

BACKGROUND

F757 of the CMS State Operations Manual Appendix PP provides guidance to Long Term Care Facility (LTCF) surveyors regarding **Unnecessary Medications**.

Last month's Compliance Cue, covering F756 – Medication Regimen Reviews, noted that medication "irregularities" captured by the MRR should include **unnecessary medications**. Surveyors are instructed to cite inappropriately addressed issues of unnecessary medication utilization via the F757 tag.

REQUIREMENTS

§483.45(d) Drug Regimen Review

Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—

- (1) In excessive dose (including duplicate drug therapy)
- (2) For excessive duration
- (3) Without adequate monitoring
- (4) Without adequate indications for its use
- (5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued
- (6) Any combinations of [these] reasons

EXCESSIVE DOSE (INCLUDING DUPLICATE THERAPY)

- Administering medication that exceeds the amount prescribed, recommended by the manufacturer, per current clinical practice guidelines or evidence-based studies, or per accepted standards of practice for a resident's age and condition (without a documented clinically pertinent rationale); or
- Failure to periodically consider the continued necessity of the dose or possibility of dose tapering; or
- Failure to consider each resident's clinical condition as a factor in determining an appropriate dose; or
- Failure to document a clinical rationale for using multiple medications of the same pharmacological class.





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, per current clinical practice guidelines, evidence-based studies, or per 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
 - E.g.: use of an antibiotic beyond the recommended duration per clinical guidelines or the facility policy without adequate reassessment and evaluation of the resident.
 - Drug orders for acute conditions (those that may resolve in the foreseeable future) should utilize finite durations, to encourage evaluation of whether it is necessary to continue said medication(s) at future timepoints.

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.

INADEQUATE INDICATIONS FOR USE

• 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.

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 and/or respond to the presence of adverse consequences related to the use of medications (e.g., particularly high-risk medications, such as warfarin, insulin, opioids, or medications requiring monitoring of blood work).

*A FREQUENT SOURCE OF POTENTIAL DEFICIENCIES IDENTIFIED BY PHARMERICA'S CONSULTANT PHARMACISTS!

KEY QUESTIONS FOR SURVEYORS

Did the facility ensure that each resident's medication regimen was free from unnecessary medications?

If a 'No' response is warranted, surveyors may cite F757.

Note: if the unnecessary medication in question is a psychotropic medication, surveyors may cite F758.

NONCOMPLIANCE DEFICIENCY EXAMPLE

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.





STEPS TO FACILITY COMPLIANCE

- Employ the services of a licensed pharmacist to conduct MRRs that include focused evaluations for unnecessary drugs and the reporting of any such identified irregularities, examining for:
 - o Documented indication and clinical need for every medication ordered
 - o Appropriateness of ordered medication dose (including duplicate therapy)
 - Appropriateness of ordered duration of therapy
 - o Adequate monitoring for efficacy and adverse consequences
 - o Preventing, identify, and responding to adverse consequences
- Establish the expectation for facility prescribers to document their review of any pharmacistidentified irregularities with action taken, such that unnecessary drugs are not continued.
- Develop, implement and maintain policies and procedures for facility prescribers to consider and document the necessity of every medication ordered, with indications clearly provided in resident medical charts.
- Ensure care plans consider non-pharmacologic interventions before or adjunct to pharmacologic therapies and that documentation records evaluation of their effectiveness.

HOW PHARMERICA CAN HELP

- Experienced and knowledgeable consultant pharmacists available to provide MRRs to evaluate for unnecessary drugs.
- Consultant pharmacists may be utilized to provide in-services and education to facility staff regarding pharmacy-related F-tags, including F757 – Unnecessary Drugs.

RESOURCES

Be aware that surveyors are encouraged to use the <u>Unnecessary Medications, Psychotropic</u> <u>Medications, and Medication Regimen Review Critical Element Pathway</u> (https://www.cms.gov/files/ zip/survey-resources.zip) [LTC Survey Pathways ⇔ CMS-20082] when investigating concerns related to Unnecessary Drugs.

