



HIGHLIGHTS OF F428 "Guidance to Surveyors" covered by E.P.I.C.

Location and Notification of Medication Regimen Review Findings

The pharmacist is expected to document either that no irregularity was identified or the nature of any identified irregularities. The pharmacist is responsible for reporting any identified irregularities to the attending physician and director of nursing. The timeliness of notification of irregularities depends on factors including the potential for, or presence of, serious adverse consequences. For example, immediate notification is indicated in cases of bleeding in a resident who is receiving anticoagulants or in cases of possible allergic reactions to antibiotic therapy. If no irregularities were identified during the review, the pharmacist includes a signed and dated statement to that effect. The facility and the pharmacist may collaborate to identify the most effective means for assuring appropriate notification. This notification may be done electronically.

The pharmacist does not need to document a continuing irregularity in the report each month if the pharmacist has deemed the irregularity to be clinically insignificant or evidence of a valid clinical reason for rejecting the pharmacist's recommendation was provided. In this situation, the pharmacist need only reconsider annually whether to report the irregularity again or make a new recommendation.

The pharmacist's findings are considered part of each resident's clinical record. If documentation of the findings is not in the active record, it is maintained within the facility and is readily available for review. The interdisciplinary team is encouraged to review the reports and to get the pharmacist's input on resident problems and issues. Establishing a consistent location for the pharmacist's findings and recommendations can facilitate communication with the attending physician, the director of nursing, the remainder of the interdisciplinary team, the medical director, the resident and his or her legal representative (in accord with 42 CFR 483.10(b)(2), (d)(2)), ombudsman (with permission of the resident in accord with 42 CFR 483.10(j) (3)), and surveyors.

Response to Irregularities Identified in the MRR

Throughout this guidance, a response from a physician regarding a medication problem implies appropriate communication, review, and resident management, but does not imply that the physician must necessarily order tests or treatments recommended or requested by the staff, unless the physician determines that those are medically valid and indicated.

For those issues that require physician intervention, the physician either accepts and acts upon the report and potential recommendations or rejects all or some of the report and provides a brief explanation of why the recommendation is rejected, such as in a dated progress note. It is not acceptable for a physician to document only that he/she disagrees with the report, without providing some basis for disagreeing.

If there is the potential for serious harm and the attending physician does not concur with or take action on the report, the facility and the pharmacist should contact the facility's medical director for guidance and possible intervention to resolve the issue. The facility should have a procedure to resolve the situation when the attending physician is also the medical director. For those recommendations that do not require a physician intervention, such as one to monitor vital signs or weights, the director of nursing or designated licensed nurse addresses and documents action(s) taken.

Investigative Protocol

Refer to the Investigative Protocol at F329 for evaluation of medication regimen review, "Determination of Compliance" (Task 6, Appendix P)

Synopsis of regulation (F428)

- This requirement has four aspects relating to the safety of the resident's medication regimen, including:
- A review by the pharmacist of each resident's medication regimen at least once a month or more frequently depending upon the resident's condition and the risks or adverse consequences related to current medication(s) ;
 - The identification of any irregularities;
 - Reporting irregularities to the attending physician and the director of nursing; and
 - Action in response to irregularities reported.

Criteria for compliance

Compliance with 42 CFR 483. 60(c)(1) and (2), F428, Medication Regimen Review

The facility is in compliance with this requirement if:

- The pharmacist has performed a medication regimen review on each resident at least once a month or more frequently depending upon the resident's condition and/or risks or adverse consequence associated with the medication regimen;
- The pharmacist has identified any existing irregularities;
- The pharmacist has reported any identified irregularities to the director of nursing and attending physician; and
- The report of any irregularities has been acted upon.

For a complete copy of the CMS Guidelines contact your Pharma-Care/Creative Care Consultant or call 732-943-3573