Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

Use for a resident who has potentially unnecessary medications, is prescribed psychotropic medications or has the potential for an adverse outcome to determine whether facility practices are in place to identify, evaluate, and intervene for potential or actual unnecessary medications. Use also to evaluate the medication regimen review (MRR) process.

NOTE: If the resident has a diagnosis of dementia and is receiving any psychotropic medications (including but not limited to antipsychotic medications) the surveyor should refer to the Dementia Care Critical Element Pathway as a guide to determine the facility's compliance at F744.

Review the Following in Advance to Guide Observations and Interviews:

☐ Review the most current comprehensive and most recent quarterly (if the comprehensive isn't the most recent assessment) MDS/CAAs for areas pertinent to the medications ordered such as adverse consequences and behaviors.

☐ Review all medications currently ordered or discontinued going back to the most recent signed recapitulation. Determine if the facility:

- ✓ **Documents an acceptable clinical indication for use.**
  - Medication is prescribed for a diagnosed condition and not being used for convenience or discipline.
  - Medication is clinically indicated to manage a resident's symptoms or condition where other causes have been ruled out.
  - Signs, symptoms, or related causes are persistent or clinically significant enough (e.g., causing functional decline) to warrant the initiation or continuation of medication therapy.
  - Intended or actual benefit is sufficient to justify the potential risk(s) or adverse consequences associated with the medication, dose, and duration.
- ✓ **Demonstrates use of written protocols or resources to guide antibiotic use.**
  - The use of infection assessment tools for antibiotic use for one or more infections (e.g., use of a Situation, Background, Assessment and Recommendation (SBAR) communication tool for UTI assessment, application of the Loeb minimum criteria for initiation of antibiotics).
- ✓ **Demonstrates monitoring for each medication as appropriate.**
  - The following medications pose a high risk for adverse consequences and should be monitored:
    - **Opioids –** assess pain, implement bowel program.
    - **Anticoagulant –** bleeding/bruising, protime/international normalized ratio (PT/INR), interaction with other medications, facility must have policies around monitoring, lab work, communication of lab values, implementation of new orders in response to lab values and/or symptoms.
    - **Diuretics –** edema, potassium level, signs of electrolyte imbalance.
    - **Insulin –** monitoring of blood glucose levels, hemoglobin A1c (HbA1c), and symptoms of hyper/hypoglycemia.
    - **Antibiotics –** interactions with other medications (e.g., warfarin), adverse events (e.g., rash, diarrhea); prescriptions must include documentation of indication, dose, route and duration and be reviewed 2-3 days after antibiotic initiation to assess response and labs, and prescriber should reassess antibiotic selection as appropriate.

- **All psychotropics –** monitor behavioral expressions or indications of distress.

- Facility staff, along with the pharmacist and prescribing practitioner recognize and evaluate the onset or worsening of signs or symptoms, or a change in condition to determine whether these potentially may be related to the medication regimen; and follow up as necessary upon identifying adverse consequences.
- Facility staff monitor the effectiveness of each medication and make changes to the pharmacological intervention, when necessary.

✓ **Demonstrates appropriate dosing for each medication.**

- Is there documentation of a rationale for any medication that exceeds the manufacturer's recommendations, clinical practice guidelines, evidence based guidelines or standards of practice?

✓ **Documents duration for each medication.**

- Medications are not used for an excessive duration.

✓ **Documents clinical rationale for continued use for the medications, as required.**

- Tapering when clinically indicated in an effort to discontinue or reduce the dose.
- Concomitant use of two or more medications in the same pharmacological class.
- Potential incompatibilities between medications.

✓ **Demonstrates a system that monitors and addresses the presence of or potential for adverse consequences.**

- A clear clinical rationale from the attending physician/prescribing practitioner for continuing a medication that may be causing an adverse consequence, including risks and benefits.

✓ **Demonstrates a system for and documents gradual dose reduction (GDR) for psychotropic medications, unless contraindicated.**

- Within the first year in which a resident is admitted on a psychotropic medication or after the facility has initiated a psychotropic medication:
  - GDR attempts in two separate quarters with at least one month between the attempts.
  - The GDR must be attempted annually thereafter unless clinically contraindicated.
  - Non-pharmacological approaches must be attempted and documented instead of using psychotropic medications, along with use of psychotropic medications, and while GDR is attempted.

✓ **Demonstrates adherence to requirements for as needed (PRN) psychotropic and antipsychotic medications.**

- Residents do not receive PRN psychotropic medications unless necessary to treat a diagnosed specific condition which must be documented in the record.
- PRN orders for psychotropic medications which **are not** antipsychotic medications are limited to 14 days. The attending physician/prescriber may extend the order beyond 14 days if he or she believes it is appropriate. If the attending physician extends the PRN for the psychotropic medication, the medical record must contain a documented rationale and determined duration.
- PRN orders for psychotropic medications which **are** antipsychotic medications are limited to 14 days. A PRN order for an antipsychotic cannot be renewed unless the attending physician/prescriber evaluates the resident to determine if it is appropriate to write a new PRN order for the antipsychotic medication. The evaluation entails direct evaluation of the resident and assessment of the

resident's current conditions and progress to determine if the PRN antipsychotic medication is still needed. Attending physician/prescribing practitioner documentation of the evaluation should address:

- Whether the antipsychotic medication is still needed on a PRN basis?
- What is the benefit of the medication to the resident?
- Have the resident's expressions or indications of distress improved as a result of the PRN antipsychotic medication?

☐ Review the care plan for medications, especially high risk medications, and individualized approaches to care, including non-pharmacological interventions.

Observations:

☐ Are care planned interventions implemented for medications that pose a high risk for adverse consequences?

☐ What non-pharmacological approaches to care are used? Are they effective?

☐ What pharmacological interventions are used? Why was the medication used and was it effective (e.g., pain is relieved, distress is addressed)?

☐ How does staff respond and interact with the resident?

☐ Does the resident continue to show expressions or indications of distress? If so, how does staff respond?

☐ Are staff using a medication for convenience or discipline? If so, describe. (For concerns related to a medication that involves an inadequate indication for use and evidence shows the medication is also being used for the purpose of discipline or convenience rather than to treat the resident's medical symptoms, surveyors should assess compliance with §483.10(e)(1) and §483.12(a)(2), F605, Right to Be Free From Chemical Restraints.)

☐ Does the resident have psychosocial, behavioral, mental, or physical adverse consequences that may be related to a medication:

- ○ Anorexia/unplanned weight changes, edema;
- ○ Decline in physical functioning (e.g., mobility or activities of daily living (ADLs));
- ○ Rash, pruritus;
- ○ Bleeding or bruising, spontaneous or unexplained;
- ○ Respiratory changes;
- ○ Bowel dysfunction (e.g., cramping abdominal pain);
- ○ Urinary retention, incontinence;
- ○ Dehydration or swallowing difficulty;
- ○ Falls, dizziness, or headaches;
- ○ Muscle/nonspecific pain or unexplained abnormal movement;
- ○ Psychomotor agitation (restlessness, pacing, hand wringing);
- ○ Psychomotor retardation (slowed speech, thinking, movement);
- ○ Subdued, sedated, lethargic, or withdrawn;
- ○ Insomnia or sleep disturbances;
- ○ Mental status changes;
- ○ Behavioral changes or unusual behavior patterns; or
- ○ Depression, apathy or mood disturbance.

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Resident, Family or Resident Representative Interview:

- ☐ What medications do you get and why do you need to take them?
- ☐ What are your goals for your medications?
- ☐ What information on the risk, benefits and potential side effects of medications were you provided?
- ☐ What changes in your medications have occurred, including gradual dose reductions for psychotropic medications?

  NOTE: Permission given by or a request made by the resident and/or representative does not serve as a sole justification for the medication itself.

- ☐ What alternatives to taking some of the medications, including non-pharmacological approaches, has staff told you about?
- ☐ Do you think the medication has helped (e.g., pain control, improvements in function, decrease in edema, mood)? If not, why?
- ☐ What side effects have you had from the medication (ask about specific medications)? Have you experienced any changes in what you are able to do since starting or changing a medication(s)? Do you have allergies to any medication(s)?
- ☐ Have you participated in discussions and/or care plan meetings about your medications?

Staff Interviews (Nursing Aides, Nurse, Director of Nursing (DON), Social Services):

- ☐ What, when, and to whom do you report changes in the resident's status (e.g., indications of distress or pain)?
- ☐ How do you learn what the resident's daily care needs are?
- ☐ What non-pharmacological approaches are used?
- ☐ What is the clinical indication for the medication?
- ☐ How does the facility monitor the medication?
  - ○ What monitoring tools or systems are used?
  - ○ How did the interdisciplinary team (IDT) determine what should be monitored?
  - ○ For psychotropic medications, how did you determine what behavior to monitor?
  - ○ How do you assure orders for medication monitoring are implemented (e.g., HbA1c, PT/INR)?
  - ○ How do you communicate relevant information regarding medication monitoring for this resident to other team members?
- ☐ How do you assess whether each medication is effective?
- ☐ Why does the resident have two medications in the same class?
- ☐ How does the IDT determine what dose and duration is clinically indicated?
- ☐ If the amount of any medication exceeds the manufacturer's recommendations, clinical or evidence-based practice guidelines, or standards of practice, what is the rationale?
- ☐ How do you monitor for significant adverse consequences?
- ☐ Has the resident had a change in condition, diet, weight loss, dehydration, or acute illness? If so, what was done to assess the possible complications for these changes due to medications?
- ☐ Has the resident had an adverse reaction? If so, what and how was the adverse reaction addressed?
- ☐ How do you evaluate whether medications should be initiated, continued, reduced, discontinued, or otherwise modified? How often is the evaluation for modification conducted?

Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

- ☐ How does the facility ensure a review of medications for GDRs?
- ☐ If the resident is on a psychotropic medication: When did you attempt to reduce the medication in the last year and what were the results?
- ☐ If the practitioner denied a GDR: Did the practitioner provide a risk-benefit statement describing the contraindications for a GDR?
- ☐ How do you monitor staff to ensure they are implementing care planned approaches?
- ☐ What was the rationale for the practitioner's decisions in managing the resident's medications or medication-related concerns?
- ☐ How did you involve the resident in decisions regarding medications?
- ☐ How often is the MRR conducted and are medical charts included in this review?
- ☐ Under what circumstances is the MRR conducted more often than monthly?
- ☐ Are there policies and procedures in place to address issues which include the different steps in the MRR process and steps to take when an identified irregularity requires immediate action?
- ☐ How are medication-related issues communicated to other staff, the attending practitioner or prescribing practitioner, and resident and, if appropriate, resident representative?
- ☐ How is the MRR process conducted for short-stay residents?
- ☐ Has there been a change in the resident's overall function and mood that potentially may indicate unnecessary medications or adverse reactions? If so, describe.
- ☐ If the resident is receiving PRN psychotropic or antipsychotic medication(s): How is this medication monitored and how does the IDT determine if the PRN medication is clinically indicated and ensure the PRN orders are consistent with PRN requirements for psychotropic and antipsychotic medications?
- ☐ Ask about any other related concerns the surveyor has identified.

Pharmacist Interview:

- ☐ Do you perform a monthly MRR (or more frequently if needed)?
- ☐ Do you include each resident's medical record in this monthly review?
- ☐ How do you evaluate PRN medications, specifically PRN psychotropic and antipsychotic medications?
- ☐ What are you reviewing (e.g., adequate indication, dose, continued need, and adverse consequences)?
- ☐ Did you identify and report to the attending physician, medical director, and DON any irregularities with this resident's medication regimen? Did you use a separate, written report?
- ☐ If the pharmacist didn't identify a specific issue, ask why the issue was not identified as an irregularity on the MRR.
- ☐ What is the MRR process for short-stay residents?
- ☐ What protocols to do you have in place (e.g., lab to monitor for adverse events and drug interactions related to use of antibiotics and other high-risk medications)?
- ☐ Are you part of the IDT who reviews this resident's medication?
- ☐ What steps do you take when an irregularity requires immediate action? Are these steps part of facility policy?

Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

Attending Practitioner, Medical Director, and DON Interviews:

- ☐ Did you receive a written report of irregularities identified during the MRR?
- ☐ Did you make a change in the resident's medication in response to the identified irregularity(ies) or document a rationale if you didn't make a change in the medication regimen?
- ☐ What is the rationale behind why the medication is being used (e.g., antipsychotic for dementia or other high risk medications)?
- ☐ What other approaches were attempted prior to the use of a psychotropic medication and/or while attempting a GDR?
- ☐ When was a GDR last completed? What was the result?
- ☐ Are you included in the IDT meeting for this resident?

Record Review:

- ☐ Was the underlying cause (medical, environmental, or psychosocial stressors) of the conditions or symptoms requiring the medication identified?
- ☐ If a medication was discontinued, was there evidence of a GDR, if applicable (e.g., for psychotropic and antipsychotic medications)?
- ☐ Did the pharmacist conduct an MRR for the resident at least once a month that included a review of the resident's medical record?
- ☐ Did the pharmacist identify and report all medication irregularities to the attending physician, medical director, and DON? Were the irregularities documented on a separate, written report? Were the reports acted upon?
- ☐ Did the attending physician document in the medical record that the irregularity was reviewed? What, if any, action was taken? What rationale was documented if no change was made to the medication regimen?
- ☐ If the resident had a change in condition such as, dehydration or acute illness, was the medication regimen reviewed? Did the pharmacist complete a MRR?
- ☐ Is there evidence of actual or potential adverse events, such as allergic reactions, inadequate monitoring? (Refer to the CMS Adverse Drug Event Trigger Tool).
- ☐ Was there a "significant change" in the resident's condition (i.e., will not resolve itself without intervention by staff or by implementing standard disease-related clinical interventions; impacts more than one area of health; requires IDT review or revision of the care plan)? If so, was a significant change comprehensive assessment conducted within 14 days?
- ☐ Is the MAR accurate, complete and followed according to standards of practice?
- ☐ For antibiotics: Are signs or symptoms of infection documented? Have appropriate diagnostic tests been obtained to inform antibiotic selection and continuation?
- ☐ What is the facility response when monitoring indicates a lack of progress toward the therapeutic goal?
- ☐ What individualized, non-pharmacological approaches were documented, specifically for residents who receive psychotropic medications?
- ☐ Review the facility's policies regarding psychotropic medications and MRR. Are they updated and maintained? Does the policy include timeframes for the steps in the process? Does the policy include the steps the licensed pharmacist must take for a medication irregularity that requires urgent action?

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Critical Elements Decisions:

1. 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 No to any of the above, cite F756

2. For **Unnecessary Medications**: Did the facility ensure that each resident's medication regimen was free from unnecessary medications? (Note: If the unnecessary medication is a psychotropic medication, cite F758)
   If No, cite F757

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3. For **Psychotropic Medications**, did the facility ensure that:
   - they are used only to treat a specific, diagnosed, and documented condition;
   - a GDR was attempted, unless clinically contraindicated, and non-pharmacological approaches to care were implemented;
   - PRN use is only if necessary to treat a specific, diagnosed, and documented condition;
   - PRN orders for psychotropic medications which **are not** for antipsychotic medications are limited to 14 days,unless the attending physician/prescribing practitioner documents a rationale to extend the medication;
   - PRN orders which **are** for antipsychotic medications are limited to 14 days, without exception and the attending physician/prescribing practitioner did not renew the order without first evaluating the resident?

   If No to any of the above, cite F758
   NA, the resident was not prescribed psychotropic medications.

4. Did the facility conduct ongoing review for antibiotic stewardship?
   If No, cite F881

5. For newly admitted residents and if applicable based on the concern under investigation, did the facility develop and implement a baseline care plan within 48 hours of admission that included the minimum healthcare information necessary to properly care for the immediate needs of the resident? Did the resident and resident representative receive a written summary of the baseline care plan that he/she was able to understand?
   If No, cite F655.
   NA, the resident did not have an admission since the previous survey OR the care or service was not necessary to be included in a baseline care plan.

6. If the condition or risks related to medications were present at the time of the required comprehensive assessment, did the facility comprehensively assess the resident's physical, mental, and psychosocial needs to identify the risks and/or to determine underlying causes, to the extent possible, and the impact upon the resident's function, mood, and cognition?
   If No, cite F636
   NA, condition/risks were identified after completion of the required comprehensive assessment and did not meet the criteria for a significant change MDS OR the resident was recently admitted and the comprehensive assessment was not yet required.

7. If there was a significant change in the resident's status, did the facility complete a significant change assessment within 14 days of determining the status change was significant?
   If No, cite F637
   NA, the initial comprehensive assessment had not yet been completed therefore a significant change in status assessment is not required OR the resident did not have a significant change in status.

8. Did staff who have the skills and qualifications to assess relevant care areas and who are knowledgeable about the resident's status, needs, strengths and areas of decline, accurately complete the resident assessment (i.e., comprehensive, quarterly, significant change in status)?
   If No, cite F641

9. Did the facility develop and implement a comprehensive person-centered care plan that includes measureable objectives and timeframes to meet a resident's medical, nursing, mental, and psychosocial needs and includes the resident's goals, desired outcomes, and preferences?
   If No, cite F656
   NA, the comprehensive assessment was not completed.

10. Did the facility reassess the effectiveness of the approaches and review and revise the resident's care plan (with input from the resident and, if appropriate, the resident representative) to meet the resident's needs?
    If No, cite F657
    NA, the comprehensive assessment was not completed OR the care plan was not developed OR the care plan did not have to be revised.

Other Tags, Care Areas (CA), and Tasks (Task) to Consider: Right to be Informed and Participate F552, F553, Notification of Change F580, Chemical Restraints F605, Choices (CA), Social Services F745, Admission Orders F635, Professional Standards F658, Pain (CA), General Pathway (CA) for Diabetic Management, Dementia Care (CA), ADLs (CA), Urinary Incontinence (CA), Behavioral-Emotional Status (CA), Nutrition (CA), Hydration (CA), Sufficient and Competent Staffing (Task), Physician Services F710, F711, Pharmacy Services F755, QAA/QAPI (Task).

- *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 §483.70(h), 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 §483.75(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.*
- *42 CFR §483.70(i), 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.*

F756

(Rev. 173, Issued: 11-22-17, Effective: 11-28-17, Implementation: 11-28-17)

§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, 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.

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

***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), F758, 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(h), 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 consequences.*

F757

(Rev. 173, Issued: 11-22-17, Effective: 11-28-17, Implementation: 11-28-17)

§483.45(d) Unnecessary Drugs—General.
Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—

§483.45(d)(1) In excessive dose (including duplicate drug therapy); or

§483.45(d)(2) For excessive duration; or

§483.45(d)(3) Without adequate monitoring; or

§483.45(d)(4) Without adequate indications for its use; or

§483.45(d)(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or

§483.45(d)(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.

F758

(Rev. 173, Issued: 11-22-17, Effective: 11-28-17, Implementation: 11-28-17)

§483.45(c)(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:
(i) Anti-psychotic;