COMPLIANCE CUE F756

Drug Regimen Review, Report Irregular, Act On

BACKGROUND

F756 of the CMS State Operations Manual Appendix PP provides guidance to Long Term Care Facility (LTCF) surveyors regarding the **Drug Regimen Review**.

Note: regulatory language will interchangeably use the terms Drug Regimen Review (DRR) or Medication Regimen Review (MRR). Either phrase refers to a thorough evaluation of the resident's medication regimen, with the goal of promoting positive outcomes while minimizing adverse consequences and potential medication-associated risks.

The MRR scrutinizes information that may be found across numerous sources within the resident's records (e.g., the medication administration records, prescriber orders, progress, nursing, and consultant notes, the Resident Assessment Instrument, etc). The MRR also involves collaborating with members of the interdisciplinary team, including the resident/resident representatives, to assure that they are informed about treatment options, risks, and benefits, and they are involved in the decision-making process.

REQUIREMENTS

§483.45(c) Drug Regimen Review

(1) The drug regimen of each resident must be reviewed **at least once a month** by a licensed pharmacist.

(2) This review must include a review of the resident's **medical chart**.

(4) The pharmacist must report any **irregularities** to the attending physician and the facility's medical director and director of nursing, and these reports must be acted upon.

- (i) Irregularities include, but are not limited to … an **unnecessary drug.***
- (ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified.
- (iii) The attending physician must document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.

(5) The facility must develop and maintain **policies and procedures** for the monthly drug regimen review that include, but are not limited to, **time frames**** for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

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* A drug may be considered unnecessary when used in excessive dose (including duplicate drug therapy), excessive duration, without adequate monitoring, without adequate indications for its use, in the presence of adverse consequences which indicate the dose should be reduced or discontinued, or any combination of these reasons.

** In their Frequently Asked Question Related to LTC Regulations, Survey Process, and Training resource, CMS states, "We [CMS] expect individual facility policy to address these specific timeframes. An important factor in reporting and responding to irregularities is the potential for or presence of serious adverse consequences. Some irregularities may require immediate notification and response to prevent an adverse consequence to a resident."

KEY QUESTIONS FOR SURVEYORS

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 a 'No' response is provided to any of these questions, surveyors may cite **F756**.

KEYS TO COMPLIANCE

To Improve Compliance:

I. Employ the services of a licensed pharmacist to conduct mandatory MRRs.

II. Develop, maintain, and implement policies and procedures for MRRs to be conducted for all facility residents at least monthly (or more frequently, as indicated by resident conditions).

- Work with your servicing LTC pharmacy on this P&P and keep readily available to respond to survey inquiries.*

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KEYS TO COMPLIANCE

III. Ensure these MRR policies and procedures address the expected time frames for each step of the MRR process.*

IV. Ensure these MRR policies and procedures address steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.*

V. Ensure that the facility's MRR policies and procedures require the thorough evaluation of resident medical charts.

VI. Ensure that the facility's MRR policies and procedures call for the pharmacist to identify and report medication irregularities, including, but not limited to:

- Inadequate or absent indications for use,
- Significant potential for adverse consequences or interactions,
- Excessive doses (including duplicate therapy),
- Excessive durations, and
- Inadequate monitoring.

VII. Ensure that the facility's MRR policies and procedures call for the pharmacist to identify and report medications that could be causing or associated with new, worsening, or progressive signs and symptoms.

VIII. Establish the expectation for attending physicians to document their review of any pharmacist-identified irregularities with action taken or reason for non-action to address the irregularities.

** A frequent source of potential deficiencies identified by PharMerica's Consultant Pharmacists!*

NONCOMPLIANCE DEFICIENCY EXAMPLE

On the MRR, the pharmacist identified a resident prescribed an antipsychotic medication without a clinical indication. This placed the resident at likely risk for harm such as experiencing a fall, mental status changes, or sustained negative psychosocial outcomes. The medical record did not show evidence that the attending physician had reviewed and responded to the identified irregularity.

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STEPS TO FACILITY COMPLIANCE

- ✓ Develop, implement, and educate staff on policies and procedures for monthly MRRs.
- ✓ Ensure time frames are established for MRR processes.
- ✓ Create stepwise approaches for responding to irregularities identified in the MRR, prioritizing urgent/time-sensitive recommendations.
  - High priority recommendations (regarding irregularities with high clinical significance) should be addressed by midnight of the next calendar day.
  - Normal priority recommendations should be addressed within 30 days.

HOW PHARMERICA CAN HELP

- ✓ Experienced and knowledgeable consultant pharmacists available to provide MRRs in accordance with CMS requirements.
  - Proactively notify facility staff of approximate visit dates.
  - Communicate high priority irregularities/recommendations on same day.
  - Deliver normal priority recommendations within 48 hours.
- ✓ Consultant pharmacists available upon request to review facility policies and procedures for CMS compliance, to discuss recommendation response rate at quarterly QAPI meetings, and to identify potential barriers and improve response rates.
- ✓ Consultant pharmacists may be utilized to provide as needed staff education on select drug classes and therapeutics, as knowledge gaps are identified.

RESOURCES

Be aware that surveyors are encouraged to use the Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway [LTC Survey Pathways ⇨ CMS-20082] when investigating concerns related to Medication Regimen Reviews.