condition that is not included in the "Indications and Usage" section of the labeling (so-called "off-label" or unapproved use). Federal regulations at 21 CFR 201.57 (a)(4) and (c)(1) also require manufacturers to place statements about serious problems or contraindications in a prominently displayed box that appears on the medication labelling and in greater detail in the full prescribing information that accompanies the medication. The boxed warning is reserved for prescription drugs that pose a significant risk of serious or life-threatening adverse effects, based on medical studies.

The facility's pharmacist is a valuable source of information about medications. Listings or descriptions of most significant risks, recommended doses, medication interactions, cautions, etc. can be found in widely available, standard references, and computer software and systems that provide up-to-date information. It is important to note that some of the medication

information found in many of these references is not specific to older adults or individuals residing in nursing homes. A list of resources and tools is provided at the end of this guidance.

MEDICATION MANAGEMENT

Medication management is based in the care process and includes recognition or identification of the problem/need, assessment, diagnosis/cause identification, management/treatment, monitoring, and revising interventions, as warranted as well as documenting medication management steps. The attending physician plays a key leadership role in medication management by developing, monitoring, and modifying the medication regimen in conjunction with residents, their families, and/or representative(s) and other professionals and direct care staff (the IDT).

When selecting medications and non-pharmacological approaches, members of the IDT, including the resident, his or her family, and/or representative(s), participate in the care process to identify, assess, address, advocate for, monitor, and communicate the resident's needs and changes in condition. This guidance is intended to help the surveyor determine whether the facility's medication management supports and promotes:

- *Involvement of the resident, his or her family, and/or the resident representative in the medication management process.*
- *Selection of medications(s) based on assessing relative benefits and risks to the individual resident;*
- *Evaluation of a resident's physical, behavioral, mental, and psychosocial signs and symptoms, in order to identify the underlying cause(s), including adverse consequences of medications;*
- *Selection and use of medications in doses and for the duration appropriate to each resident's clinical conditions, age, and underlying causes of symptoms and based on assessing relative benefit and risks to, and preferences and goals of, the individual resident;*
- *The use of non-pharmacological approaches, unless contraindicated, to minimize the need for medications, permit use of the lowest possible dose, or allow medications to be discontinued; and*
- *The monitoring of medications for efficacy and adverse consequences.*
- *Resident Choice –If a resident declines treatment, the facility staff and physician should inform the resident about the risks related to the lack of the medication, and discuss appropriate alternatives such as offering the medication at another time or in another dosage form, or offer an alternative medication or non-pharmacological approach.*
- *Advance Directives – A resident's advance directives may include withdrawing or withholding medications. Whether or not a resident has an advance directive, the facility is responsible for giving treatment, support, and other care that is consistent with the resident's condition and applicable care instructions, according to the resident's care plan. If there are concerns regarding Resident Choice or Advance Directives, consider investigating the requirements at §483.10, Resident Rights and §483.21, Care Planning.*

The resident's medical record documents and communicates to the entire team the basic elements of the care process and the resident's goals and preferences. Information about aspects of the care process related to medications may be found in various locations within the

record, such as: hospital discharge summaries and transfer notes, progress notes and interdisciplinary notes, history and physical examination, Resident Assessment Instrument (RAI), plan of care, laboratory reports, professional consults, medication orders, Medication Regimen Review (MRR) reports, and Medication Administration Records (MAR).

The regulations associated with medication management include consideration of:

- *Indication and clinical need for medication;*
- *Dose (including duplicate therapy);*
- *Duration;*
- *Adequate monitoring for efficacy and adverse consequences; and*
- *Preventing, identifying, and responding to adverse consequences.*

With regard to psychotropic medications, the regulations additionally require:

- *Giving psychotropic medications only when necessary to treat a specific diagnosed and documented condition;*
- *Implementing GDR and other non-pharmacologic interventions for residents who receive psychotropic medications, unless contraindicated; and*
- *Limiting the timeframe for PRN psychotropic medications, which **are not** antipsychotic medications, to 14 days, unless a longer timeframe is deemed appropriate by the attending physician or the prescribing practitioner.*
- *Limiting PRN psychotropic medications, which **are** antipsychotic medications, to 14 days and not entering a new order without first evaluating the resident.*

***NOTE:** While there may be isolated situations where a pharmacological intervention is required first, these situations do not negate the obligation of the facility to develop and implement non-pharmacological interventions. For additional information related to situations where a non-pharmacological intervention may be contraindicated, refer to §483.40(a)(2), Implementing non-pharmacological interventions.*

Indication for Use

The resident's medical record must show documentation of adequate indications for a medication's use and the diagnosed condition for which a medication is prescribed.
An evaluation of the resident by the IDT helps to identify his/her needs, goals, comorbid conditions, and prognosis to determine factors (including medications and new or worsening medical conditions) that are affecting signs, symptoms, and test results. This evaluation process is important when selecting initial medications and/or non-pharmacological approaches and when deciding whether to modify or discontinue a current medication. The evaluation also clarifies:

- *Whether other causes for the symptoms (including expressions or indications of distress that could mimic a psychiatric disorder) have been ruled out;*
- *Whether the physical, mental, behavioral, 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;*
- *Whether non-pharmacological approaches are implemented, unless clinically contraindicated for the resident or declined by the resident;*

- *Whether a particular medication is clinically indicated to manage the symptom or condition; and*
- *Whether the intended or actual benefit is understood by the resident and, if appropriate, his/her family and/or representative(s) and is sufficient to justify the potential risk(s) or adverse consequences associated with the selected medication, dose, and duration.*

The content and extent of the evaluation may vary with the situation and may employ various assessment instruments and diagnostic tools. Examples of information to be considered and evaluated may include, but are not limited to, the following:

- *An appropriately detailed evaluation of mental, physical, psychosocial, and functional status, including comorbid conditions and pertinent psychiatric symptoms and diagnoses and a description of resident complaints, symptoms, and signs (including the onset, scope, frequency, intensity, precipitating factors, and other important features);*
- *Each resident's goals and preferences;*
- *Allergies to medications and foods and potential for medication interactions;*
- *A history of prior and current medications and non-pharmacological interventions (including therapeutic effectiveness and any adverse consequences);*
- *Recognition of the need for end-of-life or palliative care; and*
- *The basis for declining care, medication, and treatment and the identification of pertinent alternatives.*
- *Documentation of indications of distress, delirium, or other changes in functional status.*

Circumstances that warrant evaluation of the resident and medication(s) include:

- *Admission or re-admission;*
- *A clinically significant change in condition/status;*
- *A new, persistent, or recurrent clinically significant symptom or problem;*
- *A worsening of an existing problem or condition;*
- *An unexplained decline in function or cognition;*
- *A new medication order or renewal of orders; and*
- *An irregularity identified in the pharmacist's medication regimen review. See F756 for guidance related to the medication regimen review.*
- *Orders for PRN psychotropic and/or antipsychotic medications which are not prescribed to treat a diagnosed specific condition or do not meet the PRN requirements for psychotropic and antipsychotic medications.*

Specific considerations related to these circumstances may include the following:

- *Admission (or Readmission) – Some residents may be admitted on medications for an undocumented chronic condition or without a clear indication as to why a medication was begun or should be continued. It is expected that the attending physician, pharmacist, and staff subsequently determine if continuing the medication is justified by evaluating the resident's clinical condition, risks, existing medication regimen, preferences, goals, and related factors.*
- *Multiple prescribers – Regardless of who the prescribers are, the continuation of a medication needs to be evaluated to determine if the medication is still warranted in the context of the resident's other medications and comorbidities. Medications prescribed by*

a specialist or begun in another care setting, such as the hospital, need to have a clinically pertinent documented rationale in the resident's medical record.

- *New medication order as an emergency measure – When a resident is experiencing an acute medical problem or psychiatric emergency (e.g., the resident's expression or action poses an immediate risk to the resident or others), medications may be required. In these situations, it is important to identify and address the underlying causes of the problem or symptoms. Once the acute phase has stabilized, the staff and prescriber consider whether medications are still relevant. Subsequently, the medication is reduced or discontinued as soon as possible or the clinical rationale for continuing the medication is documented. If the new medication is a psychotropic or antipsychotic medication ordered on a PRN basis, the PRN order(s) must be consistent with the requirements for PRN use of psychotropic and antipsychotic medications at §483.45(e)(3), (4), and (5). When psychopharmacological medications are used as an emergency measure, adjunctive approaches, such as individualized, non-pharmacological approaches and techniques must be implemented. Longer term management options should be discussed with the resident, their family, and/or representative(s).*
- *Psychiatric disorders or expressions and/or indications of distress – As with all symptoms, it is important to seek the underlying cause of the distress. Some examples of potential causes include delirium, pain, psychiatric or neurological illness, environmental or psychological stressors, dementia, or substance intoxication or withdrawal. Non-pharmacologic approaches, unless clinically contraindicated, must be implemented to address expressions or indications of distress. However, medications may be effective when the underlying cause of a resident's distress has been determined, non-pharmacologic approaches to care have been ineffective, or expressions of distress have worsened. Medications may be unnecessary and are likely to cause harm when given without a clinical indication, at too high of a dose, for too long after the resident's distress has been resolved, or if the medications are not monitored. All approaches to care, including medications, need to be monitored for efficacy, risks, benefits, and harm and revised as necessary.*

***NOTE**: Permission given by or a request made by the resident and/or representative does not serve as a sole justification for the medication itself.*

Dose

Medications are prescribed based on a variety of factors including the resident's diagnoses, signs and symptoms, current condition, age, coexisting medication regimen, review of lab and other test results, input from the IDT about the resident, including the resident's preferences and goals, the type of medication(s), and therapeutic goals being considered or used.

The route of administration influences a medication's absorption and ultimately the dose received. Examples of factors that can affect the absorption of medications delivered by transdermal patches include skin temperature and moisture, and the integrity of the patch. Similarly, the flow rate of intravenous solutions affects the amount received at a given time.

Duplicate therapy is generally not indicated, unless current clinical standards of practice and documented clinical rationale confirm the benefits of multiple medications from the same class

or with similar therapeutic effects. Some examples of potentially problematic duplicate therapy include, use of more than one product containing the same medication, concomitant use of drugs within the same class, or medications from different therapeutic categories with similar effects or properties. Additionally, the risk for duplication is particularly high during transitions of care, especially if medications are not tracked closely between locations or within the care settings. Documentation is necessary to clarify the rationale for and benefits of duplicate therapy and the approach to monitoring for benefits and adverse consequences.

Duration

Periodic re-evaluation of the medication regimen is necessary to determine whether prolonged or indefinite use of a medication is indicated. The clinical rationale for continued use of a medication(s) may have been demonstrated in the clinical record, or the staff and prescriber may present pertinent clinical reasons for the duration of use. Regarding PRN medications, it is important that the medical record include documentation related to the attending physician's or other prescriber's evaluation of the resident and of indication(s), specific circumstance(s) for use, and the desired frequency of administration for each medication. As part of the evaluation, gathering and analyzing information helps define clinical indications and provide baseline data for subsequent monitoring. Common considerations for appropriate duration may include:

- *A medication initiated as a result of a time-limited condition (for example, delirium, pain, infection, nausea and vomiting, cold and cough symptoms, or itching) is then discontinued when the condition has resolved, or there is documentation indicating why continued use is still relevant. Failure to review whether the underlying cause has resolved may lead to excessive duration.*
- *A medication administered beyond the stop date established by the prescriber, without evidence of clinical justification for continued use of the medication, may be considered excessive duration.*
- *A medication, which is prescribed on a PRN basis, is requested by the resident and/ or/administered by staff on a regular basis, indicating a more regular schedule may be needed.*

Monitoring for Efficacy and Adverse Consequences

The information gathered during the initial and ongoing evaluations and through conversations with the resident and, as appropriate, his or her family or representative is essential to:

- *Verify or differentiate the underlying diagnoses or other underlying causes of signs and symptoms.*
- *Incorporate into a comprehensive care plan that reflects person-centered medication related goals and parameters for monitoring the resident's condition, including the likely medication effects and potential for adverse consequences. Examples of this information may include the FDA boxed warnings or warnings of adverse consequences that may be rare, but have sudden onset, or that may be irreversible. If the facility has established protocols for monitoring specific medications and the protocols are accessible for staff use, the care plan may refer staff to these protocols;*
- *Optimize the therapeutic benefit of medication therapy and minimize or prevent potential adverse consequences;*
- *Establish parameters for evaluating the ongoing need for the medication; and*
- *Track progress and/or decline towards the therapeutic goal.*

Sources of information to facilitate defining the monitoring criteria or parameters may include cautions, warnings, and identified adverse consequences from:

- *Manufacturers' package inserts and boxed warnings;*
- *Facility policies and procedures;*
- *Pharmacists;*
- *Clinical practice guidelines or clinical standards of practice;*
- *Medication references; and*
- *Clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.*

Monitoring and accurate documentation of the resident's response to any medication(s) is essential to evaluate the ongoing benefits as well as risks of various medications. Monitoring should also include evaluation of the effectiveness of non-pharmacological approaches, such as prior to administering PRN medications.

Monitoring involves several steps, including:

- *Identifying the essential information and how it will be obtained and reported-- It is important to consider who is responsible for obtaining the information, which information should be collected, and how the information will be documented. The information that is collected depends on therapeutic goals, detection of potential or actual adverse consequences, and consideration of risk factors, such as:*
  - *Medication-medication, medication-food interactions;*
  - *Clinical condition (for example renal disease);*
  - *Properties of the medication;*
  - *Boxed warnings; and*
  - *Resident's history of adverse consequences related to a similar medication.*
- *Determining the frequency of monitoring-- The frequency and duration of monitoring needed to identify therapeutic effectiveness, achievement of resident goals, and adverse consequences will depend on factors such as clinical standards of practice, facility policies and procedures, manufacturer's specifications, and the resident's clinical condition and choices. Monitoring involves three aspects:*
  - *Periodic planned evaluation of progress toward the therapeutic goals;*
  - *Continued vigilance for adverse consequences; and*
  - *Evaluation of identified adverse consequences.*
- *Defining the methods for communicating, analyzing, and acting upon relevant information-- The monitoring process needs to identify who is to communicate with the prescriber, what information is to be conveyed, and when to ask the prescriber to evaluate and consider modifying the medication regimen.*
- *If the therapeutic goals are not being met or the resident is experiencing adverse consequences, it is essential for the prescriber in collaboration with facility staff, the pharmacist, and the resident to consider whether current medications and doses continue to be appropriate or should be reduced, changed, or discontinued. Serum concentration monitoring may be necessary for some medications. Abnormal or toxic serum concentrations must be evaluated for dosage adjustments. If serum concentrations are*

within normal ranges, each resident should still be evaluated for effectiveness and side effects.

- *Re-evaluating and updating monitoring approaches-- Modification of monitoring may be necessary when the resident experiences changes, such as:*
  - *Acute onset of signs or symptoms or worsening of chronic disease;*
  - *Addition or discontinuation of medications and/or non-pharmacological approaches, for example, a resident who takes warfarin regularly starts on a medication that interacts with warfarin, therefore more frequent blood work may be needed;*
  - *Addition or discontinuation of care and services such as enteral feedings; and*
  - *Significant changes in diet that may affect medication absorption or effectiveness or increase adverse consequences.*

Additional examples of circumstances that may indicate a need to modify the monitoring include: changes in manufacturer's specifications, FDA warnings, pertinent clinical practice guidelines, or other literature about how and what to monitor.

Adverse consequences related to medications are common enough to warrant serious attention and close monitoring. An HHS Office of the Inspector General (OIG) report released in February 2014 found approximately one in five SNF residents experienced at least one adverse even during their SNF stay. Thirty-seven percent of these events were related to medications and were often preventable, See the full report, Adverse Events in Skilled Nursing Facilities: National Incidence among Medicare Beneficiaries at http://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf.

Some adverse consequences may be avoided by:

- *Following relevant clinical guidelines and manufacturer's specifications for use, dose, administration, duration, and monitoring of the medication;*
- *Defining appropriate indications for use; and*
- *Determining that the resident:*
  - *Has no known allergies to the medication;*
  - *Is not taking other medications, nutritional supplements including herbal products, or foods that would be incompatible with the prescribed medication; and*
  - *Has no condition, history, or sensitivities that would preclude use of that medication.*
- *Responding to the resident's reported experience with medications and treatments they have received.*

The risk for adverse consequences increases with both the number of medications being taken regularly and with medications from specific pharmacological classes, such as anticoagulants, diuretics, psychotropic medications, anti-infectives, and anticonvulsants.[32] Adverse consequences can range from minimal harm to functional decline, hospitalization, permanent injury, and death. Use of a tool, such as the CMS Adverse Drug Event Trigger Tool may assist in identifying resident risk factors and triggers for adverse drug events as well as determine whether a facility has systems and processes in place to minimize risk factors and mitigate harm

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32 Handler, S.M., Wright, R.M., Ruby, C.M., Hanlon, J.T. (2006). Epidemiology of medication-related adverse events in nursing homes. The American Journal of Geriatric Pharmacotherapy, 4, pp. 264-272. Retrieved from http://www.sciencedirect.com/science/article/pii/S1543594606000559.

to residents. The tool is available on the CMS Nursing Home Quality Assurance and Performance Improvement website, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/Adverse-Drug-Event-Trigger-Tool.pdf.

One common adverse consequence is delirium, which presents as an alteration in attention and awareness associated with a change in cognition not explained by a current or emerging neurocognitive disorder. Delirium may result from medications as well as other factors including electrolyte imbalances or infections. While delirium is not always preventable, identifying and addressing risk factors may reduce the occurrence. 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.[33]

Delirium may go undiagnosed, be misinterpreted as dementia, or misdiagnosed as a psychiatric disorder, such as bipolar disorder. Delirium develops rapidly over a short period of time, such as hours or days, and usually follows a fluctuating course throughout the day. Additionally, the resident may have difficulty paying attention and be less aware of his or her surroundings. Delirium can be characterized as hyperactive (e.g., extreme restlessness, climbing out of bed), hypoactive (e.g., sluggish and lethargic), or mixed (e.g., normal level of activity with lowered awareness). Delirium is particularly common post-hospitalization; signs and symptoms may be subtle and therefore are often missed. Although generally thought to be short lived, delirium can persist for months. Recognizing delirium is critical, as failure to act quickly to identify and treat the underlying causes may result in poor health outcomes or death.

Negative psychosocial outcomes can also occur in relation to unnecessary medications, including psychotropic medications. These adverse consequences 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.

Psychotropic Medications and Antipsychotic Medications (F758 Only Guidance)

As clarified in the section on Indication for Use, residents must not receive any medications which are not clinically indicated to treat a specific condition. The medical record must show documentation of the diagnosed condition for which a medication is prescribed. This requirement is especially important when prescribing psychotropic medications which, as defined in this guidance, include, but are not limited to, the categories of anti-psychotic, anti-depressant, anti-anxiety, and hypnotic medications. All medications included in the psychotropic medication definition may affect brain activities associated with mental processes and behavior. Use of psychotropic medications, other than antipsychotics, should not increase when efforts to decrease antipsychotic medications are being implemented, unless the other types of psychotropic medications are clinically indicated. Other medications which may affect brain activity such as central nervous system agents, mood stabilizers, anticonvulsants, muscle relaxants, anti-cholinergic medications, antihistamines, NMDA receptor modulators, and over the counter natural or herbal products must also only be given with a documented clinical indication consistent with accepted clinical standards of practice. Residents who take these medications

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33 Fong, T.G., Davis, D., Growdon, M.E., Albuquerque, A., Inouye, S.K. (2015). The interface between delirium and dementia in elderly adults. The Lancet, 14, pp.823-832. Retrieved from http://thelancet.com/journals/laneur/article/PIIS1474-4422(15)00101-5/fulltext.

must be monitored for any adverse consequences, specifically increased confusion or over-sedation. The regulations and guidance concerning psychotropic medications are not intended to to supplant the judgment of a physician or prescribing practitioner in consultation with facility staff, the resident and his/her representatives and in accordance with appropriate standards of practice. Rather, the regulations and guidance are intended to ensure psychotropic medications are used only when the medication(s) is appropriate to treat a resident's specific, diagnosed, and documented condition and the medication(s) is beneficial to the resident, as demonstrated by monitoring and documentation of the resident's response to the medication(s).

Use of Psychotropic Medications in Specific Circumstances

***Acute or Emergency Situations**: When a psychotropic medication is being initiated or used to treat an emergency situation (i.e., acute onset or exacerbation of symptoms or immediate threat to health or safety of resident or others) related to a documented condition or diagnosis, a clinician in conjunction with the IDT must evaluate and document the situation to identify and address any contributing and underlying causes of the acute condition and verify the need for a psychotropic medication. Use of psychotropic medication to treat an emergency situation must be consistent with the requirements regarding PRN orders for psychotropic and antipsychotic medications and any continued use must be consistent with the requirements for gradual dose reduction (GDR).*

***Enduring Conditions**: Psychotropic medications may be used to treat an enduring (i.e., non-acute; chronic or prolonged) condition. Before initiating or increasing a psychotropic medication for enduring conditions, the resident's symptoms and therapeutic goals must be clearly and specifically identified and documented. Additionally, the facility must ensure that the resident's expressions or indications of distress are:*

- *Not due to a medical condition or problem (e.g., pain, fluid or electrolyte imbalance, infection, obstipation, medication side effect or poly-pharmacy) that can be expected to improve or resolve as the underlying condition is treated or the offending medication(s) are discontinued;*
- *Not due to environmental stressors alone (e.g., alteration in the resident's customary location or daily routine, unfamiliar care provider, hunger or thirst, excessive noise for that individual, inadequate or inappropriate staff response), that can be addressed to improve the symptoms or maintain safety;*
- *Not due to psychological stressors alone (e.g., loneliness, taunting, abuse), anxiety or fear stemming from misunderstanding related to his or her cognitive impairment (e.g., the mistaken belief that this is not where he/she lives or inability to find his or her clothes or glasses, unaddressed sensory deficits) that can be expected to improve or resolve as the situation is addressed; and*
- *Persistent--The medical record must contain clear documentation that the resident's distress persists and his or her quality of life is negatively affected and, unless contraindicated, that multiple, non-pharmacological approaches have been attempted and evaluated in any attempts to discontinue the psychotropic medication.*

***New Admissions:** Many residents are admitted to a SNF/NF already on a psychotropic medication. The medication may have been started in the hospital or the community, which can make it challenging for the IDT to identify the indication for use. However, the attending physician in collaboration with the consultant pharmacist must re-evaluate the use of the*

psychotropic medication and consider whether or not the medication can be reduced or discontinued upon admission or soon after admission. Additionally, the facility is responsible for:

- *Preadmission screening for mental illness and intellectual disabilities, see §483.20(k), F645 and F646; and*
- *Obtaining physician's orders for the resident's immediate care, see §483.20(a), F635.*

Monitoring of Psychotropic Medications: *When monitoring a resident receiving psychotropic medications, the facility must evaluate the effectiveness of the medications as well as look for potential adverse consequences. After initiating or increasing the dose of a psychotropic medication, the behavioral symptoms must be reevaluated periodically (at least during quarterly care plan review, if not more often) to determine the potential for reducing or discontinuing the dose based on therapeutic goals and any adverse effects or functional impairment.*

If the record shows evidence of adding other psychotropic medications or switching from one type of psychotropic medication to another category of psychotropic medication, surveyors must review the medical record to determine whether the prescribing practitioner provided a rationale.

Potential Adverse Consequences: *The facility assures that residents are being adequately monitored for adverse consequences such as:*

- ***General****: anticholinergic effects which may include flushing, blurred vision, dry mouth, altered mental status, difficulty urinating, falls, excessive sedation, constipation*
- ***Cardiovascular:*** *signs and symptoms of cardiac arrhythmias such as irregular heart beat or pulse, palpitations,lightheadedness, shortness of breath, diaphoresis, chest or arm pain, increased blood pressure, orthostatic hypotension*
- ***Metabolic:*** *increase in total cholesterol and triglycerides, unstable or poorly controlled blood sugar, weight gain*
- ***Neurologic:*** *agitation, distress, EPS, neuroleptic malignant syndrome (NMS), parkinsonism, tardive dyskinesia, cerebrovascular event (e.g., stroke, transient ischemic attack (TIA).*

If the psychotropic medication is identified as possibly causing or contributing to adverse consequences as identified above, the facility and prescriber must determine whether the medication should be continued and document the rationale for the decision. Additionally, the medical record should show evidence that the resident, family member or representative is aware of and involved in the decision. In some cases, the benefits of treatment may outweigh the risks or burdens of treatment, so the medication may be continued.

Antipsychotic Medications

As with all medications, the indication for any prescribed first generation (also referred to as typical or conventional antipsychotic medication) or second generation (also referred to as atypical antipsychotic medication) antipsychotic medication must be thoroughly documented in the medical record. While antipsychotic medication may be prescribed for expressions or indications of distress, the IDT must first identify and address any medical, physical, psychological causes, and/or social/environmental triggers. Any prescribed antipsychotic

medication must be administered at the lowest possible dosage for the shortest period of time and is subject to the GDR requirements for psychotropic medications.

Antipsychotic medications (both first and second generation) have serious side effects and can be especially dangerous for elderly residents. When antipsychotic medications are used without an adequate rationale, or for the sole purpose of limiting or controlling expressions or indications of distress without first identifying the cause, there is little chance that they will be effective, and they commonly cause complications such as movement disorders, falls with injury, cerebrovascular adverse events (cerebrovascular accidents (CVA, commonly referred to as stroke), and transient ischemic events) and increased risk of death. The FDA Boxed Warning which accompanies second generation anti-psychotics states, "Elderly patients with dementia-related psychosis treated with atypical anti-psychotic drugs are at an increased risk of death," https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053171.htm. The FDA issued a similar Boxed Warning for first generation antipsychotic drugs, https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124830.htm. .

Diagnoses alone do not necessarily warrant the use of an antipsychotic medication. Antipsychotic medications may be indicated if:

- *behavioral symptoms present a danger to the resident or others;*
- *expressions or indications of distress that cause significant distress to the resident;*
- *If not clinically contraindicated, multiple non-pharmacological approaches have been attempted, but did not relieve the symptoms which are presenting a danger or significant distress; and/or* [34]
- *GDR was attempted, but clinical symptoms returned.*

If antipsychotic medications are prescribed, documentation must clearly show the indication for the antipsychotic medication, the multiple attempts to implement care-planned, non-pharmacological approaches, and ongoing evaluation of the effectiveness of these interventions.

Gradual Dose Reduction for Psychotropic Medications

The requirements underlying this guidance emphasize the importance of seeking an appropriate dose and duration for each medication and minimizing the risk of adverse consequences. The purpose of tapering a medication is to find an optimal dose or to determine whether continued use of the medication is benefiting the resident. Tapering may be indicated when the resident's clinical condition has improved or stabilized, the underlying causes of the original target symptoms have resolved, and/or non-pharmacological approaches have been effective in reducing the symptoms.

There are various opportunities during the care process to evaluate the effects of medications on a resident's physical, mental, and psychosocial well-being, and to consider whether the

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34 Steinberg, M., Lyketsos, C.G. (2012). Atypical antipsychotic use in patients with dementia: managing safety concerns. The American Journal of Psychology, 169, pp. 900-906. Retrieved from http://ajp.psychiatryonline.org/doi/full/10.1176/appi.ajp.2012.12030342.

medications should be continued, reduced, discontinued, or otherwise modified. Examples of these opportunities include:

- *During the monthly medication regimen review, the pharmacist evaluates resident-related information for dose, duration, continued need, and the emergence of adverse consequences for all medications;*
- *When evaluating the resident's progress, the attending physician or prescribing practitioner reviews the total plan of care, orders, the resident's response to medication(s), and determines whether to continue, modify, or stop a medication; and*
- *During the quarterly MDS review, the facility evaluates mood, function, behavior, and other domains that may be affected by medications.*

The time frames and duration of attempts to taper any medication must be consistent with accepted standards of practice and depend on factors including the coexisting medication regimen, the underlying causes of symptoms, individual risk factors, and pharmacologic characteristics of the medications. Some medications (e.g., antidepressants, sedative/hypnotics, opioids) require more gradual tapering so as to minimize or prevent withdrawal symptoms or other adverse consequences. Close monitoring while medications are tapered will enable facility staff to determine whether a resident is experiencing side effects, changes in behavior, or withdrawal symptoms that originally prompted prescribing of the drug. However, some residents with specific, enduring, progressive, or terminal conditions such as chronic depression, Parkinson's disease psychosis, or recurrent seizures may need specific types of psychotropic medications or other medications which affect brain activity indefinitely.

***NOTE:** If the resident's condition has not responded to treatment or has declined despite treatment, it is important to evaluate both the medication and the dose to determine whether the medication should be discontinued or the dosing should be altered, whether or not the facility has implemented GDR as required, or tapering.*

The regulation addressing the use of psychotropic medications identifies the process of tapering as a GDR and requires a GDR, unless clinically contraindicated.

Within the first year in which a resident is admitted on a psychotropic medication or after the prescribing practitioner has initiated a psychotropic medication, the facility must attempt a GDR in two separate quarters (with at least one month between the attempts), unless clinically contraindicated. After the first year, a GDR must be attempted annually, unless clinically contraindicated.

For any individual who is receiving a psychotropic medication to treat expressions or indications of distress related to dementia, the GDR may be considered clinically contraindicated for reasons that include, but that are not limited to:

- *The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility; and*
- *The physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or increase distressed behavior.*

For any individual who is receiving a psychotropic medication to treat a disorder other than expressions or indications of distress related to dementia (for example, schizophrenia, bipolar mania, depression with psychotic features, or another medical condition, other than dementia, which may cause psychosis), the GDR may be considered clinically contraindicated for reasons that include, but that are not limited to:

- *The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or exacerbate an underlying medical or psychiatric disorder; or*
- *The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or exacerbate an underlying medical or psychiatric disorder.*

PRN Orders for Psychotropic and Antipsychotic Medications

In certain situations, psychotropic medications may be prescribed on a PRN basis, such as while the dose is adjusted, to address acute or intermittent symptoms, or in an emergency. However, residents must not have PRN orders for psychotropic medications unless the medication is necessary to treat a diagnosed specific condition. The attending physician or prescribing practitioner must document the diagnosed specific condition and indication for the PRN medication in the medical record.

The table below explains additional limitations for PRN psychotropic (other than antipsychotic medications) and PRN antipsychotic medications.

Type of PRN order	***Time Limitation***	***Exception***	***Required Actions***
PRN orders for psychotropic medications, excluding antipsychotics	*14 days*	*Order may be extended beyond 14 days if the attending physician or prescribing practitioner believes it is appropriate to extend the order.*	*Attending physician or prescribing practitioner should document the rationale for the extended time period in the medical record and indicate a specific duration.*
PRN orders for antipsychotic medications only	*14 days*	*None*	*If the attending physician or prescribing practitioner wishes to write a new order for the PRN antipsychotic, the attending physician or prescribing practitioner must first evaluate the resident*

Type of PRN order	*Time Limitation*	*Exception*	*Required Actions*
			to determine if the new order for the PRN antipsychotic is appropriate.

The required evaluation of a resident before writing a new PRN order for an antipsychotic medication entails the attending physician or prescribing practitioner directly examining the resident and assessing the resident's current condition and progress to determine if the PRN antipsychotic medication is still needed. As part of the evaluation, the attending physician or prescribing practitioner should, at a minimum, determine and document the following in the resident's medical record:

- *Is the antipsychotic medication still needed on a PRN basis?*
- *What is the benefit of the medication to the resident?*
- *Have the resident's expressions or indications of distress improved as a result of the PRN medication?*

***NOTE:** Report of the resident's condition from facility staff to the attending physician or prescribing practitioner does not constitute an evaluation.*

KEY ELEMENTS OF NONCOMPLIANCE
If any of the elements the sections below involve psychotropic medications, investigate F758. For all other medications, investigate F757.

To cite deficient practice at F757and/or F758, the surveyor's investigation will generally show:
Inadequate Indications for Use

***NOTE:** For concerns related to a medication that involves an inadequate indication for use and evidence shows the medication is also being used for the purpose of discipline or staff convenience rather than to treat the resident's medical symptoms, surveyors should evaluate whether evidence shows the medication is being used to sedate the resident or restrict the resident's movement or cognition and assess compliance with §483.10(e)(1) and §483.12(a)(2), F605, Right to Be Free From Chemical Restraints instead of citing both at F605 and F757 or F758 for the same evidence.*

- *Failure to document a clinical reason or a clinically pertinent rationale, for using medication(s) for a specific resident or for continuing medication(s) that may be causing an adverse consequence; or*
- *Prescribing or administering a medication despite an allergy to that medication, or without clarifying whether a true allergy existed; or*
- *Failure to consider relative risks and benefits or potentially lower risk medications before initiating medication(s) that present clinically significant risks; or*
- *Failure to provide a clinically pertinent explanation for concomitant use of two or more medications in the same pharmacological class; or*
- *Failure to consider other factors that may be causing expressions or indications of distress before initiating a psychotropic medication, such as an underlying medical*

condition (e.g., urinary tract infection, dehydration, delirium), environmental (lighting, noise) or psychosocial stressors; or

- *Administering a psychotropic medication(s), which the resident has not previously received, when it is not necessary to treat a specific condition that has been diagnosed and documented in the clinical record; or*
- *Failure to attempt non-pharmacological approaches, unless clinically contraindicated, in efforts to discontinue psychotropic medications.*

Inadequate Monitoring –

- *Failure to monitor the responses to or effects of a medication, or*
- *Failure to respond when monitoring indicates a lack of progress toward the therapeutic goal (e.g., relief of pain or normalization of thyroid function) or the emergence of an adverse consequence; or*
- *Failure to monitor for changes in psychosocial engagement resulting from adverse consequences of medications, (e.g., resident no longer participates in activities because medication causes confusion or lethargy); or*
- *Failure to monitor a medication consistent with the current standard of practice or manufacturer's guidelines; or*
- *Failure to carry out the monitoring that was ordered or failure to monitor for potential adverse consequences; or*
- *Failure to consider whether the onset or worsening of symptoms, or a change of condition, may be related to a medication; or*
- *Failure to monitor effectiveness of non-pharmacological approaches, unless clinically contraindicated, before prescribing and administering medications.*

NOTE: *Additional information as well as examples of non-pharmacological approaches may be found in other guidance for regulations at §483.40, Behavioral Health Services and §483.25, Quality of Care and Quality of Life.*

Excessive Dose (including duplicate therapy) –

- *Giving a total amount of any medication at one time or over a period of time that exceeds the amount recommended by the manufacturer's recommendations, clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or standards of practice for a resident's age and condition, without a documented clinically pertinent rationale; or*
- *Failure to consider periodically the continued necessity of the dose or the possibility of tapering a medication; or*
- *Failure to provide and/or document a clinical rationale for using multiple medications from the same pharmacological class.*
- *Failure to consider each resident's clinical condition as a factor in determining an appropriate dose, as adverse consequences may occur even when medication serum concentration levels are in the therapeutic range.*

Excessive Duration –

- *Continuation beyond the manufacturer's recommended time frames, the stop date or duration indicated on the medication order, facility-established stop order policies, or*

clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or current standards of practice, without documented clinical justification; or

- *Continuation of a medication after the desired therapeutic goal has been achieved, without evaluating whether there is a continued need for the medication, for example, use of an antibiotic beyond the recommended clinical guidelines or the facility policy without adequate reassessment and evaluation of the resident.*

Adverse Consequences

- *Failure to act upon (i.e., discontinue a medication or reduce the dose or provide clinical justification for why the benefit outweighs the adverse consequences) or report the presence of adverse consequence(s); or*
- *Failure to monitor for the presence of adverse consequences related to the use of medications (particularly high risk medications, such as warfarin, insulin, opioids, or medications requiring monitoring of blood work); or*
- *Failure to respond to the presence of adverse consequences related to the use of medications (particularly high risk medications, such as warfarin, insulin, or opioids).*

Psychotropic Medications

- *Failure to present to the attending physician or prescribing practitioner the need to attempt GDR in the absence of identified and documented clinical contraindications; or*
- *Use of psychotropic medication(s) without documentation of the need for the medication(s) to treat a specific diagnosed condition; or*
- *PRN psychotropic medication ordered for longer than 14 days, without a documented rationale for continued use; or*
- *Failure to implement person-centered, non-pharmacological approaches in the attempt to reduce or discontinue a psychotropic medication; or*
- *Administering a new PRN antipsychotic medication for which the resident had a previous PRN order (for 14 days) but the medical record does not show that the attending physician or prescribing practitioner evaluated the resident for the appropriateness of the new order for the medication.*

PROCEDURES: §483.45(d) Unnecessary drugs and §483.45(c)(3) and (e) Psychotropic Drugs

Investigating Concerns Related to Medication Regimen Review, Unnecessary Medications, and Psychotropic Medications

Use the Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element (CE) Pathway along with the interpretive guidelines when determining if the facility meets the requirements for, and when investigating concerns related to, Medication Regimen Review, Unnecessary Medications, and Psychotropic Medications.

Review the medications (prescription, over-the-counter medications, and nutritional supplements such as herbal products) currently ordered and/or discontinued by the prescriber at least back to the most recent signed recapitulation of all medications. Obtain a copy of the current orders if necessary. Gather information regarding the resident's mental, physical, functional, and

psychosocial status and the medication-related therapeutic goals identified in the care plan as the basis for further review.

Use the table below to guide observations, record review, and interviews with the resident or representative and relevant staff. Symptoms and signs described in the table may also be related to a resident's condition or disease. The surveyor may seek clarification about the basis of specific signs and symptoms from the attending physician and/or pharmacist.

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS	***REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT***

Determine if the resident has been transferred to acute care since the last survey and/or has recently (e.g., the previous 3 months) experienced a change in condition or currently has signs and symptoms, such as:
 	
• *Anorexia and/or unplanned weight loss, or weight gain*
• *Apathy*
• *Behavioral changes, unusual patterns (including increased expressions or indications of distress, social isolation or withdrawal)*
• *Bleeding or bruising, spontaneous or unexplained*
• *Bowel dysfunction including diarrhea, constipation and impaction*
• *Dehydration, fluid/electrolyte imbalance*
• *Depression, mood disturbance*
• *Dysphagia, swallowing difficulty*
• *Falls, dizziness, or evidence of impaired coordination*
• *Gastrointestinal bleeding*
• *Headaches, muscle pain, generalized or nonspecific aching or pain*
• *Lethargy*
• *Mental status changes, (e.g., new or worsening confusion, new cognitive decline, worsening of dementia (including delirium), 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).*
• *Psychomotor retardation (e.g., slowed speech, thinking, and body movements)*
• *Rash, pruritus*
	Review the record (including the care plan, comprehensive assessment, and other parts of the record as appropriate) to determine whether it reflects the following elements related to medication management for the resident:
	
	• *Clinical indications for use of the medication*
	• *Implementation of person-centered, non-pharmacological approaches to care*
	• *Dose, including excessive dose and duplicate therapy*
	• *Duration, including excessive duration*
	• *Consideration of potential for tapering/GDR or rationale for clinical contraindication*
	• *Monitoring for and reporting of:*
	  ○ *Response to medications and progress toward therapeutic goals and resident's goals*
	  ○ *Emergence of medication-related adverse consequences*
	• *Adverse consequences, if present and potentially medication-related, note if there was:*
	  ○ *Recognition, evaluation, reporting, and management by the IDT*
	  ○ *Physician action regarding potential medication-related adverse consequences*
	• *The residents goals and preferences for medications and treatments*

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS	*REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT*
• *Respiratory difficulty or changes* • *Sedation (excessive), insomnia, or sleep disturbance* • *Seizure activity* • *Urinary retention or incontinence* *If observations or record review indicate symptoms or changes in condition that may be related to medications, determine whether the facility considered medications as a potential cause of the change or symptom.*	

Interview the resident, his or her family, and representative(s) and the IDT, as needed to gather information about use of medications in the nursing home.

NOTE: *This review is not intended to direct medication therapy. However, surveyors are expected to review factors related to the implementation, use, monitoring, and documentation of medications.*

The surveyor is not expected to prove that an adverse consequence was directly caused by a medication or combination of medications, but rather that there was a failure in the care process related to considering and acting upon such possibilities.

If during the course of this review, the surveyor needs to contact the attending physician regarding questions related to the medication regimen, it is recommended that the facility's staff have the opportunity to provide the necessary information about the resident and the concerns to the physician for his/her review prior to responding to the surveyor's inquiries.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

Examples of some of the related requirements that may be considered when concerns have been identified include the following:

- *42 CFR §483.10(g)(14), F580, Notification of Changes*
  - *Review whether the facility contacted the attending physician regarding a significant change in the resident's condition in relation to a potential adverse consequence of a medication, or if the resident has not responded to medication therapy as anticipated and/or indicated.*
- *42 CFR §483.10 (c), F552, Planning and Implementing Care*
  - *Determine whether the resident was advised of her/his medical condition and therapy and was informed about her/his treatment including medications and the right to refuse treatments.*
- *42 CFR §483.24(c), F679, Activities*
  - *Review whether the facility provides activities that address a resident's needs and*

may permit discontinuation or reduction of psychotropic medications. Review also whether adverse consequences of medications interfere with a resident's ability to participate in activities.

- *42 CFR §483.24(a), F676, Activities of Daily Living*
  - *Review whether the facility had identified, evaluated, and responded to a new or rapidly progressive decline in function, development or worsening of movement disorders, increased fatigue and activity intolerance that affected the resident's ADL ability in relation to potential medication adverse consequences.*
- *42 CFR §483.40, F740, Behavioral Health Services*
  - *Review whether the facility had identified, evaluated, and responded to a change in behavior and/or psychosocial changes, including depression or other mood disturbance, distress, restlessness, increasing confusion, or delirium in relation to potential medication adverse consequences.*
- *42 CFR §483.30(a), F710, Physician Supervision*
  - *Review if the attending physician supervised the resident's medical treatment, including assessing the resident's condition and medications, identifying the clinical rationale, and monitoring for and addressing adverse consequences.*
- *42 CFR §483.30(b), F711, Physician Visits and 42 CFR §483.30(c), F712, Frequency of Physician Visits*
  - *Review if the attending physician or designee reviewed the resident's total program of care and wrote, signed, and dated progress notes covering pertinent aspects of the medication regimen and related issues.*
- *42 CFR §483.70(h), F841, Medical Director*
  - *Review whether the medical director, when requested by the facility, interacted with the attending physician regarding a failure to respond or an inadequate response to identified or reported potential medication irregularities and adverse consequences; and whether the medical director collaborated with the facility to help develop, implement, and evaluate policies and procedures for the safe and effective use of medications in the care of residents.*

DEFICIENCY CATEGORIZATION

See also the Psychosocial Outcome Severity Guide in Appendix P, Section E for additional information on evaluating the severity of psychosocial outcomes.

Examples of noncompliance that demonstrate severity at Level 4 include, but are not limited to:

- *Facility failure to take appropriate action (e.g., suspending administration of the anticoagulant) in response to an elevated INR for a resident who is receiving warfarin, resulting in either the potential or actual need to transfuse or hospitalize the resident.*
- *Failure to respond appropriately to an INR level that is above or 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 developing serotonin syndrome (e.g., confusion, motor restlessness, tremor) in a resident receiving a SSRI antidepressant, leading to the addition of medications with additive serotonin effect or medication to suppress the symptoms.*

- *Failure to recognize and respond to signs and symptoms of neuroleptic malignant syndrome (NMS).*
- *In the presence of initial gastrointestinal bleeding, i.e. blood in stool, the failure to recognize medication therapies (such as NSAIDs or COX-2 inhibitors, bisphosphonates) as potentially causing or contributing to the gastrointestinal bleed, resulting in the continued administration of the medication, until the resident required hospitalization for severe bleeding.*
- *Failure to recognize that symptoms of increased confusion and that newly developed inability to do activities of daily living are the result of an increased dose of a psychotropic medication given without adequate clinical indication.*
- *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 that they previously enjoyed, has difficulty concentrating and carrying on conversations, and spends most of the day isolated in his or her room, sleeping in a recliner or in bed. Use of the antipsychotic medication without an adequate clinical indication, GDR attempts, and non-pharmacological approaches resulted in psychosocial harm.*
- *Failure to re-evaluate the appropriateness of continuing a PRN antipsychotic medication, originally prescribed for acute delirium, which resulted in significant side effects from the medication. The resident, who had been ambulatory, 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.*

Examples of Level 3, Actual harm (physical or psychosocial) that are not immediate jeopardy, include, but are not limited to:

- *The facility failed to evaluate a resident's new medication regimen as the source of a resident's recent nausea. The prescriber then added a medication to treat the nausea, which caused agitation and insomnia.*
- *Failure to evaluate a resident for a GDR for a psychotropic medication originally prescribed to treat delirium. Delirium symptoms subsided but the resident remained drowsy and inactive.*

Examples of Level 2, No actual harm with a potential for more than minimal harm that is not immediate jeopardy, may include but are not limited to:

- *Facility failure to identify and act upon minor symptoms of allergic response to medications, such as a rash with mild itching to the abdomen and no other symptoms, causing minimal discomfort.*
- *The facility failed to monitor for response to interventions or for the emergence or presence of adverse consequences for a resident receiving a psychotropic medication. The resident has not yet experienced an adverse consequence or decline in function, but there is no evidence that the facility periodically monitors for social withdrawal, loss of interest in activities that were previously enjoyed, or over sedation.*
- *Facility failure to monitor for response or for the emergence or presence of adverse consequences for a resident who has not yet experienced an adverse consequence or*

decline in function, such as by monitoring hydration status and basic metabolic profile for a resident receiving diuretics or ACE inhibitors.

Severity Level 1: No Actual Harm with Potential for Minimal Harm

Severity Level 1 does not apply for this regulatory requirement because the failure of the facility to provide appropriate care and services to manage the resident's medication regimen to avoid unnecessary medications and minimize negative outcome places residents at risk for more than minimal harm.

RESOURCES AND TOOLS

The following resources and tools provide information on medications including box warnings, appropriate dosing, medication categories, drug interactions, and medication safety information. Some of these resources also assist in identifying the correct class of a medication (e.g., identifying whether a medication is an antipsychotic or other category of psychotropic medication). Additionally, the list includes some of the recognized clinical resources available for understanding the overall treatment and management of medical problems, symptoms and medication consequences and precautions.

- *U.S. Department of Health and Human Services, National Institute of Mental Health Web site, which includes publications and clinical research information www.nimh.nih.gov*
- *MedlinePlus, https://www.nlm.nih.gov/medlineplus/druginformation.html*
- *National Library of Medicine Drug Information Portal, http://druginfo.nlm.nih.gov/drugportal/drug/categories (medication class information).*
- *The Food and Drug Administration (FDA) webpage, Medwatch: The FDA Safety Information and Adverse Event Reporting Program, http://www.fda.gov/Safety/MedWatch/default.htm*
- *The University of Maryland Medical Center Drug Interaction Tool, http://umm.edu/health/medical/drug-interaction-tool*
- *American Medical Directors Association, www.amda.com*
- *American Society of Consultant Pharmacists, www.ASCP.com*

This list is not all-inclusive. CMS is not responsible for the content or accessibility of pages found at these sites. URL addresses were current as of the date of this publication.