Stage 2 Critical Elements for Psychoactive Medications

Facility Name: _____ Facility ID: _____ Date: _____

Surveyor Name: _____

Resident Name: _____ Resident ID: _____

Initial Admission Date: _____ Interviewable: ☐ Yes ☐ No Resident Room: _____

Care Area(s): _____

Use

Use this protocol for a sampled resident who triggers for:

☐ The use of antipsychotic medications without an indication for use;

☐ The use of long-acting benzodiazepines; or

☐ The use of medications, such as anxiolytics and/or hypnotics.

Note: In addition, use if, during the review of other CEs or medication administration observation, the surveyor identifies potential issues related to the use of psychoactive medication use.

Procedure

☐ Briefly review the assessment, care plan, and orders to identify facility interventions and to guide observations to be made.

☐ Corroborate observations by interview and record review.

Observations

☐ Briefly review a resident's assessment and care plan for the therapeutic goals and monitoring plan for the medications. ☐ Observe the resident's functioning and behavior over time and various shifts. ☐ For **closed record review**, determine whether the interdisciplinary team evaluated the impact of the medications upon the resident. ☐ In addition, observe for:	**Notes:**

Stage 2 Critical Elements for Psychoactive Medications

Observations	
▪ Signs of medication side effects such as unsteady gait; tardive dyskinesia (involuntary movement of the facial, limbs and trunk muscles); ▪ Parkinson like symptoms (shuffling gait, rigid muscles, shaking); ▪ Frequent falls; ▪ Refusing to eat; ▪ Difficulty swallowing; ▪ Dry mouth, depression, suicidal ideations, social isolation, blurred vision; ▪ Diarrhea, fatigue, insomnia, loss of appetite, weight loss; and ▪ Muscle cramps, nausea, and vomiting or other behavioral/symptomatic changes uncharacteristic of the resident.	
For the resident who is on a hypnotic:	
Determine whether staff are implementing sleep hygiene techniques, such as: ☐ Limiting caffeine intake; ☐ Decreasing noise to the extent possible; ☐ Providing lighting levels to the tolerance of the resident; ☐ Providing regular bedtime routine; and ☐ Maximizing daily activities and encouraging socialization.	**Notes:**

Stage 2 Critical Elements for Psychoactive Medications

Observations	
For the resident who is on an antipsychotic and/or anti-anxiety medication:	
Determine whether staff are: ☐ Observing and monitoring target behaviors, such as pacing, wandering in other resident rooms, disrobing, inappropriate response to verbal communication, displays of violent/aggressive behavior towards staff and/or other residents, or other symptoms identified on the care plan as part of the behavior management program; ☐ Monitoring for behaviors that cause the resident or others distress; and ☐ Observe staff interactions with the resident in response to behavior management plan.	**Notes:**

Resident/Representative Interview	
Interview the resident, family, or responsible party as appropriate to identify: ☐ The resident's/representative's involvement in the development of the care plan, defining the approaches and goals, and whether interventions reflect choices and preferences; ☐ Awareness and involvement in the development of the medication regime; ☐ Involvement in the development of a behavior management program; ☐ Whether the resident/representative was provided information on the risk and benefits of psychoactive medications and has an understanding of this information; and ☐ If interventions were declined or refused, what the reasons were for the decline and whether alternative approaches were offered.	**Notes:**

Stage 2 Critical Elements for Psychoactive Medications

Staff Interviews	
Determine whether: ☐ Nursing assistants and other support staff know what behavioral changes to report; and ☐ Nurses have a working knowledge and understanding of, and monitor for, the intended effect and potential adverse effects of the psychoactive medication the resident receives.	**Notes:**

Stage 2 Critical Elements for Psychoactive Medications

Assessment	
Review the RAI, physician orders, progress notes, history and physical, consultant reports and other appropriate interdisciplinary notes and any other documentation (MARs, TARs) necessary to evaluate the appropriateness of the treatment regime.	
For the resident on antipsychotic and/or anti-anxiety medications:	
Determine whether the assessment includes (but not limited to): ☐ Involvement of social services and activities staff in team decisions for non-medication interventions/treatment of the resident; ☐ Identification of environmental stimuli, infection, delirium, pain, etc., before medication is used; ☐ A medical justification for its use, such as an Organic Mental Syndrome (dementia, delirium, etc.) and that the behaviors demonstrated by the resident are psychotic in nature, persistent, and cause the resident or others distress, including the medical justification for ongoing use of a medication initiated as an emergency measure; ☐ The identification of: ▪ Risks/benefits of the medication use; ▪ Possible adverse consequences related to the medication, such as hypersensitivity, idiosyncratic response and/or toxic reaction, or side effects; ▪ An objective for the medication being used; ▪ A baseline of behaviors for which the medication is prescribed; and ▪ Behaviors to be monitored and type of monitoring necessary (socially inappropriate behavior, etc.). ☐ The assessment for gradual dose reductions for antipsychotic agents and other psychotherapeutic medications (except cognitive enhancers and antidepressants), unless clinically contraindicated;	**Notes:**

Stage 2 Critical Elements for Psychoactive Medications

Assessment	
☐ A review of the medication in relation to the age and medical condition of the resident based on manufacturer's recommendations, and if the manufacturer's recommended dose is not used, a clinically-based explanation and physician rationale for the dose provided; ☐ The duration for which the medication is to be administered, including an explanation for the reason administration of a medication is extended and assessed for possible complications; and ☐ The identification of duplicative medication therapy (multiple medications for the same indications or the same medication duplicated), and provided an explanation, reason, or physician rationale for the duplication.	
For the resident on sedative/hypnotic medications:	
Determine whether the assessment: ☐ Identified the cause of the insomnia and the justification for the use of medication; ☐ Considered alternatives to the use of medication, such as a sleep hygiene program; ☐ Identified the risk and side effects as a result of the use of medication; ☐ Identified the type of clinical monitoring for medication effect; ☐ Identified the duration for which the medication is to be administered; and ☐ Included an explanation for the reason administration of a medication is extended and assessed for possible complications related to extended duration.	**Notes:**

Stage 2 Critical Elements for Psychoactive Medications

Assessment	
☐ Determine whether there was a "significant change" in the resident's condition and whether the facility conducted a significant change comprehensive assessment within 14 days. A "significant change" is a decline or improvement in a resident's status that: 1. Will not normally resolve itself without intervention by staff or by implementing standard disease-related clinical interventions, is not "self-limiting" 2. Impacts more than one area of the resident's health status; and 3. Requires interdisciplinary review and/or revision of the care plan. If there was a "significant change" in the resident's condition and the facility did not conduct a significant change comprehensive assessment within 14 days, initiate **F274, Resident Assessment When Required**. If a comprehensive assessment was not conducted, also cite F272.	
1. If the condition or risks 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) of the resident's condition and the impact of use of the medication on the resident's function, mood, and cognition? ☐ Yes ☐ **No** **F272** ☐ **NA, condition/risks were identified after completion of the required comprehensive assessment and did not meet the criteria for a significant change MDS** *NOTE: Although Federal requirements dictate the completion of RAI assessments according to certain time frames, standards of good clinical practice dictate that the assessment process is more fluid and should be ongoing.* *The comprehensive assessment is not required to be completed until*	**Notes:**

Stage 2 Critical Elements for Psychoactive Medications

Assessment	
14 days after admission. For newly admitted residents, before the 14–day assessment is complete, the lack of sufficient assessment and care planning to meet the resident's needs should be addressed under ***F281, Professional Standards of Quality****.*	

Care Planning	
If the comprehensive assessment was not completed (CE#1 = No), mark CE#2 "NA, the comprehensive assessment was not completed". Review the care plan for specific interventions, measurable objectives, and timetables. Determine whether the care plan: ☐ Lists measurable goals in behavioral terms for use of psychoactive medications; ☐ Identifies non-drug interventions, such as a sleep hygiene program that consist of behavioral interventions (soft lights, music, massage, no caffeine after 4 p.m., and limits naps); ☐ Identifies medications, doses, and duration for the age and clinical condition of the resident; ☐ Identifies who is responsible for monitoring medical parameters and for side effects, and how often monitoring is to be done; ☐ Lists potential troublesome medication side effects listed in the plan of care, and lists non-drug interventions to address medication side effects, such as increased fluids for a drug that causes dry mouth; ☐ Identifies side effects for antipsychotic medications, such as ▪ Tardive dyskinesia, dry mouth, constipation, blurred vision, drowsiness, weight gain, increased risk of obesity, diabetes and high cholesterol, restlessness, stiffness, tremors, and muscle spasms; ▪ Extrapyramidal effects such as contraction of the muscles of neck (torticollis), eyes (oculogyric crisis), tongue (which can cause	**Notes:**

Stage 2 Critical Elements for Psychoactive Medications

Care Planning	
airway obstruction), jaw and other muscle groups; and ▪ Neuroleptic malignant syndrome. ☐ Lists behavioral interventions, including who is to carry them out and how often; ☐ Identifies how and when dose reductions will be attempted (if not clinically contraindicated); and ☐ Identifies behavioral interventions that reflect current standards of practice in conjunction with psychoactive medications.	
For psychoactive medications used for residents with dementia:	
☐ Determine whether the care plan provides for gradual dose reduction, unless clinically contraindicated.	**Notes:**

Stage 2 Critical Elements for Psychoactive Medications

Care Planning	
For antipsychotic and anti-anxiety medications:	
☐ Doses are started at a low level and increased as needed, and if doses are decreased, a slow taper is used.	**Notes:**
For hypnotic medications:	
☐ The medication is prescribed and used on a PRN rather than a routine basis, and if used more than 10 consecutive days, a dose reduction is attempted, unless clinically contraindicated (most sedatives will lose effectiveness after 2 weeks continuous use).	**Notes:**

Stage 2 Critical Elements for Psychoactive Medications

Care Planning	
2. Did the facility develop a plan of care with measurable goals and interventions to address the use of medications, prevent adverse effects or side effects, and monitor to determine whether the medications are providing intended affects, in accordance with the assessment, resident's wishes, and current standards of practice? ☐ Yes ☐ **No** **F279** ☐ **NA, the comprehensive assessment was not completed** *The comprehensive care plan does not need to be completed until 7 days after the comprehensive assessment (the assessment completed with the RAPS). Lack of sufficient care planning to meet the needs of a newly admitted resident should be addressed under* ***F281, Professional Standards of Quality****.*	**Notes:**

Stage 2 Critical Elements for Psychoactive Medications

Care Plan Implementation by Qualified Persons	
Observe care and interview staff over several shifts and determine whether: ☐ Care is being provided by qualified staff, and/or ☐ The care plan is adequately and/or correctly implemented. **3. Did the facility provide or arrange services to be provided by qualified persons in accordance with the resident's written plan of care?** ☐ Yes ☐ **No** **F282** ☐ **NA, no provision in the written plan of care for the concern being evaluated** *NOTE: If there is a failure to provide necessary care and services, the related care issue should also be cited when there is actual or potential outcome.*	**Notes:**

Stage 2 Critical Elements for Psychoactive Medications

Care Plan Revision	
If the comprehensive assessment was not completed (CE#1 = No), OR, if the care plan was not developed (CE#2 = No), mark CE#4 "NA, the comprehensive assessment was not completed OR the care plan was not developed". ☐ Determine whether the facility evaluated and assessed: ▪ The effectiveness of the medication therapy; ▪ The potential and monitoring for adverse consequences of the medication therapy in accord with the nature of the medication and recommended standards of practice; and ▪ Any additional or increasing signs or symptoms of deterioration that have been evaluated as related potentially to the medication therapy (e.g., a resident with dementia who is receiving medication(s) with a potential for somnolence and reduced ability to respond is evaluated objectively for adverse medication effect before the declining condition is ascribed to worsening of the dementia). ☐ Determine whether revisions were made to the care plan based upon the following: ▪ Outcomes and the continued use of the medication (clinical indication for the continued use of the medications); ▪ Side effects occurred, and the resident and/or responsible party were informed of the risk/benefit analysis and involved/allowed to make a decision on treatment; ▪ Identification of adverse effects indicated that the drug dose should be decreased or discontinued; and ▪ When a dose reduction is to be attempted (if a reduction is not clinically contraindicated) and the reduction is planned in a manner that will promote the success of the reduction.	**Notes:**

Stage 2 Critical Elements for Psychoactive Medications

Care Plan Revision	
Note: Dose reductions should be attempted twice a year for antipsychotics, and every four months for anti-anxiety medication, unless contraindicated. **4. Did the facility reassess the effectiveness of the interventions and review and revise the plan of care (with input from the resident or representative, to the extent possible), if necessary, to meet the needs of the resident?** ☐ Yes ☐ **No F280** ☐ **NA, the comprehensive assessment was not completed OR the care plan was not developed**	

Provision of Care and Services	
Determine whether staff have followed the care process prior to prescribing and administering medication, including: ☐ Identifying the medical justification, including defining diagnoses (to the extent possible); ☐ Weighing the risk benefit of the anticipated medication individually and in combination with the remainder of the medication regimen; ☐ Eliminating environmental causative factors; ☐ Using non-medication interventions, when appropriate, prior to or in conjunction with medication therapy; ☐ Identifying and implementing parameters for monitoring for effectiveness and potential, or actual, adverse consequences; and ☐ Recognizing actual or potential MRPs, evaluating the resident, and modifying the regimen or weighing the risk-benefit, and defining the clinical rationale for continuing the regimen while addressing the negative outcome.	**Notes:**

Stage 2 Critical Elements for Psychoactive Medications

Provision of Care and Services	
5. Based on observation, interviews, and record review, did staff provide care to prevent adverse effects and use only necessary antipsychotic, anti-anxiety, and/or hypnotic drugs? ☐Yes ☐ **No F329**	

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
During the investigation of the use of antipsychotics, anti-anxiety, and/or hypnotic medication use, the surveyor may have identified concerns with related structure, process and/or outcome requirements, such as the examples listed below. If an additional concern has been identified, the surveyor should initiate the appropriate care area or F tag and investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance. ☐ **F154, Notice of Rights, and Choices (Free Choice)** — Determine whether the resident was advised of her/his medical condition and was allowed to exercise informed consent about his/her treatment including medications and has been advised of her/his therapy and condition. ☐ **Notification of Change** — Determine whether staff: ▪ Consulted with the physician regarding significant changes in the resident's condition, including the need to alter treatment significantly or failure of the treatment plan; and ▪ Notified the resident's representative (if possible) of significant changes in the resident's condition. ☐ **F278, Accuracy of Assessments** — Determine whether staff that are qualified to assess relevant care areas and are knowledgeable about the resident's status, needs, strengths, and areas of decline conducted an accurate assessment.	**Notes:**

Stage 2 Critical Elements for Psychoactive Medications

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
☐ **F281, Professional Standards of Quality** __ Determine whether the interventions defined or care provided appear not to be consistent with recognized standards of practice: ▪ Interview health care practitioners and professionals to determine whether there is evidence of an event or situation that actually or potentially interfered with the intended or desired outcome of medication therapy. Note: The surveyor is not expected to prove that an adverse event was directly caused by a medication related problem (MRP), but rather that there was a failure in the care process. ▪ Evidence of a potential MRP (such as an adverse outcome or decline potentially related to the therapy) may include but not limited to: - A change in mental status or increasing lethargy, confusion, agitation, or mood disturbance; - New onset or recurrent dizziness or falling; or - Anorexia or unplanned weight loss. Note: The most common MRPs include medication use with no indication; inadequate effectiveness of medication; ADR; unintended medication interaction; excessively high dose or duration; and medication use without adequate monitoring. ▪ If there is a potential MRP, ask for evidence that the care process was followed, including the identification and assessment for the need, and monitoring during the use of the medication. Investigate whether evidence exists in the record (including the MRR report) that indicates: - The facility identified, acknowledged, addressed, and continues to monitor the potential MRP and/or resident response;	

Stage 2 Critical Elements for Psychoactive Medications

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
- The facility identified the risk(s) involved with the use of the individual medication or combination of medications; - The facility could explain why the benefit of the medication(s) or dose(s) outweighed the risks of a potential MRP, or dose reduction is contraindicated, or a particular medication is the one of choice for a resident despite its risks (any medication may be appropriate therapy, if there is documentation substantiating the choice and the benefit, for example, the resident lacks seizure control unless the dose and blood level exceed the usual recommended therapeutic levels, and the facility is actively monitoring for potential MRPs); - The risk/benefit of the medication use was provided to the resident or representative; - The pharmacist identified and reported in a timely manner to the attending physician and the DON the potential MRP; - There has been action based upon the pharmacist's notice, or the decision to not take action is documented with a clinically-based rationale; and - The duration for which the medication is to be administered, including an explanation for the reason administration of a medication is to be extended. ▪ If an explanation is not provided, record the medication, dosage, date ordered, and date the medication should have been reevaluated, if known. ▪ Interview the physician, pharmacist, clinical nurse (including medication administration staff, as appropriate) and/or DON, regarding: - The potential MRP and the therapeutic effectiveness of the medication regimen; - The monitoring that is in place;	

Stage 2 Critical Elements for Psychoactive Medications

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
- The process of the MRR (e.g., computer screening or in-facility review and discussion with direct care staff); - Reporting to the practitioner; - The practitioner follow-up; and - Re-evaluations by the team. Note: Allow the facility to provide a rationale for the use of medications prescribed outside the information provided in the interpretive guidelines for Tags F329 and F428. The facility may not justify the use of a medication prescribed outside these guidelines solely on the basis of, "The doctor ordered it." This justification would render the regulations meaningless. The rationale must be based on a clinically valid review of risks and benefits, the resident's symptoms and responses to treatment, determination of the ongoing need to treat the target symptom(s), potential adverse effects of the medication, and standards of practice. Examples of evidence that would support a justification of why a medication is being used outside these Guidelines, but in the best interest of the resident, may include, but are not limited to, the following: - A physician's note indicating, for example, why the dosage, duration, indication, or monitoring are clinically appropriate, or otherwise demonstrating that the physician has carefully considered relevant issues and the impact on the resident; - Documentation of a medical or psychiatric consultation or evaluation that supports the physician's judgment that use of a medication outside the Guidelines is in the best interest of the resident; - Quantitative and qualitative instruments (e.g., Mini-Mental Status Exam, Geriatric Depression Scale, or Behavioral	

Stage 2 Critical Elements for Psychoactive Medications

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
Pathology in Alzheimer's Disease rating scale) establishing treatment benefits; - Physician, nursing, or other health professional documentation indicating that the resident is being monitored for adverse consequences or complications of the medication therapy and that therapy within the Guidelines has been ineffective; - Documentation confirming that previous attempts at dosage reduction have been unsuccessful; - Documentation showing that a resident's decline or deterioration is evaluated by the interdisciplinary team and provides evidence that a particular medication, or a particular dose or duration of therapy, is not the cause or a major contributing factor; - Documentation showing why the resident's age, weight, or other factors would require a unique medication dose or medication duration, indication, or monitoring approach; and - Documentation of current literature substantiating the use of the medication in the specific condition being treated which is outside of the regulatory guidelines. ▪ Determine whether: - The use of the medication is routinely monitored (i.e., therapeutic effects, side effects, and adverse effects) according to manufacturer's specifications or standards of practice; - Necessary labs, weights, vital signs, etc., are taken and recorded in the clinical record (See drug reference); - Doses are appropriately titrated up or down for an elderly person, including planned dose reductions (See drug reference); - The resident has renal or hepatic impairment and that the dose been adjusted (see drug reference); and	

Stage 2 Critical Elements for Psychoactive Medications

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
- Whether there is an association between the resident's medications(s) and the recently identified symptoms or condition change such as a fall/recurrent falls, decline in ADLs, or decreased sensorium/increased somnolence. ▪ If there is a concern identified regarding MRP: - Review the performance of the facility in identifying and monitoring medication therapy. - Determine whether the consultant pharmacist: Conducts a review of the regimen and signed and dated the MRR at least monthly, or more frequently, if indicated by factors such as abrupt changes in the resident's clinical condition, numerous changes in, or initiation of, a complex medication regimen; and Reports any concerns to the prescriber and DON. ▪ Determine whether the facility responded to the concern and the type of action taken. Note: A record of the pharmacist's MRR and the report of irregularities might be part of the clinical record or be retained separately. If not part of the active clinical record, request the report(s). ☐ **Sufficient Nursing Staff** __ Determine whether the facility has sufficient staff: ▪ To timely administer medications, ▪ To evaluate the response of the resident to the medications, ▪ To implement non–pharmacologic interventions when appropriate to avoid use of unnecessary medication, and ▪ To identify and respond to changes in resident condition, which may indicate an MRP.	

Stage 2 Critical Elements for Psychoactive Medications

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
☐ **F385, Physician Supervision** __ Determine whether the physician supervised the resident's medical treatment, assessing the resident's condition (need for medication), and developing a treatment plan. ☐ **F386, Physician Visits** __ Determine whether the physician or her/his designee: ▪ Reviewed the resident's total program of care including medications, ▪ Wrote relevant progress notes at each visit required, ▪ Assessed for underlying causative factors, ▪ Established a treatment regimen which considered non-pharmacological interventions as well as medication; and ▪ Reviewed the medication regimen for potential unnecessary medications and the effectiveness as well as potential complications of the regimen. ☐ **F428, Drug Regimen Review** __ Determine whether the licensed pharmacist has: ▪ Performed a review at least monthly (or more frequently if the resident has had frequent changes in the medication regimen or at least initially for short stay residents); ▪ Identified actual or potential MRPs; ▪ Provided a report to the DON and attending physician; - That the attending physician and facility have acted upon these reports; and - The facility has retained these reports and incorporated the reports into the clinical record.	

Stage 2 Critical Elements for Psychoactive Medications

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
☐ **F501, Medical Director** __ Determine whether the medical director: ▪ Has been involved in the coordination of medical care, which includes, in collaboration with the facility, the development of policies and procedures regarding the provision of care and services for residents who receive psychoactive medications; and ▪ Whether the medical director was involved in the evaluation of medication irregularities that are identified or reported, and has been working with the facility and practitioners to take appropriate action. ☐ **F514, Clinical Records -** Determine whether the clinical records: ▪ Accurately and completely document the resident's status, the care and services provided in accordance with current professional standards and practices; and ▪ Provide a basis for determining and managing the resident's progress, including response to treatment, change in condition, and changes in treatment.	