

Unnecessary Meds/Med Regimen Review Critical Element Pathway

Use for a sampled resident who has potentially unnecessary medications and has experienced a potential adverse outcome to determine whether facility practices are in place to identify, evaluate, and intervene for potential or actual unnecessary medications.

****If the resident has a diagnosis of dementia and is receiving any psychopharmacological medications (including but not limited to antipsychotic medications) the surveyor should refer to the checklist “Care for a Resident with Dementia” as a guide to determine the facility’s compliance at F309.****

Review the following to guide your observations and interviews:

1. Review all of the meds currently ordered and or discontinued by the prescriber going back to the most recent signed recapitulation. (Refer to the guidance at F329 of the SOM Appendix PP. Utilize Tables I and II). Determine if the facility:
 - Documents an acceptable clinical indication for use**
 - The following are not appropriate reasons to use antipsychotics
 - Wandering, restlessness or mild anxiety
 - Poor self-care or inattention or indifference to surroundings
 - Impaired memory
 - Insomnia
 - Sadness or crying alone that is not related to depression or other psychiatric disorders
 - Fidgeting or nervousness
 - Uncooperativeness (e.g., refusal/difficulty receiving care)
 - Demonstrates monitoring for each medication as appropriate**
 - The following high risk meds should be monitored
 - **Narcotics**- assess pain, implement bowel program
 - **Anticoagulant**- bleeding/bruising, PT/INRs, interaction with other medications
 - **Diuretics**- edema, K+ level, signs of electrolyte imbalance
 - Track appropriate behaviors for all **psychoactive medications**
 - Hypnotics, causes for insomnia, hours of sleep
 - Antidepressants, duplicative therapies, effectiveness
 - Demonstrates appropriate dosing of each medication**
 - Is there documentation of a rationale for any med that exceeds the manufacturer’s recommendations, clinical practice guidelines, evidence based guidelines or standards of practice?
 - Documents clinical rationale for continued use of the medication(s) as appropriate**
 - Including a clinical explanation for the concomitant use of two or more meds in the same pharmacological class
 - Potential incompatibilities between meds
 - Demonstrates a system that monitors and addresses the presence of or potential for adverse consequences as appropriate**
 - Ensure the physician provided a clear clinical rationale for continuing a med that may be causing an adverse consequence, including risks and benefits.
 - Demonstrates a system for and documents considerations for GDR as appropriate**
 - For a resident who is receiving an antipsychotic, a GDR is required, unless clinically contraindicated.
 - An attempt must be made with the first year in which a resident is admitted or after the facility has initiated an antipsychotic. The facility must make the attempts in two separate quarters with at least one month between the attempts and then annually thereafter unless clinically contraindicated.

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Review the following to guide your observations and interviews (continued)

2. Did the pharmacist conduct a MRR (medication regimen review),
 - Did the pharmacist identify and report any med irregularities?
 - Did the MD and DON act on the reported irregularities?
3. Allergies,
4. The most recent comprehensive MDS/CAAS (focus on areas pertinent to the meds ordered such as adverse consequences and behaviors, etc.), and
5. Care plan for high risk meds and individualized interventions, including non-pharmacological interventions.

Observation

Make observations as appropriate, over various shifts to corroborate the information obtained during the record review. You may also find it important to make further observations for information obtained from staff interviews. Potential pertinent observations are listed below. If further guidance is needed, surveyors should refer to the regulation and IG as they conduct the investigation.

- Are care planned interventions implemented for meds that pose a high risk for adverse consequences?
- Are non-pharmacological interventions being used?
- Observe for med effectiveness such as;
 - Analgesics – is pain relieved?
 - Psychoactive – is identified behavior/mood addressed?
- How does staff respond and interact with the resident?
- Does staff address the resident request for a med appropriately?
- Does the resident show mood or behavior concerns?
 - Does staff appropriately interact when the resident shows mood or behavior concerns (e.g., redirected, invited to an activity)?
- Observe for side effects and/or adverse consequences that may be related to the resident's current medication regimen.
 - Anorexia/unplanned weight changes, edema;
 - Behavioral changes or unusual behavior patterns;
 - Mental status changes or decline in physical functioning;
 - Sedation (excessive), changes in alertness;
 - Insomnia or sleep disturbances;
 - Rash, pruritus;
 - Bleeding or bruising, spontaneous or unexplained;
 - Respiratory changes;
 - Bowel dysfunction, urinary retention, incontinence;
 - Dehydration or swallowing difficulty;
 - Fall, dizziness, or headaches; and
 - Muscle/nonspecific pain or unexplained abnormal movement.

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Interview

*As part of the investigation, surveyors should attempt to initially interview **the most appropriate direct care staff member first**. Your interview question should be specific to the investigation at hand and based on findings from the record review and observations. Consider interviewing the CNA, DON, MD, CNP, PA, social services, and/or pharmacist as needed to complete the investigation. Only ask the probes that are pertinent to your investigation. If further guidance is needed, surveyors should refer to the regulation, IG, and investigative protocol as they conduct the investigation.*

Resident and/or representative:

- Has staff talked to you about which meds you are on and why you need to take them?
- Did staff discuss with you any goals for your meds?
- Were you provided any information on the risk and benefits of meds?
- Did staff discuss with you other alternatives (when appropriate) to taking some of the meds? Do you think that the med has helped (e.g., pain control, improvements in function, decrease in edema, mood)?
- Have you had any side effects from the med (ask about specific meds)?
- Do you have any allergies to any medications?

Staff, as appropriate:

- What, when, and to whom do you report changes (e.g., behavior or pain)?
- How are you made aware of the resident's daily care needs?
- What non-pharmacological approaches are used?
- What is the clinical indication for the high risk med?
- What is the facility monitoring for each high risk med?
 - What monitoring tools or systems are used?
 - How did the IDT team determine what should be monitored?
 - For antipsychotic or anti-anxiety meds, how did you determine what behavior to monitor?
 - How do you assure MD orders for med monitoring are implemented (e.g., hgA1C, PT/INR monitoring)?
 - How do you communicate relevant information regarding med monitoring for this resident to other team members?
- How do you assess whether each med is effective?
- Why does the resident have two meds in the same med class?
- How does the IDT team determine what dose and duration is clinically indicated?
 - If the amount of any med exceeds the manufacturer's recommendations, clinical practice guidelines, evidence-based guidelines or standards of practice, what is the rationale?
- How do you monitor for potentially clinical significant adverse consequences?
- Has the resident had a change in medical regimen, diet, weight loss, dehydration, or acute illness? If so, what was done to assess the possible consequences/complications for these changes due to possible meds?
- Has the resident had an adverse reaction? If so, what and how was the adverse reaction addressed?
- How does the facility evaluate whether meds should be continued, reduced, discontinued, or otherwise modified? And how often?
- How does the facility ensure a review of meds for required GDRs?
 - If the resident is on an antipsychotic: When did you attempt to reduce the med in the last year and what were the results?
 - If the MD denied a GDR: Did the MD provide a risk-benefit statement describing the contra-indications for a GDR?
- How do you monitor staff to ensure they are implementing care planned interventions?
- What was the rationale for the MD's decisions in managing the resident's meds and/or med-related issues or concerns?
- How did you involve the resident in decisions regarding meds?
- If problems were identified with the Medication Regimen Review (MRR):
 - How is the MRR conducted and how often?
 - Under what circumstances is the MRR conducted more often than monthly?
 - How are medication-related issues communicated to other staff, MD, residents/families?
 - 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 meds or adverse reactions?

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Pharmacist and physician, as appropriate:

- Pharmacist interview
 - Do you perform a monthly med review (or more frequently if needed)?
 - What are you reviewing (e.g., adequate indication, dose, continued need, and adverse consequences)?
 - Did you identify and report to the DON and attending MD any irregularities with this resident's med regimen?
 - If the pharmacist didn't identify your issue, ask the following:
 - What do you think of this issue?
 - Is this something you should've identified during the monthly review?
 - How is the MRR process conducted for short stay residents?
- Physician interview
 - Were you notified of med-related concerns?
 - If the MD wasn't notified, ask for his/her assessment of the med-related concern?
 - If the MD was notified about a med issue and the MD declined to address the issue: Why?
 - If a med is being used inappropriately (e.g., Seroquel for dementia): What is the rationale behind why the med is being used?

Record Review

You may need to return to the record to corroborate information from the observations and interviews. Potential pertinent items in the record are listed below. If further guidance is needed, surveyors should refer to the regulation, IG, and investigative protocol as they conduct the investigation.

- Underlying cause (medical, environmental, or psychosocial stressors) of the conditions or symptoms requiring the med?
- If a med was discontinued, was there evidence of tapering, if applicable (e.g., antipsychotic meds)?
- If the resident had a change in condition such as dietary needs, dehydration or acute illness, was the medication regimen reviewed? Did the pharmacist complete a MRR?
- Has the care plan been revised to reflect any changes?
- Ensure the MAR is accurate and followed according to standards of practice.
- Review facility policy and procedures for systems of monitoring residents on psychoactive meds?
- Facility response when monitoring indicates a lack of progress toward the therapeutic goal?

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Make compliance decisions below by answering the six Critical Elements.

Note: Remember if the facility failed to complete a comprehensive assessment resulting in a citation at F272, surveyors should not cite F279 and F280 as the facility could not have developed or revised a plan of care based on a comprehensive assessment they did not complete.

Critical Element

1. 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) of the resident's condition and the impact of use of the medication on the resident's function, mood, and cognition?
If No, cite F272
NA, condition/risks were identified after completion of the required comprehensive assessment and did not meet the criteria for a significant change MDS OR a comprehensive assessment is not required yet.
2. Did the facility develop a plan of care based on the assessment of the resident's conditions, risks, needs, and behaviors that was consistent with the resident's therapeutic goals and considered the need to monitor for effectiveness based on those therapeutic goals and for the emergence or presence of interventions to address the use of medications and prevent adverse consequences?
If No, cite F279
NA, the comprehensive assessment was not completed.
3. Did the facility provide or arrange for services to be provided by qualified persons in accordance with the resident's written plan of care and did the facility implement the care plan adequately and/or correctly?
If No, cite F282
NA, no provision in the written plan of care for the concern being evaluated.
4. Did the facility reassess the effectiveness of the interventions and review and revise the plan of care (with input from the resident or representative, to the extent possible), if necessary, to meet the needs of the resident?
If No, cite F280
NA, the comprehensive assessment was not completed OR the care plan was not developed OR the care plan did not have to be revised.
5. Did the facility ensure that each resident's medication regimen was free from unnecessary medications? An unnecessary medication is a medication used:
 - In excessive doses (including duplicate therapy); or
 - For excessive duration; or
 - Without adequate monitoring; or
 - Without adequate indication for its use; or
 - In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
 - Any combination of the reasons above.**If No, cite F329**
6. Did the licensed pharmacist:
 - Conduct a review of the drug regimen of the resident at least once a month?
 - Report irregularities if any to the attending physician and the director of nursing?
 - If there were irregularities, were these reports acted upon?**If No, cite F428**
N/A, the resident was just admitted and monthly drug regimen review is not required yet.

Other Tags and Care Areas to consider: F154, F155, Notification of Change (F157), F222, Abuse (F223, F224, F226), Choices (F155, F242, F246), Social Services (F250), F271, F274, F278, F281, Pain (F309), General Pathway for Diabetic Management (F309), F309 (dementia care), ADLs (F310, F311, F312), Urinary Incontinence (F312, F315), Behavioral and Emotional Status (F309, F319, F 320), Nutrition (F325), Hydration (F327), Sufficient Staffing (F353, F354), F385, F386, F425, Infection Control (F441), F498, F501, F514, QA&A (F520).

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Notes: