- Determine if the facility diverted a resident's medication, including, but not limited to, controlled substances for staff use or personal gain. If it is determined that a resident's medications were diverted, the State Agency must make referrals to appropriate agencies, such as local law enforcement; Drug Enforcement Administration; State Board of Nursing; State Board of Pharmacy; the state Medicaid Fraud Control Unit, and possibly the State licensure board for Nursing Home Administrators.

- 42 CFR §483.35, F725, Sufficient Staff and F726, Competent Staff
  - Determine if the facility had competent staff in sufficient numbers available to provide medications on a 24-hour basis to meet the needs of the residents, based upon the comprehensive assessment and care plan.

- 42 CFR §483.45(g) and (h), F761, Labeling and Storage of Drugs and Biologicals
  - Determine if the facility properly labeled and stored all drugs and biological in accordance with currently accepted professional principles.

- 42 CFR §483.70(g), F841, Medical Director
  - Determine whether the medical director, in collaboration with the facility and the pharmacist, and based on current standards of practice, helped the facility develop procedures for the safe and accurate provision of medications to meet the needs of the residents.

- 42 CFR §483.70(h), F842, Medical Records
  - Determine whether the facility has maintained clinical records, including medication administration, in accordance with accepted professional standards and practices that are complete, accurately documented, and readily accessible.
- 42 CFR §483.75(g), F867, Quality Assessment and Assurance
  - If concerns regarding pharmaceutical services have been identified, determine whether the quality assessment and assurance committee has identified and responded to those concerns, as appropriate, and has developed, implemented, and monitored appropriate plans of action to correct identified quality deficiencies.

F756

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.45(c) Drug Regimen Review.

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

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

§483.45(c)(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, any drug that meets the criteria set forth in paragraph (d) of this section for 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.

§483.45(c)(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.

INTENT §483.45(c)(1), (2), (4), and (5)

The intent of this requirement is that the facility maintains the resident's highest practicable level of physical, mental and psychosocial well-being and prevents or minimizes adverse consequences related to medication therapy to the extent possible, by providing oversight by a licensed pharmacist, attending physician, medical director, and the director of nursing (DON).

NOTE: Although the regulatory language refers to "drug regimen review," the guidance in this document generally will refer to "medication regimen review," except in those situations where the term "drug" has become part of an established pharmaceutical term (e.g., adverse drug event, and adverse drug reaction or consequence).

DEFINITIONS §483.45(c)(1), (2), (4), and (5)

Definitions are provided to clarify terminology related to pharmaceutical services and the management of each resident's medication regimen for effectiveness and safety.

"Adverse consequence" is a broad term referring to unwanted, uncomfortable, or dangerous effects that a drug may have, such as impairment or decline in an individual's mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease) (adapted from The Merck Manual Professional

Version, http://www.merckmanuals.com/professional/clinical-pharmacology/adverse-drug-reactions/adverse-drug-reactions.)

NOTE: Adverse drug reaction (ADR) is a form of adverse consequence. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic and helpful effects of the medication or any response to a medication that is noxious and unintended and occurs in doses used for prophylaxis, diagnosis, or therapy. The term "side effect" is often used interchangeably with ADR; however, side effects are but one of five ADR categories. The others are hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not rise to the level of being an adverse consequence.

"Clinically significant" means effects, results, or consequences that materially affect or are likely to affect an individual's mental, physical, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.

"Dose" is the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.

"Irregularity" refers to use of medication that is inconsistent with accepted standards of practice for providing pharmaceutical services, not supported by medical evidence, and/or that impedes or interferes with achieving the intended outcomes of pharmaceutical services. An irregularity also includes, but is not limited to, use of medications without adequate indication, without adequate monitoring, in excessive doses, and/or in the presence of adverse consequences, as well as the identification of conditions that may warrant initiation of medication therapy. (See reference to F757 Unnecessary Drugs which defines unnecessary drugs in opening regulatory language.)

"Medication Interaction" is the impact of another substance (such as another medication, herbal product, food or substances used in diagnostic studies) upon a medication. The interactions may alter absorption, distribution, metabolism, or elimination. These interactions may decrease the effectiveness of the medication or increase the potential for adverse consequences.

"Medication Regimen Review (MRR)" or Drug Regimen Review is a thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences and potential risks associated with medication. The MRR includes review of the medical record in order to prevent, identify, report, and resolve medication-related problems, medication errors, or other irregularities. The MRR also involves collaborating with other members of the IDT, including the resident, their family, and/or resident representative.

GUIDANCE §483.45(c)(1), (2), (4), and (5)

A. OVERVIEW

Many nursing home residents have been identified as being at high risk for adverse consequences related to medications. Some adverse consequences may mimic symptoms of chronic conditions, the aging process, or a newly emerging condition.

This guidance is not intended to imply that all adverse consequences related to medications are preventable, but rather to specify that a system exists to assure that medication usage is evaluated on an ongoing basis, that risks and problems are identified and acted upon, and that medication-related problems must be considered when the resident has a change in condition. This guidance will discuss the following aspects of the facility's MRR component of the pharmaceutical services systems:

- A pharmacist's review of the resident's medication regimen and medical record to identify and report irregularities; and

- Acting upon identified irregularities in order to minimize or prevent adverse consequences, to the extent possible.

NOTE: The surveyor's review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents, including whether or not the resident, resident's family and/or representative were informed about risks, benefits and treatment options and involved in the decision-making process.

The review should take into account resident preferences and provide recommendations that assist facility staff in understanding and communicating to the resident any risks related to their preferences regarding medications or medication administration, as well as modifications that can be made to mitigate those risks.

Transitions in care such as a move from home or hospital to the nursing home, or vice versa, increase the risk of medication-related issues. Medications may be added, discontinued, omitted, or changed. It is important, therefore, to review the medications. Currently, safeguards to help identify medication issues around transitions in care and throughout a resident's stay include:

- The pharmacist performing the medication regimen review, which includes a review of the resident's medical record, at least monthly;

- The pharmacist reporting any irregularities in a separate written report to the attending physician, medical director, and director of nursing; and

- The attending physician reviewing and acting on any identified irregularities.

B. MEDICATION REGIMEN REVIEW (MRR)

The MRR is an important component of the overall management and monitoring of a resident's medication regimen. The pharmacist must review each resident's medication regimen at least once a month in order to identify irregularities and to identify clinically significant risks and/or actual or potential adverse consequences which may result from or be associated with medications. It may be necessary for the pharmacist to conduct the MRR more frequently, for example weekly, depending on the resident's condition and the risks for adverse consequences related to current medications. Regulations prohibit the pharmacist from delegating the medication regimen reviews to other staff. The requirement for the MRR applies to all residents (whether short or long-stay) without exceptions.

The pharmacist performing the monthly MRR must also review the resident's medical record to appropriately monitor the medication regimen and ensure that the medications each resident receives are clinically indicated. Certain circumstances which may include residents who have multiple medical conditions, concurrent administration of certain medications, administration of medications which require close monitoring through lab work, and transitions of care may also increase the risk of adverse consequences. Review of the medical record as part of the MRR may prevent errors due to drug-drug interactions, omissions, duplication of therapy, or miscommunication during the transition from one team of care providers to another.

Facilities must develop policies and procedures to address the MRR. The policies and procedures must specifically address:

- The appropriate time frames for the different steps in the MRR process; and
- The steps a pharmacist must follow when he or she identifies an irregularity that requires immediate action to protect the resident and prevent the occurrence of an adverse drug event.

MRR policies and procedures should also address, but not be limited to:

- MRRs for residents who are anticipated to stay less than 30 days;
- MRRs for residents who experience an acute change of condition and for whom an immediate MRR is requested after appropriate staff have notified the resident's physician, the medical director, and the director of nursing about the acute change.

While conducting the MRR in the facility is not required for compliance, important information about indications for use, actual or potential medication irregularities or adverse consequences (such as symptoms of tardive dyskinesia, dizziness, anorexia, or falls) may be attainable only by talking to the staff, reviewing the medical record, and

observing and speaking with the resident, the resident's family and/or representative. However, electronic health and medication records and other available technology may permit the pharmacist to conduct some components of the review outside the facility.

Electronic transmission of information may enable facilities to quickly communicate resident-specific information to an off-site pharmacy or pharmacist, however, electronic communication must remain secure to protect individually identifiable information as mandated by the Health Insurance Portability and Accountability Act (HIPAA) of 1996. With secure electronic communication the pharmacist may promptly identify actual or potential medication-related problems before a medication is initiated or soon afterwards. However, brief communication via secure devices to address or prevent immediate or potential problems does not constitute a complete MRR. All information that is needed to perform an MRR may not be available electronically, for example, flow sheets that monitor a resident's pain or that document other observations or symptoms.

Resources are available to facilitate evaluating medication concerns related to the performance of the MRR, such as:

- U.S. Department of Health and Human Services, Food and Drug Administration (FDA) http://www.fda.gov/medwatch/safety.htm.

- American Society of Consultant Pharmacists (ASCP) http://ascp.com/;

- American Medical Directors Association – The Society for Post-Acute and Long-Term Care Medicine (AMDA) http://www.paltc.org/;

- National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) http://www.nccmerp.org;

- American Geriatrics Society (AGS) http://www.americangeriatrics.org; and

NOTE: References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

Identification of Irregularities

An objective of the MRR is to try to minimize or prevent adverse consequences by identifying irregularities including, for example: syndromes potentially related to medication therapy, emerging or existing adverse medication consequences (e.g., drug reactions or medication errors). The resident's record may contain information regarding possible and/or actual medication irregularities. Possible sources to obtain this information include: the medication administration records (MAR); prescribers' orders; progress, nursing and consultants' notes; the Resident Assessment Instrument (RAI);

laboratory and diagnostic test results, and other sources of information about documented expressions or indications of distress and/or changes in condition. The pharmacist may also obtain information from the Quality Measures/Quality Indicator reports, the attending physician, facility staff, and (as appropriate) from interviewing, assessing, and/or observing the resident.

The pharmacist's review considers factors such as:

- Whether the physician and staff have documented objective findings, diagnoses, symptom(s), and/or resident goals and preferences to support indications for use;
- Whether the physician and staff have identified and acted upon, or should be notified about, the resident's allergies and/or potential side effects and significant medication interactions;

- Whether the medication dose, frequency, route of administration, and duration are consistent with the resident's condition, manufacturer's recommendations, and applicable standards of practice;

- Whether the physician and staff have documented progress towards, decline from, or maintenance of the resident's goal(s) for the medication therapy;

- Whether the physician and staff have documented any attempts for gradual dose reduction (GDR) or added any non-pharmacological approaches, in an effort to reduce or discontinue a drug;

- Whether the physician and staff have obtained and acted upon laboratory results, diagnostic studies, or other measurements (such as bowel function, intake and output) as applicable;

- Whether medication errors exist or circumstances exist that make them likely to occur; and

- Whether the physician and staff have noted and acted upon possible medication-related causes of recent or persistent changes in the resident's condition such as worsening of an existing problem or the emergence of new signs or symptoms. Some examples of changes potentially related to medication use that could occur include:

    - Anorexia and/or unplanned weight loss, or weight gain;

    - Expressions or indications of distress, or other changes in a resident's psychosocial status;

    - Bowel function changes including constipation, ileus, impaction;

    - Confusion, cognitive decline, worsening of dementia (including delirium);

- Dehydration, fluid/electrolyte imbalance;
- Excessive sedation, insomnia, or sleep disturbance;
- Falls, dizziness, or evidence of impaired coordination;
- Headaches, muscle pain, generalized aching or pain;
- Rash, pruritus;
- Spontaneous or unexplained bleeding, bruising; and
- Urinary retention or incontinence.

Upon conducting the MRR, the pharmacist may identify and report irregularities in one or more of the following categories:

- The use of a medication without identifiable evidence of adequate indications for use, such as, the use of a medication to treat a clinical condition without identifiable evidence that safer alternatives or more clinically appropriate medications have been considered;
- The use of homeopathic or herbal options (e.g., St. John's Wort) that may interfere with the effectiveness of clinically appropriate medications;
- The use of an appropriate medication that is not helping attain the intended treatment or resident's goals because of timing of administration, dosing intervals, sufficiency of dose, techniques of administration, or other reasons;
- The use of a medication in an excessive dose (including duplicate therapy) or for excessive duration, thereby placing the resident at greater risk for adverse consequences or causing existing adverse consequences;
- The presence of an adverse consequence associated with the resident's current medication regimen;
- The use of a medication without evidence of adequate monitoring; i.e., either inadequate monitoring of the response to a medication or an inadequate response to the findings;
- Presence of medication errors or the risk for such errors;
- Presence of a clinical condition that might warrant initiation of medication therapy; and

NOTE: The presence of a diagnosis or symptom does not necessarily warrant medication, but often depends on the consideration of many factors simultaneously.

- A medication interaction associated with the current medication regimen.

NOTE: Concomitant use of certain medication combinations is not necessarily inappropriate. Often, several medications with documented interactions can be given together safely. However, concomitant use of certain medications warrants careful consideration of potential alternatives, possible need to modify doses, and diligent monitoring.

Websites for organizations such as AMDA - The Society for Post-Acute and Long-Term Care Medicine (American Medical Directors Association) have made information available regarding problematic medication interactions in the long-term care population:

- https://www.amda.com/tools/clinical/m3/topten.cfm; and

- https://www.crediblemeds.org/healthcare-providers/drug-drug-interaction, Woosley, RL and Romero, KA, www.Crediblemeds.org, QTdrugs List, [Accessed March6, 2017], AZCERT, Inc. 1822 Innovation Park Dr., Oro Valley, AZ 85755.

NOTE: References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

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, the facility's medical director, 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. The pharmacist must document any identified irregularities in a separate, written report. The report may be in paper or electronic form. If no irregularities were identified during the review, the pharmacist includes a signed and dated statement to that effect.

The pharmacist does not need to document a continuing irregularity in the report each month if the attending physician has documented a valid clinical rationale for rejecting the pharmacist's recommendation unless warranted by a change in the resident's condition or other circumstances.

The pharmacist's findings are considered part of each resident's medical record and as such are available to the resident/representative upon request. If documentation of the findings is not in the active record, it is maintained within the facility and is readily available for review. 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 IDT, the medical director, the resident and his or her legal representative, the ombudsman, and surveyors.

Response to Irregularities Identified in the MRR

The medical record must show documentation that the attending physician reviewed any irregularities identified by the pharmacist. For those issues that require physician intervention, the attending physician either accepts and acts upon the report and recommendations or rejects all or some of the report and should document his or her rationale of why the recommendation is rejected in the resident's medical record. It is not acceptable for an attending physician to document only that he/she disagrees with the report, without providing some clinical basis for disagreeing.

The facility should have a procedure for how to resolve situations where:

- The attending physician does not concur with or take action on identified irregularities, and;

- The attending physician is also the medical director.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F756, the surveyor's investigation will generally show that:

- The MRR was not conducted by a licensed pharmacist; or

- The pharmacist failed to conduct a complete MRR, at least monthly (or more frequently, as indicated by the resident's condition) for every resident of the facility; or

- The pharmacist's findings in the MRR did not show evidence that the pharmacist also reviewed the resident's chart, for example, the pharmacist did not reference the resident response to a particular medication that was cited as an irregularity; or

- The pharmacist failed to identify or report the absence of or inadequate indications for use of a medication, or a medication or medication combination with significant potential for adverse consequences or medication interactions; or

- The pharmacist failed to identify and/or report medications prescribed or administered in excessive dose (including but not limited to duplicate therapy); or

- The pharmacist failed to identify and/or report medications prescribed or administered for excessive duration; or

- The pharmacist failed to identify and/or report medications prescribed or administered without adequate monitoring; or

- The pharmacist failed to identify or report medications in a resident's regimen that could (as of the review date) be causing or associated with new, worsening, or progressive signs and symptoms; or

- The pharmacist failed to identify and report the absence of any explanation as to why or how the benefit of a medication(s) with potential for clinically significant adverse consequences outweighs the risk; or

- The attending physician failed to document that he or she reviewed the pharmacist's identified irregularities and/or failed to document the action taken or not taken to address the irregularities; or

- The facility failed to develop, maintain, and implement policies and procedures which address the time frames for the steps in the MRR process; or

- The facility failed to develop and implement policies and procedures which address steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

PROCEDURE

Use the Unnecessary Medications, *Chemical Restraints/*Psychotropic Medications, and Medication Regimen Review Critical Element Pathway, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to Medication Regimen Review.

NOTE: In addition to actual or potential physical harm, always *observe for visual cues of psychosocial distress and* consider whether psychosocial harm has occurred when determining severity level (*See guidance on Severity and Scope Levels and* Psychosocial Outcome Severity Guide *located in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes*).

DEFICIENCY CATEGORIZATION

Examples of noncompliance that demonstrate severity at Level 4 include, but are not limited to:

- Despite identifying irregularities with the potential for serious harm or death in a resident's medication regimen, the pharmacist did not report the irregularities to the attending physician, DON, and medical director or action was not taken on the irregularities reported.

- On the MRR, the pharmacist identified that a resident was 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.

Examples of Level 3, Actual harm (physical or psychosocial) that are not immediate jeopardy, include, but are not limited to:

- The pharmacist's MRR failed to identify the indication for continued use for opioid analgesics that had been prescribed for a resident's acute pain which had resolved. As a result of prolonged duration of use, the resident continued to be or became more lethargic and/or withdrawn.

- The pharmacist's MRR identified that the staff were crushing medications that should not be crushed. As a result of facility failure to act upon the notification, the resident experienced clinically significant adverse consequences such as hypoglycemia or hypotension that required medical intervention.

- The attending physician failed to act in response to the pharmacist's MRR which identified the indefinite continuation of an antidepressant in a resident who had no history of depression, who had been placed on the antidepressant without an evaluation to confirm presence of depression, and whose function and mood were not monitored while getting the medication for months. The resident experienced clinically significant adverse consequences such as falls without serious injury, constipation, or change in weight.

Examples of Level 2, No actual harm with a potential for more than minimal harm that is not immediate jeopardy, may include but are not limited to:

- The facility failed to respond to the pharmacist's notification that the resident was not receiving an over-the-counter (OTC) dietary supplement that had been prescribed. Currently, there was no change in the resident's condition, such as a weight loss.

- The pharmacist's MRR failed to evaluate and report on the potential adverse consequences of a medication that may increase the possible side effects of another clinically appropriate medication that had been prescribed. The resident had not yet experienced side effects from the combined medications.

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm

Severity Level 1 does not apply for this regulatory requirement because the failure to perform the MRR according to the regulatory provisions creates the potential for more than minimal harm.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

Examples of some of the related requirements that should be considered when concerns have been identified include the following:

- 42 CFR §483.10(g)(14), F580, Notification of Changes
  - Review whether a member of the IDT contacted the attending physician regarding a significant change in the resident's condition in relation to a potential adverse consequence of a medication, or a need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a different form of treatment).

- 42 CFR §483.45(d), F757, Unnecessary Drugs and 42 CFR §483.45(e), F*605*, Psychotropic Medications

  - Review whether the resident is receiving any medications without an indication for use, in excessive dose or duration, with inadequate monitoring, or in the presence of any adverse consequences that indicate that the dose should be reduced or discontinued.

- 42 CFR §483.30(a), F710, Physician Supervision

  - Review whether the attending physician supervised the resident's medical treatment, including assessing the resident's condition, identifying the need for and continuing use of medication to address the resident's needs, and identifying and addressing adverse consequences related to medications.

- 42 CFR §483.30(b), F711 Physician Visits and 42 CFR §483.30(c), F712, Frequency of Physician Visits

  - Review whether the attending physician or another designated practitioner reviewed the resident's total program of care including the beneficial and adverse effects of medications and treatment, and provided a relevant progress note at each visit.

- 42 CFR §483.45(a), (b)(1)-(3), F755, Pharmacy Services

  - Review whether the licensed pharmacist has provided consultation regarding all aspects of pharmaceutical services.

- 42 CFR §483.70(g), F841, Medical Director

  - Review whether the medical director, when requested by the facility, interacted with the attending physician regarding an inadequate response to identified or reported potential medication irregularities and adverse