Alabama Nursing Home Association
Important Information and Websites

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

   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:

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
Procedure so that you can do it at home?

Why did you select the facility discussed when you visited?

Was the facility discussed when you visited?

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IF NO, GET P661
B. Develop a post-discharge plan of care, including discharge instructions.

Reconciliation of all medications and post-discharge medications?

a. Develop a discharge summary which includes a recapture of the resident's stay, a final summary of the resident's status, and

2) Did the facility:

IF NO, GET P661

LTC hospital)

a. 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, or LTC

b. Document that the resident was asked about their interest in receiving information about transitioning to the community

c. Evaluate the DL, resident and/or resident representatives in developing a discharge plan that reflects the resident's current discharge needs

C. Critical Element Decisions

Critical Element Decisions:

1) Did the facility:

a. Provide updated notice when there were changes to the notification and was it presented to the resident

b. Did the notification include all required components (Reason, the accommodation to the discharge to the resident; resident representative, and a copy to the omnibus)

c. IF this was a facility-initiated discharge, was advance notice given

2) Did the facility provide a discharge summary to the receiving provider which includes all required components at P661?

Discharge Critical Element Pathway

CENTERS FOR MEDICAL & MENTAL SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
F658, Medicare/Fee Base Services F745, Residency Records F842, QAV/GAPPI (Task), Notification of Change F580, Professional Standards

OTHER TASKS, CARE AREAS (CA) AND TASKS (TASK) TO CONSIDER: Participation in Care Plan F553, Notification of Change F580, Professional Standards.

IF NO, the F623

understood at least 30 days in advance of the discharge? Did the notice meet all requirements at 483.15(c)(3) through (g) and (c)(8)?

IF NO, the F622

Was required discharge information documented in the resident's record and communicated to the receiving facility?

IF NO, the F622

non-participation, or the facility no longer operates.

(3) Does the resident's discharge meet the requirements at 483.15(c)(1) (c.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 individual in the facility was endangered, the facility, the resident no longer required services provided by the facility, the health or safety of the individual in the facility was endangered.

Discharge Critical Element Pathway
Preadmission Screening and Resident Review Critical Element Pathway
2. If pre-admission screening of residents expecting to be in the facility 30 days or less is not performed, in accordance with the State PASAR.

3. If there is evidence of Level 1 pre-screening of the resident to determine if the newly admitted resident has or may have had a MD, ID or a related condition prior to admission to the facility.

Critical Elements: Decisions

- Initial the behavior pathway [ ]
- Service interventions of consultation ( ) [If concerns are identified, mental health or disability services are being provided ( )]

- Review resident policies and procedures regarding Level 1 screening [ ]
- Review resident policies and procedures regarding Level 2 screening [ ]

Record Review:

- Admission was pre-screened ( )
- Admission was post-screened ( )
- Admission was determined after admission ( )
- Admission was determined after pre-screening ( )

Record Review for Level II PASAR evaluation and determination:

- The resident was not admitted to the facility for Level II PASAR evaluation and determination [ ]
- The resident was not admitted to the facility for Level II PASAR evaluation and determination [ ]

Other comments:

- Admission was determined after pre-screening [ ]
- Admission was post-screened [ ]
- Admission was determined after admission [ ]
- Admission was pre-screened [ ]
Pre Admission Screening and Resident Review Critical Element Pathway

1. Pre-admission screening was not identified with new evidence of possible serious MD, ID or a related condition.

2. The facility failed to document, or the appropriate state-designated authority, in accordance with the PASARR program, findings of assessment and the necessary care plan.

3. The facility failed to identify the resident to the Appropriate State-designated authority, in accordance with the PASARR program, findings of assessment and the necessary care plan.

4. The facility failed to document, or the appropriate state-designated authority, in accordance with the ongoing PASARR evaluation and documentation.

5. The facility failed to document, or the appropriate state-designated authority, in accordance with the PASARR program, findings of assessment and the necessary care plan.

6. The facility failed to document, or the appropriate state-designated authority, in accordance with the PASARR program, findings of assessment and the necessary care plan.

7. The facility failed to document, or the appropriate state-designated authority, in accordance with the PASARR program, findings of assessment and the necessary care plan.

8. The facility failed to document, or the appropriate state-designated authority, in accordance with the PASARR program, findings of assessment and the necessary care plan.
Resident assessment was not completed. The care plan was not developed or the plan did not have to be revised.

13. Did the facility reassess the effectiveness of the interventions and review and revise the resident care plan (with input from the resident or the resident’s representative) as needed?

12. Did the facility develop and implement a comprehensive, person-centered care plan that includes measurable objectives and interventions to meet the resident's medical, nursing, mental, and psychosocial needs and includes the resident's goals, desired outcomes, and preferences?

11. Did staff have the skills and qualifications to assess relevant care areas and who are knowledgeable about the resident's status, needs, strengths, and potential for change in status?

10. Was there 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?

9. If the condition or status were present at the time of the required comprehensive resident assessment and did not meet the criteria for a significant change in status assessment.

8. If the condition or status were present at the time of the required comprehensive resident assessment and did not meet the criteria for a significant change in status assessment, but the resident's mood, function, and cognition, physical needs or psychosocial needs were identified after completion of the required comprehensive resident assessment, did the facility: a. complete the required comprehensive resident assessment within 14 days of identifying the resident's condition or status?

7. If the comprehensive resident assessment was not completed or the care plan was not developed or the plan did not have to be revised.
Behavioral and Emotional Critical Element Pathway
Behavioral and Emotional Status Critical Element Pathway

Review the following in advance to guide observations and interventions:

- Review the most current comprehensive and most recent quarterly (if the comprehensive isn't the most recent) NDS/CAS
- Review the most recent OQ
- Review the most recent functional status (PSAR/AAP)

The necessary care and services necessary:

- Use this pathway to determine if the facility is providing the necessary care and services.
- Use this pathway to determine if the facility is providing the necessary care and services consistent with the resident's health care needs.
- If there are sufficient complaints to ensure resident safety and acceptable quality care principles.
- Psychosocial disorders to determine whether staff consistently apply resident's behavioral health care needs and service needs are being met?
- Are staff implementing care planned interventions to ensure the resident's well-being?
- Does the resident's self-isolation and service needs are being met?
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Care Plan

Care plan development to determine the rationale for the current interventions and changes in the resident's condition.

How often does the MDT meet to discuss the resident's behavioral condition and changes in both the care plan and condition communicated to the other Interdisciplinary team (IDT) members across various shifts?

Care Plan

Behavioral and Emotional Status Critical Element Pathway

Centers for Medicare & Medicaid Services
Department of Health and Human Services

When are the underlying causes of the resident's behavioral and emotional status identified?

Behavioral and Emotional Status Critical Element Pathway

Centers for Medicare & Medicaid Services
Department of Health and Human Services

When are the underlying causes of the resident's behavioral and emotional status identified?

Behavioral and Emotional Status Critical Element Pathway

Centers for Medicare & Medicaid Services
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When are the underlying causes of the resident's behavioral and emotional status identified?

Behavioral and Emotional Status Critical Element Pathway

Centers for Medicare & Medicaid Services
Department of Health and Human Services

When are the underlying causes of the resident's behavioral and emotional status identified?
No, the resident's condition is not currently deteriorating.

Was a significant change in the resident's condition documented in the resident's medical record?

Was the care plan revised, and were these actions necessary to meet the new needs of the resident?

Does the facility have sufficient and competent direct care staff to provide nursing and related services and implement non-pharmacological interventions?

Was the care plan revised to care-plan interventions? If interventions were ineffective, was the care plan revised and were these actions necessary to meet the new needs of the resident?

Was the resident's condition changed as a result of the interventions?

Does the facility have sufficient and competent direct care staff to provide nursing and related services and implement non-pharmacological interventions?

Did the facility provide the necessary behavioral health care and services to maintain the highest practicable physical, mental, and emotional well-being in accordance with the comprehensive assessment and plan of care?
Behavioral and Emotional Status Critical Element Pathway

1. Did the resident's condition change significantly in status, i.e., did the resident complete a significant change in status assessment within 14 days of determining the change?

   a. Yes, 90 days
   b. No, the F539

2. Did the condition of risks were present at the time of the required comprehensive assessment that the facility could identify, and the impact on the resident's physical, mental, and psychological needs?

   a. Yes
   b. No, the F539

3. Did the facility develop and implement a baseline care plan?

   a. Yes, the F455
   b. No

4. Did the facility ensure that the resident whose assessment did not reveal or who does not have a diagnosis of a mental disorder or behavioral disturbance difficulty, or a documented psychiatric history, or a history of trauma?

   a. Yes, the F434
   b. No, the F434

5. Did the facility provide appropriate treatment and services to correct the assessed problem for a resident whose diagnosis is not revealed or who does not have a diagnosis of a mental disorder or psychiatric disturbance?
Abuse Critical Element Pathway
The investigation to determine if staff are implementing the policies as written. Refer to P607.

Facility's abuse prevention policies and procedures provided during the interviewing Conferences (review only those confirmed necessary during

Complaints and facility-reported allegations of abuse, including any facility investigation reports, received since the last standard survey;

- Decisions reached to abuse (CASKER Report) and
- Reports from the Long-Term Care Administrators or other Caregivers;
- Resident, Representative, or Family Interviews, Observations, or Record Reviews;
- 

Source for this information may include:

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

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

- Witness;

Witnesses;

unless an act of abuse, you must document who committed the abusive act, the nature of the abuse, where and when it occurred, and potential

actions in accordance with the requirements at P605.5, P609, and P610. Including implementing safeguards to prevent another potential abuse. If you

result from deficiencies of the administrator(s) in its position, the survey team would then determine whether the facility takes appropriate

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

Suspicion of a crime or in an allegation of relationship

Refer to the investigative Protocol for P602-Requiring Reasonable Suspicion of a Crime, if a covered individual did not report a reasonable

Neighborhood pain, avoidable pressure, urinary, poor grooming, avoidable dehydration, lack of nutrition, care or medication of;

Refer to the Neglect #3 pathway to investigate complaints or concerns. Always follow the investigation outline,

Refer to the Neglect P602 Protocol found at P602 for concerns referred to in your community;

During the survey, refer to SC-620.3.3. In addition, for investigating other concerns:

Use this pathway for investigating an alleged violation of abuse to a resident. This would include allegations where a resident was deprived of goods

Abuse Critical Event Pathway

Centers for Medicare & Medicaid Services

Department of Health and Human Services
Have there been past encounters with the alleged perpetrator?

Do you feel safe?

and revealing? When and why revealing?

Did you go to the hospital or physician’s clinic for evaluation of the alleged abuse? Please describe, including the alleged victim’s response to the injuries (e.g., pain, swelling, difficulty in the alleged abuse), prior medical history, and medical treatments.

Did you suffer any injuries (e.g., bruises, cuts, bruises) from

applicable:

for the alleged victim/resident, representative's, document as

alleged abuse? If so, what actions were taken?

do you think the alleged abuse has occurred since you reported the occurrence?

Did you report it? If so, when was the last response?

Did you report the alleged abuse to any external entities (e.g., police, physician, another resident, etc.)?

Did you contact the alleged abuse?

on reporting the alleged abuse?

who did you report it to?

voice of victim

when

could identify the alleged perpetrator and any witnesses?

When and where did the alleged abuse occur?

alleged abuse?

Witin 1 hour?

When occurred prior to dinner and immediately following the group meal?

applicable:

for the alleged victim/resident, representative/ witness, ask as

the alleged victim, in order to ensure the presence of evidence, attempt to interview the alleged victim and witness as soon as possible.

alleged victim or representative and witnesses (s) interview:

Conclude private interviews unless the alleged victim requests the presence of a

A abuse critical element pathway
Abuse Critical Event Pathway

Alleged Perpetrator Interview: If the alleged perpetrator is a staff member, the staff member may have been suspended or reassigned until the investigation.

DO you have any other information you wish to share in regard to Reporting abuse, the facility's abuse policy and procedures?

- When, where, and what was the abuse?
- What measures have you received to address prevention?
- Supervision did you receive?
- What type of orientation, training, work assignments, and responsibilities have you worked in the facility?
- Why?
- Do you continue to have access to the alleged victim?
- Do you have any concerns when you have been assigned to this resident?
- Have you had any concerns when you have been assigned to this resident?

response:

If reported, what was the abuse that may be impacting the care that they receive? If so, what was the abuse?

The resident had any behavioral symptoms (e.g., combative behavior, frequent requests for assistance, calling our group name, etc.)

Do you remember the incident as it was described?

Have you noticed any negative changes (e.g., weight loss, behavior change) since the event?

When, where, and what was the response?

Was the staff member adequate?

For an allegation that a resident was deprived of goods or services:

- Was your relationship, if any, to the alleged victim?
- So which were you at?
- Were you present in the facility at the time of the alleged abuse?

- Where were you at?
- What information can you provide regarding the alleged abuse?
Abuse Critical Element Pathway

Did you report the alleged abuse? If so, describe.

Did the alleged perpetrator exhibit any behaviors or actions that were inappropriate in the context of the alleged abuse? If so, describe.

Has the resident had any changes in medication (e.g., psychiatric medicines) that may be impacting the resident’s health?

Has the resident had any changes in medication (e.g., weight loss, pressure ulcers) because of the failure to receive the care that the resident needs?

If so, to whom was the resident referred, if any?

If the alleged perpetrator was a visitor, did the visitor exhibit any behaviors or actions that were inappropriate in the context of the alleged abuse? If so, describe.

How did you report the alleged abuse to any supervisors/administrators?

If not reported, why not? What was their response?

If reported, do you think the information was received since you reported it?

If you report it, whom do you report it to, and were they able to address the issue?

Did the alleged perpetrator exhibit any behaviors or actions that were inappropriate in the context of the alleged abuse? If so, describe.

Did you have any concerns about the manner in which care is provided to the resident? If yes, describe.

If you took any actions to address the incident, what were they?

Did you take any actions to address the incident, if any?

How did the alleged perpetrator and victim exhibit any behaviors that were inappropriate in the context of the alleged abuse?

If you were familiar with the alleged victim, how did you react?

If you are familiar with the alleged victim, how did you react?

What actions did you take in response to the alleged abuse?

If you were familiar with the alleged victim, how did you react?

If you were familiar with the alleged victim, how did you react?

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If you were familiar with the alleged victim, how did you react?
Was the care plan implemented?

Did the care plan identify interventions to address any identified circumstances of what occurred prior to, during and after the alleged abuse?

Did you document any interventions referred to the alleged abuse and receive a referral to the internal investigation?

If the alleged perpetrator was a Resident:

Was any external entities (e.g., APS or law enforcement) contacted (i.e., who made the report to whom, and when?)

Did you report the alleged abuse?

If not reported, what was their response?

Did you report the alleged abuse to administration? Why did you address this?

If the alleged perpetrator was not a Resident:

Did the alleged perpetrator exhibit any behaviors that would provoke one another? If so, what actions were taken?

Was the alleged perpetrator provided with assistance?

Did the alleged perpetrator receive any treatment for grief?

Did you interview the alleged victim and identify the alleged perpetrator?

Did you interview the alleged victim, an eyewitness, and/or the alleged perpetrator?

Were there any impacts to the alleged victim's relationships?

Was there any evidence of a physical or psychological change in the alleged victim?

Was there any indication of a prior history of abuse, aggression, or assault?

If the alleged perpetrator is a visitor:

Were the visitor's review access and/or access to the facility reviewed?

Did you conduct an assessment of the alleged abuse?

Do you have knowledge of the alleged abuse?

If yes, do you have knowledge of the alleged abuse?

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If yes, do you have knowledge of the alleged abuse?

If yes, do you have knowledge of the alleged abuse?
When and when received results of the investigation? □
If yes, were questions related to the allegations raised.
When were any photographs or videos obtained related to the allegations raised?
Record reviews conducted related to the allegations raised and
Repetition, mistreatment, alleged perpetrator's actions, and behavior.
Describe if information was obtained.
□
Describe information was obtained.
□
Describe information was obtained.
□
Describe information was obtained.
□
Describe information was obtained.
□
Describe if information was reported to you related to the allegations raised.
When and where action was taken to resolve the alleged perpetrator?
Did medical/mental health care providers issue any recommendations?
When and where action was taken to resolve the alleged perpetrator?
What actions were taken to resolve the alleged perpetrator?
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What actions were taken to resolve the alleged perpetrator?
When and where action was taken to resolve the alleged perpetrator?
What actions were taken to resolve the alleged perpetrator?
Prevent abuse?

Did the QA/AA Committee receive the results of the investigation for the allegation of abuse?

QA/AA Person Interview:

What happened as a result of the investigation?

What was responsible for the investigation?

Advisory Interview:

Was there any related information regarding the allegation that may not be included in the investigation report?

Revisions:

When did you monitor reported allegations of abuse?

Have staff reported any concerns to you about the resident in a care or at the bedside?

Who is responsible for supervising and monitoring the delivery of care at the bedside, and what did you do?

Resident reports an allegation of abuse?

For an allegation that a resident was deprived of goods or services, was the resident reports an allegation of abuse?

Resident reports an allegation of abuse?

Was the resident deprived of goods or services that were taken, removed, destroyed, disposed of in any way, or without a resident's permission?

If the alleged perpetrator is an employee, were these previous allegations of abuse?

How do you monitor for potential or actual reported allegations of abuse?
new interventions implemented?

If interventions were unsuccessful, was the physician notified? Were the plans to monitor and supervise the resident

AFTER THE ALLEGED ABUSE, did staff separate the alleged victim and

were they revised and if so, what was changed?

If the interventions were not effective in reducing the behaviors, were other interventions implemented?

Monitor/Redirect

of the alleged perpetrator, and include interventions (e.g.,

provide others? Is the care plan addressing behaviors if any,

is there a portion of history of exhibiting any behaviors that would

after the alleged abuse?

What circumstances are documented (e.g., time, before, during and

Review the Alleged Perpetrators’ Records, if a resident:

walking?)

on the basis of increases, or recent difficulty with mobility or

Are there potential indicators of sexual abuse (e.g., STD’s, pregnancy or

scarring and/or STI’s symptoms)?

complaining of pain in general area, pulling/tearing

and there are sudden changes (e.g., sudden, unexpected or

are these changes in the alleged victim’s mood or demeanor before

were physical injuries noted related to the alleged abuse?

were resident’s relationships noted that other

When was the resident’s representation, protectivestaff observed?

When (if at all) did the alleged occur? When was it discovered

In what way have the residents’ inclusion?

review and by whom?

interpersonal or mitigate risks?

What steps/actions did the facility implement to reduce the alleged incidents in the facility? Can the facility ensure that, once a social

Was the alleged victim was assessed at risk for abuse (e.g., as

Review the Alleged Victim’s Records:

Abuse Critical Element Pathway
Abuse Critical Element Pathway

1. Did the facility have non-resident personnel who have: (tick)
   - JF No, the F600 or mental anguish?
   - JF Yes

2. Did the facility process a resident's request to be free from any type of abuse that results in, or has the likelihood to result in physical harm, pain,
   - JF No, the F600 or mental anguish?
   - JF Yes

Criteria: Decision:

Conducted an investigation:
   - AP's, Professional Licensing Board, and Law Enforcement

Review a copy of the report if another investigation is requested (i.e.,

- Investigative Report from Other Investigative Agencies (AP's, Professional Licensing Boards, Law Enforcement)

- Precedent History of Competency Concerns
- Was there a history of competency concerns?
- Were annual performance reviews conducted? Was there a management, abuse, neglect/abuse, and neglect/abuse? Was there a review of the above abuse? If so, describe.
- If a nurse aide:

- In the alleged perpetrator's personal file?

- Abuse Critical Element Pathway

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Abuse Critical Element Pathway

AND/OR

1) Did the facility develop, implement, and maintain in effective training program for all new and existing staff that includes training on activities investigated any such allegations and include training as required at paragraphs §438.957?

2) Did the facility develop and implement written policies and procedures that prohibit and prevent abusive, exploitive, or indecent activities?

3) 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

4) Did the facility develop, implement, and maintain in effective training program for all new and existing staff that includes training on activities

5) Does the facility’s in-service training for nurse aides include resident abuse prevention?

6) Did the facility develop and implement written policies and procedures to ensure reporting of suspected crimes within mandated timelines?

7) Identify the situation as an alleged violation involving abuse, including influenza of unknown source?

8) Immediately report the allegation to the administrator and to other officials, including to the State survey and certification agency, and APS.

9) Report the results of all investigations within five working days to the administrator of the designated representative and to other

10) Did the facility investigate thoroughly and report the results of all investigations within five working days to the administrator of the designated representative and to other

11) If no, cite P609

12) Whether employee against whom the complaint was made was evaluated as a result of investigation?

13) Whether employee against whom the complaint was evaluated was reprimanded or demoted, or reprimanded and retrained abuse prevention?

14) Did the facility develop, implement, and maintain in effective training program for all new and existing staff that includes training on activities investigated any such allegations and include training as required at paragraphs §438.957?

15) 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

16) For alleged violations of abuse, did the facility:

17) In accordance with State law (including to the State survey and certification agency)?

18) Officials in accordance with State law (including to the State survey and certification agency)?

19) Report the results of all investigations within five working days to the administrator of the designated representative and to other

20) Did the facility develop and implement written policies and procedures to ensure reporting of suspected crimes within mandated timelines?

21) Did the facility develop, implement, and maintain in effective training program for all new and existing staff that includes training on activities investigated any such allegations and include training as required at paragraphs §438.957?

22) 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

23) For alleged violations of abuse, did the facility:

24) In accordance with State law?
Sufficient and Competent Steering (Task) - QA/QAPI (Task).

Consequences R529, Reporting Reasonable Suspicion of a Crime R608, Accidents (CA), Social Services R745, Behavioral-Emotional Stress (CA),

Other Tasks - Care Areas (CA), and Tasks (Task) to Consider: Dignity (CA), Visions R562/R564, Notice of Rights and Rules R572, Privacy (CA),

IF NO to any of the above, file R610.

○ Take corrective action following the investigation if the allegation is verified.

Abuse Critical Element Pathway
Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway
Documentation of Indication, dose, route, duration and be reviewed 2-3 days after antibiotic initiation to assess response and:

- **Antibiotics** - interactions with other medications (e.g., warfarin), adverse effects (e.g., rash, diarrhea); prescriptions must include:
  - **Insulin** - monitoring of blood glucose levels, hyperglycemia (e.g., hyperglycemia), and symptoms of hypoglycemia.
  - **Diabetes** - oedema, proteinuria, signs of electrolyte imbalance.
  - **Valproate, thiazide diuretics**.

Ongoing assessments of lab values, implementation of new orders in response to lab values, documentation of lab values, implementation of new medications, testing, and other relevant changes should be monitored.

The following medications pose a high risk for adverse consequences and should be monitored:

- **Opioids** - assess pain, implement power program.
- **Anticoagulants** - Bleeding/bruising, monitoring, INR.
- **Antihypertensives** - Blood pressure, heart rate.

Demonstrate monitoring for each medication as appropriate:

- **Antibiotics** - use of infection assessment tools, antibiotic use, inotropic use.
- **Rashes** - demonstration of new medications, assessment of rash, background, assessment, and duration.
- **Interventions** - consider interventions to justify the potential risk(s) of adverse consequences, associated with the medication, dose, and duration.

Signs of symptoms, or side effects are present, consider additional investigations (e.g., calcium, vitamin D, electrolytes, electrolyte levels, potassium, liver function tests, kidney function tests, complete blood count).

Medication is discontinued, review for all medications previously ordered to determine if they are no longer indicated.

**DOCUMENT ANY ACCIDENTAL CLINICAL INDICATION FOR USE.**

Review all medications currently ordered or discontinued 90 days prior to the most recent medication reconciliation. Determine if the following:

- **Review** the most current comprehensive and most recent quarterly (if the comprehensive is not the most recent assessment), MedS/CAS for areas contributing to adverse outcomes, and evaluate.

**NOTE:** If the resident has a diagnosis of dementia and is receiving any psychotropic medications (including but not limited to antipsychotics, the Meds/CAS pathway may not be applicable.

**unnecessary medications,** psychotropic medications, and medication regimen review

**Critical Element Pathway**

Centers for Medicare & Medicaid Services
Department of Health and Human Services

unnecessary medications, psychotropic medications, and medication regimen review
The evaluation entails direct evaluation of the resident and assessment of the resident's needs. Direct observation, communication, and in-depth discussion with the resident and/ or family are crucial.

- A new PRN order for the psychotropic medication can be written unless the attending physician states otherwise. The resident is evaluated 14 days after the order is written.
- PRN orders for psychotropic medications are to be reviewed every 14 days. The attending physician may extend the order beyond 14 days if the resident is deemed appropriate by the attending physician.
- PRN orders for psychotropic medications are not to exceed 14 days. The attending physician must document in the record.
- PRN orders do not exceed PRN psychotropic medications unless necessary to treat a diagnosed specific condition which must be documented in the record.

- Demonstrate adherence to recommendations for as needed (PRN) psychotropic and antipsychotic medications.
- Non-pharmacological approaches must be attempted and documented instead of using psychotropic medications, where feasible.
- The PRN must be reviewed monthly to ensure clinical efficacy and continuation.
- GFRs are reported in two separate quarters with at least one month between the assessments.
- Within the first year in which a resident is admitted on a psychotropic medication or within the facility has initiated a psychotropic medication, a GFR must be completed and documented within 6 months of initiating treatment. The GFR will be reviewed and updated quarterly.

- Demonstrate a system for and documentation of general dose reduction (GDR) for psychotropic medications unless contraindicated.
- Advise the healthcare provider, including nurses and physicians, about the need for continued monitoring and addressing the presence of potential for adverse consequences.
- A clear clinical rationale from the attending physician/specialist for continuing a medication that may be causing an adverse reaction to the medication.

- Document the correlation between medications.
- Contamination with other medications in the same pharmacological class.
- Medications are not discontinued until the physician/specialist agrees.

- Document clinical rationale for continued use for the medication, as required.
- Document duration for each medication.
- Examine the patient's baseline performance of standards of practice.
- Document appropriate dosage for each medication.
- Examine the patient's overall effectiveness of each medication and make changes to the pharmacological intervention, when necessary.
- Preclude early termination of each medication, as required.
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- Preclude early termination of each medication, as required.

- All psychotropics — monitor behavioral expressions of disorientation, delusions, and hallucinations.

- Clinical Element Pathway
  - Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review

- Center for Medicare & Medicaid Services
- Department of Health and Human Services
Depression, apathy, or mood disturbance.

Behavioral changes or unusual behavior patterns or suicidal ideation.

Insomnia or sleep disturbances.

Sudden, serious, or unexplained abnormal weight gain.

Psychometic retardation (slowed speech, thinking, movement).

Psychomotor agitation (restlessness, pacing, hand wringing).

Muscle/spasticity path or unexplained abnormal movements.

Falls, dizziness, or headaches.

Difficulty swallowing.

Urinary retention, incontinence.

Bowel dysfunction (e.g., constipation, abdominal pain).

Breathing/holding, spontaneous or unexplained.

Rash, pruritus.

Dizziness.

Decrease in physical functioning (e.g., mobility or activities of daily living (ADLs)).

Anorexia/appetite changes, weight loss.

Adverse consequences that may be related to a medication:

Does the resident have psychosocial, behavioral, mental or physical

Right to be free from Chemical Restraints:

Assess compliance with §483.10(e)(1) and §483.12(a)(2), F605.

Are all of the resident's medical/surgical symptoms/etiology/other issues that would normally be addressed with a care plan now accountable for their behavior or discipline or disfigurement.

Are all of the resident's medical/surgical symptoms/etiology/other issues that would normally be addressed with a care plan now accountable for their behavior or discipline or disfigurement.

Disability?

Does the resident continue to show expressions or indicators of

How does the resident compare to other residents?

Does the resident continue to show expressions or indicators of

Does the resident compare to other residents?

When pharmacological interventions are used? Why was the
care provided?

When non-pharmacological approaches are used? Are they

Are care provided interventions implemented for medications that

Are non-pharmacological approaches implemented for care of

Preventive/health promoting activities to care? If the PRN

On a regular basis, GRP recommends medication is still needed.

Attending

Observations:

Interventions:

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

Have the resident's expression or indicators of distress improved as a result of the PRN antidepressive medication?

What is the benefit of the medication to the resident?

Whether the antidepressive medication is still needed on a PRN basis?

Whether the antidepressive medication is still needed on a PRN basis?

Resident's current conditions and progress to determine if the PRN antidepressive medication is still needed.

Attending
How do you assess whether each medication is effective?

How do you monitor for the medication to achieve the desired outcome?

How do you ensure that the medication is properly administered?

How do you monitor for significant adverse consequences?

Is the amount of medication exceeded the manufacturer's recommendations?

How do you determine what dose and duration is clinically appropriate?

How do you monitor for significant adverse consequences?

How do you monitor for medication-induced behavior?

How do you monitor for medication-induced behavior?

How do you determine what dose and duration is clinically appropriate?

How do you monitor for significant adverse consequences?

How do you ensure that the medication is properly administered?

How do you monitor for the medication to achieve the desired outcome?

How do you assess whether each medication is effective?

How do you determine what dose and duration is clinically appropriate?

How do you monitor for significant adverse consequences?

How do you ensure that the medication is properly administered?

How do you monitor for medication-induced behavior?

How do you monitor for medication-induced behavior?

How do you assess whether each medication is effective?

How do you monitor for the medication to achieve the desired outcome?

How do you ensure that the medication is properly administered?

How do you monitor for significant adverse consequences?

Is the amount of medication exceeded the manufacturer's recommendations?

How do you determine what dose and duration is clinically appropriate?

How do you monitor for significant adverse consequences?

How do you ensure that the medication is properly administered?

How do you monitor for medication-induced behavior?

How do you monitor for medication-induced behavior?

How do you assess whether each medication is effective?

How do you monitor for the medication to achieve the desired outcome?

How do you ensure that the medication is properly administered?

How do you monitor for significant adverse consequences?

Is the amount of medication exceeded the manufacturer's recommendations?

How do you determine what dose and duration is clinically appropriate?

How do you monitor for significant adverse consequences?
Question: Are these steps part of facility policy?

- Are you part of the IDT who reviews this resident's medications?
- What is the MR process for short-stay residents?
- Do you review and report to the attending physician, medical director, and DON any medications with the resident's medical need or adverse consequences?
- What are the psychotropic and multifaceted medications?
- How do you evaluate PRN medications, specifically PRN for residents who are not identified as an invalidate on the MRP?

- Do you include each resident's medical record in this monthly?
- Do you perform a monthly MRP (or more frequently if needed)?

Pharmacist Interview:

- Ask about any other elements concerning the surveyor's identified.

Psychotropic and multifaceted medications:

- Are the PRN orders consistent with PRN requirements for the resident is receiving PRN psychotropic or multifaceted
- How has the process changed for short-stay residents?
- What was the outcome for the resident's functional and overall function and quality of life?

- Under what circumstances is the MRP conducted more often than this year?
- How often is the MRP conducted and are medical charts included in the assessment?
- How did you involve the resident in decisions regarding medications?
- How did the resident's medication or medication-related concerns?
- Plan for implementation

- How do you monitor efforts to ensure they are implementing care
- How do you ensure a review of medications for GDR?
- How does the facility ensure a review of medications for GDR?
Critical Element Pathway

Critical Element: Medication, Psychotropic Medications, and Medication Review

2. For Inappropriate Medications: Did the facility ensure that each resident's medication regimen was free from unnecessary medications? (Note: If NO, cite F757)

If NO to any of the above, cite F756

Steps the pharmacist must take when an irregularity requires urgent action:
- Time frames for steps in the MRR process;
- Do they address, at a minimum:
  - C. Has the facility developed and implemented MRR policies and procedures?
  - A. Independently, if no action is taken:
  - B. Did the attending physician document:
  - Report irregularities to the attending physician, medical director, and the DON?
  - Conduct an MRR at least monthly, that included a review of the resident's medical record;

For the Medication Review (MRR):

- A. Did the licensed pharmacist:
- Conduct an MRR, at least monthly, that included a review of the resident's medical record;
Resident did not have a significant change in status.

\( N \)A. The intervention, comprehensive assessment had not yet been completed. Therefore, a significant change in status assessment is not required. OR the

Yes, the F679

the status change was significant?

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

\( N \)A. The resident was socially, physically, emotionally and psychologically isolated from the staff and residents, and did not meet criteria for a significant change assessment was not yet required. OR

\( N \)A. Conditions/issues were identified after completion of the required comprehensive assessment and did not meet the criteria for a significant change assessment.

\( N \)O. The F436 extend possible, and the impact upon the resident's function, mood, and condition.

evaluate the resident's physical, emotional, and psychological needs to identify the needs and to determine underlying causes, to the

Comprehensively assess the resident's physical, emotional, and psychological needs to identify the needs and to determine underlying causes, to the

6. If the condition of risks related to medications were present at the time of the required comprehensive assessment, did the facility

plan?

\( N \)A. 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.

\( N \)O. The F679.

5. Did the facility and resident determine and document the receive a written summary of the baseline care plan that the facility was able to understand?

Resident did not receive the order without first evaluating the resident.

\( N \)A. The resident was not prescribed psychotropic medications.

\( N \)O to any of the above, the F758

physician/physical prescription requires a written to explain the medication.

\( N \)A. Of psychotropic medications which are not for an antipsychotic medications are limited to 14 days, without exception and the remaining physical/physical prescription

\( N \)A. The resident was not prescribed psychotropic medications.

\( N \)O. The facility, psychiatric, and psychological needs to identify the needs and to determine underlying causes, to the

4. Did the facility conduct ongoing review for antipsychotic medications?

\( N \)A. The resident was not prescribed psychotropic medications.

\( N \)O to any of the above, the F758

physician/physical prescription requires a written to explain the medication.

\( N \)A. Of psychotropic medications which are not for an antipsychotic medications are limited to 14 days, without exception and the remaining physical/physical prescription

\( N \)A. The resident was not prescribed psychotropic medications.

\( N \)O. The facility, psychiatric, and psychological needs to identify the needs and to determine underlying causes, to the

3. For Psychotropic Medications, did the facility ensure that:

Critical Element Pathway

Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTER FOR MEDICA ROMA'S MEDICAL SERVICES
Federal Regulatory Groups
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: • 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.

<table>
<thead>
<tr>
<th>Type of Allegation</th>
<th>2 hour reporting</th>
<th>24 hour reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abuse without serious bodily injury</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Abuse with serious bodily injury</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Neglect without serious bodily injury</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neglect with serious bodily injury</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Mistreatment without serious bodily injury</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Mistreatment with serious bodily injury (likely rises to abuse)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Exploitation without serious bodily injury</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Exploitation with serious bodily injury (likely considered abuse)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Injuries of unknown source without serious bodily injury</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Injuries of unknown source with serious bodily injury</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Misappropriation of resident property</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

*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.
<table>
<thead>
<tr>
<th>IJ Component</th>
<th>Yes/No</th>
<th>Preliminary fact analysis which demonstrates whether key component exists.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Noncompliance:</strong> Has the entity failed to meet one or more federal health, safety, and/or quality regulations?</td>
<td>Yes/No</td>
<td>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.</td>
</tr>
<tr>
<td><strong>AND</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Serious injury, serious harm, serious impairment or death:</strong></td>
<td>Yes/No</td>
<td>Is there evidence that a serious adverse outcome occurred, or a serious adverse outcome is likely as a result of the identified noncompliance?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If Yes, in the blank space, briefly summarize the serious adverse outcome, or likely serious adverse outcome to the recipient.</td>
</tr>
<tr>
<td><strong>AND</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Need for Immediate Action:</strong></td>
<td>Yes/No</td>
<td>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?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If yes, in the blank space, briefly explain why.</td>
</tr>
</tbody>
</table>

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

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

Other ________________________________________________________________________________________

Signature ______________________________________ RN/LPN Date __/__/____ Time __/__/____ AM/PM
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)    ☐ Continued monitoring
☐ Change in/stop current med order(s)                   ☐ Lab work
☐ Provider visit (MD/NP/PA)

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
§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.

§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 labeling 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-medications, 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/oeti/reports/oeti-06-11-00370.pdf](http://oig.hhs.gov/oeti/reports/oeti-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. 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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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, anticholinergic 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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must be monitored for any adverse consequences, specifically increased confusion or oversedation. The regulations and guidance concerning psychotropic medications are not intended 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](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](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
- 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 benefitting 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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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.

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<tr>
<th>Type of PRN order</th>
<th>Time Limitation</th>
<th>Exception</th>
<th>Required Actions</th>
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<tr>
<td>PRN orders for psychotropic medications, excluding antipsychotics</td>
<td>14 days</td>
<td>Order may be extended beyond 14 days if the attending physician or prescribing practitioner believes it is appropriate to extend the order.</td>
<td>Attending physician or prescribing practitioner should document the rationale for the extended time period in the medical record and indicate a specific duration.</td>
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<tr>
<td>PRN orders for antipsychotic medications only</td>
<td>14 days</td>
<td>None</td>
<td>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.</td>
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<tr>
<td>Type of PRN order</td>
<td>Time Limitation</td>
<td>Exception</td>
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<td>to determine if the new order for the PRN antipsychotic is appropriate.</td>
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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 F757 and/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.

<table>
<thead>
<tr>
<th>SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS</th>
<th>REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>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:</td>
<td>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:</td>
</tr>
<tr>
<td>- Anorexia and/or unplanned weight loss, or weight gain</td>
<td>- Clinical indications for use of the medication</td>
</tr>
<tr>
<td>- Apathy</td>
<td>- Implementation of person-centered, non-pharmacological approaches to care</td>
</tr>
<tr>
<td>- Behavioral changes, unusual patterns (including increased expressions or indications of distress, social isolation or withdrawal)</td>
<td>- Dose, including excessive dose and duplicate therapy</td>
</tr>
<tr>
<td>- Bleeding or bruising, spontaneous or unexplained</td>
<td>- Duration, including excessive duration</td>
</tr>
<tr>
<td>- Bowel dysfunction including diarrhea, constipation and impaction</td>
<td>- Consideration of potential for tapering/GDR or rationale for clinical contraindication</td>
</tr>
<tr>
<td>- Dehydration, fluid/electrolyte imbalance</td>
<td>- Monitoring for and reporting of:</td>
</tr>
<tr>
<td>- Depression, mood disturbance</td>
<td>- Response to medications and progress toward therapeutic goals and resident’s goals</td>
</tr>
<tr>
<td>- Dysphagia, swallowing difficulty</td>
<td>- Emergence of medication-related adverse consequences</td>
</tr>
<tr>
<td>- Falls, dizziness, or evidence of impaired coordination</td>
<td>- Adverse consequences, if present and potentially medication-related, note if there was:</td>
</tr>
<tr>
<td>- Gastrointestinal bleeding</td>
<td>- Recognition, evaluation, reporting, and management by the IDT</td>
</tr>
<tr>
<td>- Headaches, muscle pain, generalized or nonspecific aching or pain</td>
<td>- Physician action regarding potential medication-related adverse consequences</td>
</tr>
<tr>
<td>- Lethargy</td>
<td>- The residents goals and preferences for medications and treatments</td>
</tr>
<tr>
<td>- Mental status changes, (e.g., new or worsening confusion, new cognitive decline, worsening of dementia (including delirium), inability to concentrate)</td>
<td></td>
</tr>
</tbody>
</table>
SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS

- 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.

REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT

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](http://www.nimh.nih.gov)
- 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](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](http://umm.edu/health/medical/drug-interaction-tool)
- American Medical Directors Association, [www.amda.com](http://www.amda.com)
- American Society of Consultant Pharmacists, [www.ASCP.com](http://www.ASCP.com)

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