Unnecessary Medications, *Chemical Restraints/*Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

Use for a resident who has potentially unnecessary medications or is prescribed psychotropic medications to determine whether facility practices are in place to identify, evaluate, and intervene for potential or actual unnecessary medications and/or chemical restraints. 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. Also review all medications currently ordered or discontinued going back to the most recent signed recapitulation.*
- ☐ *Review the care plan for medications, especially high-risk medications, and individualized approaches to care, including non-pharmacological interventions.*

Observations: For psychotropic medications, use the observations and interview questions from F757 and F605.

F757 --For evaluation of all medications:

- ☐ *Is the resident displaying any effects of the medication indicating the medication is effective or indicating the medication is not effective and/or causing adverse consequences or side effects?*
- ☐ *Does the resident have any adverse consequences that may be related to a medication?*

F605— use the questions from F757 along with the following:

- ☐ *Do residents appear sedated by being difficult to arouse or sleeping during hours that they would not ordinarily sleep?*
- ☐ *What non-pharmacological approaches to care are used? Are they effective?*
- ☐ *Does the resident continue to show expressions or indications of distress? If so, how does staff respond?*
- ☐ *Is the resident experiencing side effect(s) of a medication(s) such as mental status or behavioral changes?*

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Unnecessary Medications, *Chemical Restraints/*Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

Interviews:

Resident, Family or Resident Representative:

F757

- ☐ *What medications do you get and why do you need to take them?*
- ☐ *What are your goals for your medications?*
- ☐ *What changes in your medications have occurred?*
- ☐ *Do you think the medication has helped (e.g., pain control, improvements in function, decrease in edema, improved 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? Do you agree with the medications you are taking?*

F605 -- use the questions from F757 along with the following:

- ☐ *What changes in your medications have occurred, including gradual dose reductions for psychotropic medications?*
- ☐ *What alternatives to taking some of the medications, including non-pharmacological approaches, have staff attempted and told you about?*
- ☐ *Have you experienced any sedation that you think is related to your medication?*

Nursing Aides, Nurses, Director of Nursing (DON), Social Services:

F757

- ☐ *What, when, and to whom do you report changes in a resident's status (e.g., indications of distress or pain)?*
- ☐ *What is the clinical indication for the medication?*
- ☐ *How do staff monitor for adverse consequences or side effects of medications?*
  - ○ *How do you assure orders for medication monitoring are implemented (e.g., vital signs, HbA1c, PT/INR)?*
  - ○ *How do you communicate relevant information regarding medication monitoring to other team members?*

F605 -- use the questions from F757 along with the following:

- ☐ *What non-pharmacological approaches are used and how is their use monitored?*
- ☐ *For psychotropic medications, are target behaviors monitored?*
- ☐ *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.*

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Unnecessary Medications, *Chemical Restraints/*Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

Interviews:

- ☐ *Has a 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?*
- ☐ *How are medication-related issues communicated to other staff, the attending practitioner or prescribing practitioner, and resident and, if appropriate, resident representative?*

Attending Physician:

F757

- ☐ *What is the clinical indication for why the medication is being used (e.g., antipsychotic for dementia or other high-risk medications)?*
- ☐ *How do you assess whether each medication is effective?*
- ☐ *How did you involve the resident in decisions regarding medications?*
- ☐ *Have you been informed that the resident had any adverse reaction or side effects? If so, how were the side effects or 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?*
- ☐ *Why does the resident have multiple medications in the same class?*
- ☐ *Are you included in the IDT meeting for this resident?*
- ☐ *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?*

F605 -- use the questions from F757 along with the following:

- ☐ *If the resident is on a psychotropic medication, when did you attempt to reduce the medication and what were the results?*
- ☐ *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?*
- ☐ *If a GDR was not attempted, was a clinical rationale provided for not performing the GDR?*

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Unnecessary Medications, *Chemical Restraints/*Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

Interviews:

Attending Physician, Medical Director, and DON:

F756

- ☐ *Did you receive a written report of irregularities identified during the MRR?*
- ☐ *How is the MRR process conducted for short-stay residents?*
- ☐ *How does the facility ensure a review of medications for GDRs?*
- ☐ *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?*

Medical Director:

F757 and/or F605

- ☐ *When a concern is identified related to a practitioner's adherence to facility policies on establishing a diagnosis and prescribing medications, how are you made aware?*
- ☐ *What is your process for discussing and intervening (as appropriate) with a health care practitioner regarding medical care that is inconsistent with current professional standards of care?*
- ☐ *Were you aware that a medication was ordered for the resident and there was a a lack of documentation by the prescribing practitioner to support the diagnosis?*
  - *If yes, how did you address the lack of documentation?*
  - *If no, why not?*

Pharmacist:

F756

- ☐ *Do you perform a monthly MRR (or more frequently if needed) and are medical charts also reviewed?*
- ☐ *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 do you evaluate PRN medications, specifically PRN psychotropic and antipsychotic medications?*
- ☐ *How do you monitor for adverse consequences (e.g., labs 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?*
- ☐ *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?*

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Record Review:

F757

- ☐ *Does documentation of the resident's conditions or symptoms support the necessity of the medication?*
- ☐ *Is there evidence of actual or potential adverse events, such as allergic reactions? (Refer to the CMS Adverse Drug Event Trigger Tool).*
- ☐ *Is there documentation to confirm that residents are being adequately monitored and re-evaluated for adverse consequences and the need for tapering?*
- ☐ *For antibiotics: Are signs or symptoms of infection documented? Have appropriate diagnostic tests been obtained to inform antibiotic selection and continuation?*

F756

- ☐ *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?*
- ☐ *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?*
- ☐ *Review the facility's policies regarding the MRR. 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?*
- ☐ *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?*

F605

- ☐ *Does documentation of the resident's conditions or symptoms support the necessity of the medication?*
- ☐ *Is there evidence that a GDR has been attempted and/or is clinically contraindicated as documented in a rationale in the medical record?*
- ☐ *Does the medical record documentation reflect the date of the GDR attempt, the outcome of the dose reduction attempt, and the plan regarding future GDR attempts?*
- ☐ *Does the medical record show a change in the resident's behavior such as increased sedation, withdrawal from activities, or cognitive decline related to psychotropic medication?*
- ☐ *Were individualized, non-pharmacological approaches attempted? If not, or if discontinued, is there documentation that describes why?*
- ☐ *Is there evidence of actual or potential adverse events, such as allergic reactions? (Refer to the CMS Adverse Drug Event Trigger Tool).*
- ☐ *Is there documentation to confirm that residents are being adequately monitored and re-evaluated for adverse consequences and the need for tapering?*
- ☐ *Is there evidence that the limitations for use of PRN psychotropic and antipsychotic medications have been met?*

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Record Review:

☐ *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?*

Record Review for residents with a diagnosis of schizophrenia:

When reviewing records for unnecessary medications, surveyors may find residents who are diagnosed with schizophrenia without sufficient supporting documentation. In these situations, does the medical record include documentation that meets the criteria in the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) for diagnosing schizophrenia:

- ☐ *Symptoms, disturbances, or behaviors consistent with and for the required period of time in accordance with the DSM criteria.*
- ☐ *Evaluation of the resident's physical, behavioral, mental, psychosocial status, and comorbid conditions, ruling out physiological effects of a substance (e.g., medication or drugs) or other medical conditions, indications of distress, changes in functional status, resident complaints, behaviors, and symptoms.*

Surveyors should look for documentation that supports the diagnosis of schizophrenia, however, it is the facility's responsibility to provide evidence of compliance. Surveyors should ask the facility to direct them to the section of the resident's medical record that supports the diagnosis. If the facility cannot provide supporting documentation or directs surveyors to a section of the medical record that does not have sufficient documentation, the facility is noncompliant for failing to provide sufficient evidence that professional standards of practice were followed. Note: The documentation must have occurred prior to start of the survey.

NOTE: A medical record note stating "schizophrenia," or "Seroquel/Quetiapine for schizophrenia" alone without other documentation as described above does not meet professional standards of quality to diagnose someone with schizophrenia.

Critical Elements Decisions:

1. *For **Unnecessary Medications**: Did the facility ensure that each resident's medication regimen was free from unnecessary medications?*
   If No, cite F757.
   If No and the unnecessary medication is a psychotropic medication, cite F605.

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Unnecessary Medications, *Chemical Restraints/*Psychotropic Medications, and Medication Regimen Review Critical Element Pathway

2. ***Psychotropic Medications,*** *did the facility ensure that:*
   - *the medication is necessary to treat a specific, diagnosed, and documented condition which includes symptoms which may be causing distress to the resident or others*
   - *the medication is not sedating the resident, but rather is treating the resident's medical symptoms;*
   - *alternative treatments, such as behavioral (nonpharmacological) interventions, were attempted and that these interventions have been deemed clinically contraindicated;*
   - *a GDR was attempted and non-pharmacological approaches to care were implemented, unless clinically contraindicated;*
   - *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 F605.
   N/A, the resident was not prescribed psychotropic medications.

3. *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?*

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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.

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

5. *Does the medical record show that the resident or resident representative was informed in advance of the risks and benefits of a medication, the treatment alternatives or other options and was able to choose the option he or she prefers?*
   If No, cite F552.

6. *Did the medical director participate in implementing resident care policies by ensuring physicians and other practitioners adhere to facility policies on diagnosing and prescribing medications and intervene with a health care practitioner regarding medical care that is inconsistent with current professional standards of care?*
   If No, cite F841.

7. *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.

8. *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.

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9. *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.

10. *Does the most recent resident assessment accurately reflect the resident's status (i.e., comprehensive, quarterly, significant change in status)?*
    If No, cite F641.

11. *Did the facility develop and implement a comprehensive person-centered care plan that includes measurable 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.

12. *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.

13. *Does the resident's medical record contain documentation that the practitioner's diagnostic practices meet professional standards of quality?*
    ***NOTE**: CMS is aware of situations where residents are given a diagnosis of schizophrenia without sufficient supporting documentation. The medical record should have supporting documentation that meets the criteria in the current version of the DSM for diagnosing schizophrenia.*
    If No, cite F658.

Other Tags, Care Areas (CA), and Tasks (Task) to Consider: *Notification of Change F580, , Choices (CA), Activities (CA), Social Services F745, Admission Orders F635, 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, Medical Director F841, Antibiotic Stewardship Program (Infection Control Task), QAPI/QAA (Task).*

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Hospitalization Critical Element Pathway

Use this pathway for a resident hospitalized for a reason other than a planned elective procedure to determine if facility practices are in place to identify and assess a change in condition, intervene as appropriate to prevent hospitalizations, and evaluate compliance with requirements surrounding transfer and discharge.

Review the following in *a*dvance to *g*uide *o*bservations and *i*nterviews:

☐ *Offsite Preparation:*

- *Determine if the Ombudsman identified any resident-specific or general concerns related to a resident's hospitalization and/or transfer or discharge requirements.*
- *Review complaints and survey history for indications of noncompliance with concerns related to a resident's hospitalization and/or the requirements for transfer or discharge.*

☐ *Most current comprehensive MDS/CAAs. If the most recent MDS is a quarterly, then review both the most recent comprehensive and quarterly MDSs. Review sections* B, C, E, GG, I, J, N, and O.

☐ Physician's orders (e.g., treatment prior to being hospitalized, meds, labs and other diagnostics, transfer orders to hospital, readmission, and current orders).

☐ Pertinent diagnoses.

☐ Relevant progress notes (e.g., physician, non-physician practitioner, and/or nursing notes). Note: Surveyor may have to obtain/review records from the hospital, or request the previous medical record to review circumstances surrounding the resident's hospitalization.

☐ Care plan (e.g., symptom management and interventions to prevent re-hospitalization based on resident's needs, goals, preferences, and assessment).

Observations *(if resident is in the facility)*:

☐ Is the resident exhibiting the same symptoms that sent the resident to the hospital? Is the resident displaying:

- Physical distress;
- Mental status changes;
- A change in condition; and/or
- Pain?

☐ If symptoms are exhibited, *are they being addressed by staff*?

☐ Are care planned and ordered interventions in place to prevent a re-hospitalization (e.g., respiratory treatments, blood pressure monitoring)?

Resident, Representative Interview, or Family Interview:

☐ Why were you sent to the hospital?

☐ When did you start to feel sick, or have a change in condition?

☐ Do you feel staff responded as quickly as they could have when you had a change in condition?

☐ Has staff talked to you about your risk for additional hospitalizations and how they plan to reduce the risk?

☐ Do you have pain? If so, what does staff do for your pain?

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