

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

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

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

Review the Following in Advance to Guide Observations and Interviews:

- Review the most current comprehensive and most recent quarterly (if the comprehensive isn't the most recent assessment) MDS/CAAs for areas pertinent to the medications ordered such as adverse consequences and behaviors.
- Review all medications currently ordered or discontinued going back to the most recent signed recapitulation. Determine if the facility:
 - ✓ **Documents an acceptable clinical indication for use.**
 - Medication is prescribed for a diagnosed condition and not being used for convenience or discipline.
 - Medication is clinically indicated to manage a resident's symptoms or condition where other causes have been ruled out.
 - Signs, symptoms, or related causes are persistent or clinically significant enough (e.g., causing functional decline) to warrant the initiation or continuation of medication therapy.
 - Intended or actual benefit is sufficient to justify the potential risk(s) or adverse consequences associated with the medication, dose, and duration.
 - ✓ **Demonstrates use of written protocols or resources to guide antibiotic use.**
 - The use of infection assessment tools for antibiotic use for one or more infections (e.g., use of a Situation, Background, Assessment and Recommendation (SBAR) communication tool for UTI assessment, application of the Loeb minimum criteria for initiation of antibiotics).
 - ✓ **Demonstrates monitoring for each medication as appropriate.**
 - The following medications pose a high risk for adverse consequences and should be monitored:
 - **Opioids** – assess pain, implement bowel program.
 - **Anticoagulant** – bleeding/bruising, protime/international normalized ratio (PT/INR), interaction with other medications, facility must have policies around monitoring, lab work, communication of lab values, implementation of new orders in response to lab values and/or symptoms.
 - **Diuretics** – edema, potassium level, signs of electrolyte imbalance.
 - **Insulin** – monitoring of blood glucose levels, hemoglobin A1c (HbA1c), and symptoms of hyper/hypoglycemia.
 - **Antibiotics** – interactions with other medications (e.g., warfarin), adverse events (e.g., rash, diarrhea); prescriptions must include documentation of indication, dose, route and duration and be reviewed 2-3 days after antibiotic initiation to assess response and labs, and prescriber should reassess antibiotic selection as appropriate.

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- **All psychotropics** – monitor behavioral expressions or indications of distress.
- Facility staff, along with the pharmacist and prescribing practitioner recognize and evaluate the onset or worsening of signs or symptoms, or a change in condition to determine whether these potentially may be related to the medication regimen; and follow up as necessary upon identifying adverse consequences.
- Facility staff monitor the effectiveness of each medication and make changes to the pharmacological intervention, when necessary.
- ✓ **Demonstrates appropriate dosing for each medication.**
 - Is there documentation of a rationale for any medication that exceeds the manufacturer's recommendations, clinical practice guidelines, evidence based guidelines or standards of practice?
- ✓ **Documents duration for each medication.**
 - Medications are not used for an excessive duration.
- ✓ **Documents clinical rationale for continued use for the medications, as required.**
 - Tapering when clinically indicated in an effort to discontinue or reduce the dose.
 - Concomitant use of two or more medications in the same pharmacological class.
 - Potential incompatibilities between medications.
- ✓ **Demonstrates a system that monitors and addresses the presence of or potential for adverse consequences.**
 - A clear clinical rationale from the attending physician/prescribing practitioner for continuing a medication that may be causing an adverse consequence, including risks and benefits.
- ✓ **Demonstrates a system for and documents gradual dose reduction (GDR) for psychotropic medications, unless contraindicated.**
 - Within the first year in which a resident is admitted on a psychotropic medication or after the facility has initiated a psychotropic medication:
 - GDR attempts in two separate quarters with at least one month between the attempts.
 - The GDR must be attempted annually thereafter unless clinically contraindicated.
 - Non-pharmacological approaches must be attempted and documented instead of using psychotropic medications, along with use of psychotropic medications, and while GDR is attempted.
- ✓ **Demonstrates adherence to requirements for as needed (PRN) psychotropic and antipsychotic medications.**
 - Residents do not receive PRN psychotropic medications unless necessary to treat a diagnosed specific condition which must be documented in the record.
 - PRN orders for psychotropic medications which **are not** antipsychotic medications are limited to 14 days. The attending physician/prescriber may extend the order beyond 14 days if he or she believes it is appropriate. If the attending physician extends the PRN for the psychotropic medication, the medical record must contain a documented rationale and determined duration.
 - PRN orders for psychotropic medications which **are** antipsychotic medications are limited to 14 days. A PRN order for an antipsychotic cannot be renewed unless the attending physician/prescriber evaluates the resident to determine if it is appropriate to write a new PRN order for the antipsychotic medication. The evaluation entails direct evaluation of the resident and assessment of the

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resident's current conditions and progress to determine if the PRN antipsychotic medication is still needed. Attending physician/prescribing practitioner documentation of the evaluation should address:

- Whether the antipsychotic medication is 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 antipsychotic medication?

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

Observations:

- Are care planned interventions implemented for medications that pose a high risk for adverse consequences?
- What non-pharmacological approaches to care are used? Are they effective?
- What pharmacological interventions are used? Why was the medication used and was it effective (e.g., pain is relieved, distress is addressed)?
- How does staff respond and interact with the resident?
- Does the resident continue to show expressions or indications of distress? If so, how does staff respond?
- Are staff using a medication for convenience or discipline? If so, describe. (For concerns related to a medication that involves an inadequate indication for use and evidence shows the medication is also being used for the purpose of discipline or convenience rather than to treat the resident's medical symptoms, surveyors should assess compliance with §483.10(e)(1) and §483.12(a)(2), F605, Right to Be Free From Chemical Restraints.)
- Does the resident have psychosocial, behavioral, mental, or physical adverse consequences that may be related to a medication:
 - Anorexia/unplanned weight changes, edema;
 - Decline in physical functioning (e.g., mobility or activities of daily living (ADLs));
 - Rash, pruritus;
 - Bleeding or bruising, spontaneous or unexplained;
 - Respiratory changes;
 - Bowel dysfunction (e.g., cramping abdominal pain);
 - Urinary retention, incontinence;
 - Dehydration or swallowing difficulty;
 - Falls, dizziness, or headaches;
 - Muscle/nonspecific pain or unexplained abnormal movement;
 - Psychomotor agitation (restlessness, pacing, hand wringing);
 - Psychomotor retardation (slowed speech, thinking, movement);
 - Subdued, sedated, lethargic, or withdrawn;
 - Insomnia or sleep disturbances;
 - Mental status changes;
 - Behavioral changes or unusual behavior patterns; or
 - Depression, apathy or mood disturbance.

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Resident, Family or Resident Representative Interview:

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

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

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

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

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

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

Pharmacist Interview:

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

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Attending Practitioner, Medical Director, and DON Interviews:

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

Record Review:

- Was the underlying cause (medical, environmental, or psychosocial stressors) of the conditions or symptoms requiring the medication identified?
- If a medication was discontinued, was there evidence of a GDR, if applicable (e.g., for psychotropic and antipsychotic medications)?
- Did the pharmacist conduct an MRR for the resident at least once a month that included a review of the resident's medical record?
- Did the pharmacist identify and report all medication irregularities to the attending physician, medical director, and DON? Were the irregularities documented on a separate, written report? Were the reports acted upon?
- Did the attending physician document in the medical record that the irregularity was reviewed? What, if any, action was taken? What rationale was documented if no change was made to the medication regimen?
- If the resident had a change in condition such as, dehydration or acute illness, was the medication regimen reviewed? Did the pharmacist complete a MRR?
- Is there evidence of actual or potential adverse events, such as allergic reactions, inadequate monitoring? (Refer to the CMS Adverse Drug Event Trigger Tool).
- Was there a "significant change" in the resident's condition (i.e., will not resolve itself without intervention by staff or by implementing standard disease-related clinical interventions; impacts more than one area of health; requires IDT review or revision of the care plan)? If so, was a significant change comprehensive assessment conducted within 14 days?
- Is the MAR accurate, complete and followed according to standards of practice?
- For antibiotics: Are signs or symptoms of infection documented? Have appropriate diagnostic tests been obtained to inform antibiotic selection and continuation?
- What is the facility response when monitoring indicates a lack of progress toward the therapeutic goal?
- What individualized, non-pharmacological approaches were documented, specifically for residents who receive psychotropic medications?
- Review the facility's policies regarding psychotropic medications and MRR. Are they updated and maintained? Does the policy include timeframes for the steps in the process? Does the policy include the steps the licensed pharmacist must take for a medication irregularity that requires urgent action?

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Critical Elements Decisions:

1. For the **Medication Regimen Review (MRR)**:

A. Did the licensed pharmacist:

- Conduct an MRR, at least monthly, that included a review of the resident's medical record;
- Conduct an MRR more frequently, as needed; and
- Report irregularities to the attending physician, medical director, and the DON?

B. Did the attending physician document:

- Review of identified irregularity(ies);
- The action, if any, taken;
- A rationale if no action is taken?

C. Has the facility developed and implemented MRR policies and procedures?

- Do they address, at a minimum:
 - Time frames for steps in the MRR process;
 - Steps the pharmacist must take when an irregularity requires urgent action.

If No to any of the above, cite F756

2. For **Unnecessary Medications**: Did the facility ensure that each resident's medication regimen was free from unnecessary medications? (Note: If the unnecessary medication is a psychotropic medication, cite F758)

If No, cite F757

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

- they are used only to treat a specific, diagnosed, and documented condition;
- a GDR was attempted, unless clinically contraindicated, and non-pharmacological approaches to care were implemented;
- PRN use is only if necessary to treat a specific, diagnosed, and documented condition;
- PRN orders for psychotropic medications which **are not** for antipsychotic medications are limited to 14 days, unless the attending physician/prescribing practitioner documents a rationale to extend the medication;
- PRN orders which **are** for antipsychotic medications are limited to 14 days, without exception and the attending physician/prescribing practitioner did not renew the order without first evaluating the resident?

If No to any of the above, cite F758

NA, the resident was not prescribed psychotropic medications.

4. Did the facility conduct ongoing review for antibiotic stewardship?

If No, cite F881

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

If No, cite F655.

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

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

If No, cite F636

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

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

If No, cite F637

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

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

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

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

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