

**Job Aid 11 – Investigative Protocol  
Short Form**

## INVESTIGATIVE PROTOCOL UNNECESSARY MEDICATIONS - MEDICATION REGIMEN REVIEW CHECKLIST

Review the medications (prescription and over-the-counter medications and nutritional supplements such as herbal products) currently ordered and/or discontinued by the prescriber (e.g., physician order sheets and telephone orders), at least back to the most recent recapitulation/re-order of all medications, and obtain a copy of the current orders if necessary. Use this brief review to focus your observations of the resident.

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS	REVIEW OF MEDICATIONS RECORD REVIEW
<p>Determine if the resident has experienced a change in condition (including transfers to acute care since the last survey) or any of the following signs and symptoms:</p> <ul style="list-style-type: none"> <li>• Anorexia and/or unplanned weight loss, or weight gain</li> <li>• Behavioral changes, unusual behavior patterns (including increased distressed behavior)</li> <li>• Bowel dysfunction including diarrhea, constipation and impaction</li> <li>• Dehydration, fluid/electrolyte imbalance</li> <li>• Depression, mood disturbance</li> <li>• Dysphagia, swallowing difficulty</li> <li>• Excessive sedation, insomnia, or sleep disturbance</li> <li>• Falls, dizziness, or evidence of impaired coordination</li> <li>• Gastrointestinal bleeding</li> <li>• Headaches, muscle pain, generalized or nonspecific aching or pain</li> <li>• Mental status changes, (e.g., new or worsening confusion, new cognitive decline, worsening of dementia (including delirium))</li> <li>• Rash, pruritus</li> <li>• Seizure activity</li> <li>• Spontaneous or unexplained bleeding, bruising</li> <li>• Urinary retention or incontinence</li> </ul>	<p>Review all medications for the presence or absence of the following components:</p> <ul style="list-style-type: none"> <li>• Clinical indications for use</li> <li>• Dose, including excessive dose and duplicate therapy</li> <li>• Duration, including excessive dose</li> <li>• Monitoring</li> <li>• Adverse consequences, if present and potentially medication related. Note if there was initiation or recent discontinuation of a medication(s), or a change in dose</li> <li>• Gradual dose reduction (for antipsychotic medications unless clinically contraindicated) and behavioral interventions, when indicated</li> </ul> <p><b>NOTE:</b> Do not include medications in which the risk for harm is minimal, such as vitamins.</p>

If observations or record review indicate symptoms or changes in condition that may be related to medications, determine whether there was an evaluation of the medication regimen as a potential cause of the change or symptoms.

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RECORD REVIEW	INTERVIEWS
Review for compliance with the MRR requirements at F428.	Resident, family or responsible party: <ul style="list-style-type: none"> <li>• His/her participation in care planning and decision making</li> <li>• Whether approaches other than medications (as indicated) were discussed</li> <li>• His/her evaluation of the results of the medication therapy such as decreasing symptoms of pain, improving functional ability</li> </ul>
Determine if the pharmacist had identified and reported to the DON and attending physician any irregularities with the medication regimen including, for example: <ul style="list-style-type: none"> <li>• Emergence or existence of clinically significant adverse consequences</li> <li>• Excess dose or duration, lack of monitoring, lack of indication for use, lack of gradual dose reduction (as indicated) or behavioral interventions for residents receiving antipsychotics, medication interactions potentially affecting the medication's effectiveness</li> </ul>	If concerns about the required components or condition changes are identified that may be related to the medication regimen, interview knowledgeable staff to determine: <ul style="list-style-type: none"> <li>• Whether they were aware that the signs and symptoms may be adverse consequences related to the medication regimen</li> <li>• Whether they had contacted the attending physician to discuss the signs and symptoms and the current medication regimen</li> <li>• Whether and how the physician responded when informed of suspected adverse medication consequences</li> <li>• Whether the pharmacist had performed a medication regimen review and identified related signs and symptoms, or if the staff informed the pharmacist of them if they occurred after the last pharmacist visit</li> </ul>
Determine whether the attending physician and the director of nursing acted on any irregularities identified in the report. The responses from the attending physician could include the following: <ul style="list-style-type: none"> <li>• Changed the medication regimen in response to the concern raised in the report</li> <li>• After additional review provided a clinically pertinent rationale: <ul style="list-style-type: none"> <li>- Relevant to the resident's signs and symptoms, prognosis, test results, etc. documenting or indicating why the benefit of the medication(s) or dose(s) outweighed the risks of the adverse consequence;</li> <li>- For why any GDR (for antipsychotic medications) and/or tapering (for other medications) is contraindicated, even for a trial period; or</li> <li>- Why a particular medication, dose, or duration is appropriate for a resident despite its risks.</li> </ul> </li> </ul>	Contact the attending physician(s) to follow up on any concerns identified related to the resident's medication regimen.
If the pharmacist and/or staff identifies medication(s) that they believe may be causing a serious adverse consequence or a risk of clinically significant adverse consequences, and the attending physician did not address the risks or harm to the resident, determine what steps staff took. For example, contacting the medical director to review and address the issue with the attending physician.  See guidance at 42 CFR 483.75(i) Medical Director (F501) for additional guidance.	Interview the pharmacist, as indicated, to determine how he/she: <ul style="list-style-type: none"> <li>• Identifies a resident's condition changes or is advised of changes</li> <li>• Determines the frequency and extent of the medication review and under what circumstances a review might be conducted more often than monthly</li> <li>• Conducts the MRR for short stay residents</li> </ul>