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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-47-NH

DATE: **July 17, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Medication-Related Adverse Events in Nursing Homes

Memorandum Summary

- **Medication-Related Adverse Events –** Adverse events related to high risk medications can have devastating effects to nursing home residents. Proper management of high risk medications represents a serious challenge for nursing homes, and merits close attention by top management and staff throughout the facility. We are very concerned about the prevalence of adverse events involving such medications.

- **Focused Survey on Medication Safety Systems and Adverse Drug Event Trigger Tool -** The Centers for Medicare & Medicaid Services (CMS) has begun pilot testing a Focused Survey on Medication Safety Systems to look at nursing home systems around high risk and problem-prone medications using an Adverse Drug Event Trigger Tool. The CMS is making the draft tool available to assist surveyors in investigating medication related adverse events and to nursing home providers as a risk management tool.

Background

In February 2014, the Office of the Inspector General (OIG) released its report, "*Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries*." The OIG found that one in three skilled nursing facility (SNF) residents were harmed by an adverse event or temporary harm event within the first 35 days of a SNF stay and 37 percent of the adverse events were related to medication. The second most frequent cause of medication related adverse events was excessive bleeding related to anticoagulant use causing harm ranging from hospitalization to death. These findings are further supported by Propublica data reported in a recent Washington Post article which stated, "…from 2011 to 2014, at least 165 nursing home residents were hospitalized or died after errors involving Coumadin or its generic version, warfarin" (see http://www.washingtonpost.com/national/health-science/popular-blood-thinner-causing-deaths-injuries-in-nursing-homes/2015/07/12/be34f580-1469-11e5-89f3-61410da94eb1_story.html).

The CMS recognizes the necessity of anticoagulant therapy for many conditions in nursing home residents, but its narrow therapeutic range requires effective monitoring systems to ensure safe administration and to achieve the desired effect.

Focused Survey on Medication Safety Systems

The CMS has developed and begun pilot testing the Focused Survey on Medication Safety Systems to look at nursing home practice around high-risk and problem-prone medications, such as Coumadin. Objectives of the Focused Survey on Medication Safety Systems are to:

- Identify preventable adverse drug events that have occurred or may occur;
- Determine whether facilities identify residents' risk factors for adverse drug events and implement individualized interventions to eliminate or mitigate those risk factors; and,
- Determine if the facility has implemented effective systems to prevent adverse drug events as well as recognize and respond to adverse drug events that do occur in order to minimize harm for the individual and prevent recurrence of the event.

Adverse Drug Event Trigger Tool

The CMS collaborated with the Agency for Healthcare Research & Quality (AHRQ) and the OIG to develop a tool which includes potentially preventable medication-related adverse events, risk factors, triggers, and probes to assist surveyors in investigating actual and potential adverse events and evaluate whether systems are in place to prevent medication-related adverse events. The trigger tool is one of several tools in use for the pilot focused survey.

The CMS is releasing the draft Adverse Drug Event Trigger Tool to assist surveyors as they investigate medication related adverse events and to assess whether facilities have implemented effective systems to prevent adverse drug events. Use of this draft tool is not mandatory but may aid surveyors in assessing compliance around medication issues during standard and complaint surveys. Nursing home providers may also find it useful as a risk management tool. The draft trigger tool will be available on the CMS Nursing Home Quality Assurance and Performance Improvement (QAPI) website, http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/NHQAPI.html.

Contact: Please send questions regarding this memorandum or the draft tool to the CMS Nhqapi mailbox at Nhqapi@cms.hhs.gov.

Effective Date: Immediately. This information and the draft tool should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

Attachment - Adverse Drug Event Surveyor Trigger Tool (draft)

cc: Survey and Certification Regional Office Management

Adverse Drug Event Trigger Tool

Intended use of this tool:
This tool is intended to assist surveyors to identify:
1. The extent to which facilities have identified resident-specific risk factors for adverse drug events,
2. The extent to which facilities developed and implemented systems and processes to minimize risks associated with medications that are known to be high-risk and problem-prone, and
3. When a preventable adverse event has occurred, and evaluate if the nursing home identified the issue and responded appropriately to mitigate harm to the individual and prevent recurrence.

Definitions:
- **Adverse Event:** An untoward, undesirable, and usually unanticipated event that causes death, serious injury, harm, or the risk thereof.
- **Adverse Drug Event:** An injury resulting from drug-related medical interventions.
- **Adverse Drug Reaction:** Harm directly caused by a drug at normal doses.
- **Anticholinergic Effects:** Physical symptoms resulting from drugs that counter the action of acetylcholine including increased blood pressure, respiratory distress, clumsiness/unsteadiness, bloating/constipation/ileus, nausea/vomiting, dry mouth, delirium, drowsiness/lethargy/fatigue, urinary retention, hallucinations, memory problems, and blurred vision.
- **Prescribing Cascade:** Adverse reaction to one drug that goes unrecognized or is misinterpreted resulting in the prescriber inappropriately prescribing a subsequent drug to treat the signs/symptoms of the adverse reaction.
- **Polypharmacy:** Multiple definitions exist, but most include reference to drugs without indication and the number of medications used (e.g., more than 10).
- **Risk Factor:** Issue or condition that increases the potential for an adverse event to occur. Risk factors include resident level issues such as medications prescribed, age, and concurrent conditions as well as system level issues such as lack of staff knowledge related to high risk medications and unclear protocols to address lab results.

Adverse Drug Event Trigger Tool

Adverse Drug Event (ADE)	**Risk Factors** - These increase the potential for ADEs. Multiple factors increase risk.	**Triggers: Signs and Symptoms (S/S)** - Any of these may indicate an ADE may have occurred.	**Triggers: Clinical Interventions** - These actions may indicate an ADE occurred.	**Surveyor Probes** - These questions are designed to assist in the investigation. A negative answer does not necessarily indicate noncompliance.

Change in mental status/delirium related to opioid use	• PRN or routine use of opioid medication
	• Opioid naiveté (someone who has not been taking opioids)
	• Opioids used in combination with sedatives or other opioids
	• History of opioid abuse
	• Opioid tolerance
	• Severe pain
	• Low fluid intake/dehydration
	• Low body weight
	• History of head injury, traumatic brain injury, or seizures
		• Falls
		• Hallucinations
		• Delusions
		• Disorientation or confusion
		• Light-headedness, dizziness, or vertigo
		• Lethargy or somnolence
		• Agitation
		• Anxiety
		• Unresponsiveness
		• Decreased
		  • BP
		  • Pulse
		  • Pulse oximetry
		  • Respirations
			• Administration of Narcan
			• Transfer to hospital
			• Call to physician regarding new onset of relevant signs or symptoms
			• Abrupt stop order for medication
				• Is there an assessment and determination of pain etiology?
				• Does the resident's pain management regime address the underlying etiology?
				• For a change in mental status, is there evidence that the physician conducted an evaluation of the underlying cause, including medications?
				• Is there evidence of a system for ensuring that residents are routinely assessed for pain, including monitoring for effectiveness of pain relief and side effects of medication (e.g., over-sedation)?
				• If receiving PRN and routinely, is there consideration for the timing of administration of the PRN?
				• Can staff describe signs/symptoms of over-sedation?
				• Is there evidence of a system for ensuring "hand off" communication includes the resident's pain status and time of last dose?
				• Do the resident, family, and direct caregivers know signs and symptoms of over-sedation and steps to take if noted (e.g., alert the nurse)?
				• Is there evidence the facility implements non-pharmacological pain management approaches?
				• Is there a system to ensure extended-release formulations are delivered correctly (e.g., medications not crushed)?

Change in mental status/delirium related to	• PRN or routine use of psychotropic medication • Use of more than one	• Falls • Confusion • Sedation • Cardiac arrhythmias	• Transfer to hospital • Call to physician regarding new onset of relevant signs or	• Does the medical record include consistent documentation of clinical indication, e.g., do physician notes, care plan, and tracking sheets all address the same indication?

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psychotropic medication use (including antipsychotics, antidepressants, anxiolytics, and hypnotics)	psychotropic medication including more than one drug from the same class or different classes • Advanced age • Polypharmacy	• Orthostatic hypotension • Destabilized blood sugar • Akathisia • Parkinsonism • Anticholinergic effects	symptoms • New order for restraint • Abrupt stop order for medication	• If receiving PRN and routinely, is there consideration for the timing of administration of the PRN? • Is there evidence of a system for ensuring the resident is routinely assessed for effectiveness of the medication and signs/symptoms of adverse drug reactions/events? • Is there a system for monitoring for involuntary movements? • Is there evidence that the facility has attempted gradual dose reduction or rationale documented if not attempted? • Is there evidence the facility implements non-pharmacological approaches and interdisciplinary management of the condition that the medication targets? • Is there evidence in the medical record that the resident or representative were involved in decisions related to medication use? • Is there a system to ensure extended-release formulations are delivered correctly (e.g., medications not crushed)?

Hypoglycemia related to use of antidiabetic medication	• Insulin use
	• Sliding scale insulin use
	• Oral hypoglycemic medication use
	• Decrease in oral intake while taking antidiabetic medication
		• Hypoglycemia (e.g., <50 mg/dl)
		• Falls
		• Headache
		• Shakiness, nervousness, anxiety
		• Sweating, chills, clamminess
		• Irritability, impatience
		• Change in mental
			• Stat administration of Glucagon or IV dextrose
			• Administration of orange juice or other high sugar food or fluids in response to blood sugar reading or symptoms
			• Transfer to hospital
				• Does the care plan reflect interdisciplinary monitoring for:
				  • Signs/symptoms of hypoglycemic episodes?
				  • Changes in oral intake?
				• Is there evidence blood glucose testing and insulin administration are coordinated with meals?
				• Is there evidence the facility has addressed any pharmacy recommendations?
				• If sliding scale insulin is used, does the medical

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		status • Emotional changes (including new anger, sadness, stubbornness) • Lightheadedness, dizziness • Hunger • Nausea • Complaints of blurred or impaired vision • Tingling or numbness in lips and/or tongue • Weakness, fatigue, or somnolence • Incoordination • Seizures • Unconsciousness • Rapid heartbeat		record contain documentation of risk vs. benefits? Clinical rationale? • If an EHR is used, are finger stick glucose testing results incorporated into it? • Is there evidence that finger stick glucose results are routinely reviewed for effectiveness as part of the care plan? • Is there evidence that the facility routinely educates caregivers on risk factors and symptoms/signs of hypoglycemia? • Is the resident and family educated regarding the signs and symptoms of hypoglycemia and regarding the resident's diabetes management plan • Does the facility have low blood sugar protocols in place? • Is there a system to ensure lab results, including finger stick blood glucose results, are appropriately communicated to the physician and the dietician including when panic values are obtained? • Is there evidence that glucose monitoring equipment is maintained and that staff technique meets standards of practice.

Ketoacidosis related to insulin therapy	• Diabetic residents with concurrent illnesses
	• Infection
	• Diabetic residents with consistently high blood glucose levels
	• Episodes of high
		• Lab results indicating:
		  • Profound dehydration
		  • Elevated blood glucose
		  • Ketones in urine
		• Excessive thirst
		• Frequent urination
			• Stat order for lab testing including to evaluate blood sugar and fluid and electrolyte status
			• Stat order for insulin
			• New order for and administration of IV
				• Is there evidence of a system for routine monitoring of blood sugar?
				• If the resident refuses antidiabetic medication or consumes foods not included in usual/planned diet, is there evidence of an interdisciplinary plan to address refusals that includes the prescriber and the family, as appropriate?
				• For residents with risk factors for ketoacidosis,

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	physical and/or emotional stress or trauma • A diabetic resident that frequently declines antidiabetic medications or consumes foods not included in diet	• Nausea/vomiting • Abdominal pain • Weakness/fatigue • Shortness of breath • Fruity-scented breath • Confusion • Rapid respirations • Elevated temperature	fluids • Transfer to hospital	does the care plan reflect multi-disciplinary monitoring for signs/symptoms of ketoacidosis? • Is there evidence that the facility routinely educates caregivers on risk factors and symptoms/signs of ketoacidosis? • Does the facility have elevated blood sugar protocols in place? • If sliding scale insulin is used, does the medical record contain documentation of risk vs. benefits? Clinical rationale? • Is there a system to ensure lab results, including finger stick results, are appropriately communicated to the physician and the dietician including when panic values are obtained?
Bleeding related to antithrombotic medication use	• Anticoagulant, antiplatelet, or thrombolytic medication use • Concurrent use of more than one antithrombotic medication (e.g., use of aspirin while on anticoagulants) • History of stroke or GI bleed • NSAID medication use while on anticoagulants • Antibiotics use while on anticoagulants • Amiodarone use	• Elevated PT/INR, PTT • Low platelet count • Bruising • Nosebleeds • Bleeding gums • Prolonged bleeding from wound, IV, or surgical sites • Blood in urine, feces, or vomit • Coughing up blood • Abrupt onset hypotension	• Stat order for PT/INR, PTT, platelet count, or CBC • Abrupt stop order for medication • Administration of Vitamin K • Transfer to hospital	• Does the medical record include documentation of clinical indication? • Is there evidence the facility routinely monitors lab results of all residents on anticoagulant/antiplatelet therapy? • Is there a system to ensure lab results, including PT/INRs, are appropriately communicated to the physician including when panic values are obtained? • Is there evidence that the facility educates caregivers on risk factors and symptoms and signs that may be indicative of excessive bleeding due to antithrombotic medications? • Are residents/families educated regarding the risks associated with antithrombotic medication use and the signs and symptoms of excessive bleeding? • Is there evidence of system to alert prescribers

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	while on anticoagulants • Dietary changes affecting vitamin K intake (e.g., dark leafy greens)			and nursing staff when anticoagulants are combined with other drugs which increase the risk of bleeding? • Does the resident's dietary plan include recognition of foods that interact with antithrombotic medications (e.g., is there a plan to ensure consistent intake of foods and beverages rich in Vitamin K for residents on warfarin)?
Thrombo-embolism related to anticoagulant medication use	• Anticoagulant medication used; • Prolonged immobility • Recent major surgery • Prior history of venous thromboembolic events • Consistently sub-therapeutic PT/INR	• Pain or tenderness and swelling of upper or lower extremity • Increased warmth, edema and/or erythema of affected extremity • Unexplained shortness of breath • Chest pain • Coughing • Hemoptysis • Feelings of anxiety or dread	• Stat order for PT/INR • Stat chest x-ray, • Transfer to hospital	• Is there evidence the facility routinely monitors lab results of all residents on anticoagulant/antiplatelet therapy? • Is there a system to ensure lab results, including PT/INRs, are appropriately communicated to the physician including when sub-therapeutic values are obtained? • Is there evidence that the facility educates caregivers on risk factors and symptoms and signs that may be indicative of thromboembolism?
Prolonged constipation, ileus, or impaction related to opioid medication use	• Opioid medication use (routine or PRN) • Uncontrolled pain • Recent abdominal surgery • Advanced age • Diagnosis of dementia,	• Constipation (lack of bowel movement for three or more days or straining to move bowels regardless of frequency) • Bloating or abdominal distension	• New orders for laxative, stool softeners, suppositories and/or enemas • New order for abdominal x-rays • Transfer to hospital	• Is there evidence of a bowel regimen in place such as routine orders for stool softener/laxative? • For residents with risk factors for constipation, does the care plan reflect interdisciplinary monitoring for signs/symptoms of constipation and an interdisciplinary plan to prevent it including dietary management?

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	Parkinson's, multiple sclerosis, or quadriplegia • Low fluid intake or dehydration • Decreased mobility	• Abdominal pain • Headaches associated with symptoms above • Diarrhea or leaking stool • Decreased bowel sounds • Nausea/vomiting • Decreased or absent ability to urinate • Rapid heartbeat • Sweating • Fever • Low or elevated BP		• Is fluid intake monitored? • Are residents/families taught signs/symptoms of constipation and the importance of reporting them? • Are bowel movements (frequency and size) monitored routinely by nursing staff? • Is bowel status routinely addressed by the physician? • Upon the initiation of opioids, did the prescriber acknowledge the increased of risk of constipation and adjust the plan of care as indicated? • Is there a protocol in place to address constipation (e.g., a process to provide routine or standing order bowel medications when a resident hasn't had a bowel movement)? If so, is the staff aware of and compliant with the protocol? • Does the clinical record reflect that the dietician was made aware of an opioid being ordered so that nutritional approaches to prevent constipation could be considered? • Is there evidence of a system for ensuring that residents are routinely assessed for pain, including monitoring for effectiveness of pain relief and side effects of medication (e.g., constipation)? • Is there evidence that the facility implements non-pharmacological pain management approaches?

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Electrolyte imbalance (including dehydration and acute kidney injury) related to diuretic use	• Use of diuretics
	• Advanced age
	• Dependence in ADLs – especially eating
	• Diagnosis of dementia
	• Fluid restrictions
	• Recent diarrhea or vomiting
	• Hot weather or other trigger for increased fluid needs
	• Use of medical devices that increase fluid needs (e.g., air-fluidized mattresses)
		• Abnormal electrolytes
		• Dry skin and mucous membranes including cracked lips
		• Poor skin turgor
		• Thirst
		• Confusion
		• Concentrated urine and/or decreased output
		• Lethargy
		• Elevated temperature
		• Low BP with increase in pulse
		• Weight loss
			• Abrupt stop order for diuretic medication
			• New order for labs
			• New order for and administration of IV fluids
			• Transfer to hospital
				• For residents with risk factors for dehydration, does the care plan reflect interdisciplinary approaches for prevention including:
				  • Monitoring for signs and symptoms of dehydration, and
				  • Observation/documentation of consumption of liquids?
				• Is there evidence of a system for timely identification of residents with risk factors for dehydration?
				• Does the facility have protocols for:
				  • Hydration?
				  • Monitoring intake and output?
				  • Dehydration risk assessment?
				  • Fluid intake assessment?
				• Does every resident have access to fluids?
				• Are protocols in place to ensure hydration during extreme heat?
				• Are care plan approaches to ensure adequate hydration resident-specific and known to staff caring for the resident?
				• Are residents provided with the assistance they need to drink, including between meals?

Drug toxicity related to acetaminophen	• Concurrent routine and PRN orders for acetaminophen and medications containing acetaminophen • Failure to have a maximum daily dose of acetaminophen	• Elevated liver function tests • Fatigue or weakness • Abdominal pain • Loss of appetite • Jaundice, including yellowing of sclera • Itching • Bruising	• Abrupt stop of all acetaminophen products • Transfer to hospital • New order for liver function tests • New order for N-acetylcysteine	• Is there evidence of a system for ensuring residents with orders for routine or PRN acetaminophen do not receive more than 4 grams in a 24 hour period? • Is there evidence of a system to ensure that medications that contain acetaminophen are flagged to alert medication nurses that the resident has more than one medication containing acetaminophen ordered?

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	order or protocol in place • Maximum daily dose of acetaminophen routinely nears or exceeds 4 gm • Uncontrolled pain • Residents with liver damage • Residents that consume three or more alcoholic drinks per day	• Confusion • Edema/ascites		• Is there evidence of a system to ensure changes in condition are identified, assessed, including an assessment of medications, and communicated to the physician promptly? • Is there evidence that the facility implements non-pharmacological pain management approaches? • Is there evidence of a system for ensuring that residents are routinely assessed for pain, including monitoring for effectiveness of pain relief and side effects of medication? • Is there a system to ensure extended-release formulations are delivered correctly (e.g., medications not crushed)?
Drug toxicity related to digoxin	• Advanced age • Hypokalemia • Hypomagnesaemia • Hypothyroidism • Decreased renal function • Drugs that impair renal function • Drugs that cause hypokalemia	• Elevated digoxin level • Abnormal electrolytes • Lethargy, drowsiness, fatigue • Neuralgia • Headache • Dizziness • Confusion • Hallucinations • Seizures • Visual disturbances (e.g., yellow-green distortion, snowy vision, photophobia) • Anorexia, weight loss • Nausea/vomiting • Abdominal pain • Diarrhea	• New order for and administration of IV fluids • Transfer to hospital • New order for and administration of activated charcoal • New order for and administration of digoxin-specific antibody (e.g., Digibind) • Abrupt stop order for medication	• Does the care plan reflect interdisciplinary monitoring for signs/symptoms of digoxin toxicity? • Is apical pulse prior to administration of digoxin with the drug held when pulse rate <60 bpm (unless other parameters are set by the physician)? • Is there evidence of a system to ensure changes in condition are identified and assessed promptly, including an assessment of medications? • Is there evidence of a system for routine monitoring of renal function and serum medication concentration level? • Is there a system to ensure lab results are appropriately communicated to the physician including when panic values are obtained?

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		• Palpitations • Shortness of breath • Syncope • Lower extremity edema • Irregular or slow heart rate • Irregular respirations		
Drug toxicity related to levothyroxine	• History of thyrotoxicosis • Advanced age • Cardiac arrhythmias	• Abnormal thyroid studies, including TSH • Headache • Leg cramps • Tremors • Heat intolerance • Increased sweating • Diarrhea • Nervousness or irritability • Chest pain • Shortness of breath • Rapid or pounding heartbeat • Insomnia	• Abrupt stop order for medication • Transfer to hospital	• Is there evidence of a system to ensure changes in condition are identified and assessed promptly, including an assessment of medications? • Is there evidence of a system for ensuring lab tests to monitor thyroid functions are ordered and drawn? • Is there a system to ensure lab results are appropriately communicated to the physician including when panic values are obtained? • For residents with risk factors for drug toxicity related to levothyroxine use, does the care plan reflect interdisciplinary monitoring for signs/symptoms of adverse drug reactions to levothyroxine?
Drug toxicity related to angiotensin-converting enzyme (ACE) inhibitors	• Renal artery stenosis • Impaired renal function • Aortic valve stenosis/cardiac outflow obstruction • Congestive Heart Failure	**Hyperkalemia S/S** • Elevated potassium levels • Fatigue • Weakness • Dizziness, syncope • Headaches • Slow, weak, or	• Transfer to hospital • Stat order for lab work • Abrupt stop order for medication For hyperkalemia may also see: • Stat order for IV calcium	• Is there evidence of a system to ensure changes in condition are identified and assessed promptly, including an assessment of medications? • Is there evidence of a system for ensuring serum potassium, BUN, and creatinine levels are drawn routinely? • Is there a system to ensure lab results are appropriately communicated to the physician

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	• Dehydration
	• History of hypersensitivity to ACE inhibitors
	• Concurrent use with:
	  • Diuretics
	  • NSAIDs
	  • Anticoagulants
	  • Cyclosporine
	  • Potassium supplements
		irregular pulse
		• Nausea
		• Abnormal heart rhythm/ECG abnormalities
		
		Angioedema S/S
		• Swelling of soft tissues
		• Shortness of breath
		• Wheezing
		• Persistent non-productive cough
		
		Acute Kidney Failure S/S
		• Elevated BUN/creatinine Reduced/absent urine output
		• Swelling of feet/legs
		• Nausea/vomiting
		• Anorexia
		• Flank pain
			• Stat order for Kayexalate
			• New order for diuretics
				including when panic values are obtained?
				• For residents with risk factors for drug toxicity related to ACE inhibitor use, does the care plan reflect interdisciplinary monitoring for signs/symptoms of adverse drug reactions to ACE Inhibitors?

Drug toxicity related to phenytoin	• Advanced age • Liver impairment • Kidney impairment	• Severe mental status or mood changes • Changes in gait, balance or coordination • Drowsiness • Loss of consciousness • Uncontrollable eye movements	• Stat drug levels and CBC ordered • Abnormal therapeutic drug levels • Abrupt stop order for medication • Transfer to hospital	• Is there evidence in the medical record for clinical indication? • Is there evidence of a system for ensuring therapeutic drug levels are drawn routinely? • Is there a system to ensure lab results are appropriately communicated to the physician including when panic values are obtained? • Is there evidence of a system to ensure changes in condition are identified and assessed

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		• Uncontrollable shaking/jerking motions • Slow/slurred speech • Nausea/vomiting; • Decreased respirations		promptly, including an assessment of medications? • For residents with risk factors for drug toxicity related to phenytoin use, does the care plan reflect interdisciplinary monitoring for signs/symptoms of adverse drug reactions to phenytoin? • Is there a system to ensure extended-release formulations are delivered correctly (e.g., medications not crushed)?

Drug toxicity related to lithium	• Advanced age
	• History of lithium toxicity
	• Kidney impairment
	• Hypothyroidism
	• Decreased PO intake
	• Dehydration
	• Concurrent administration of:
	  • Diuretics
	  • ACE inhibitors
	  • NSAIDS
	  • Neuroleptics
	  • Antiepileptics
	  • Calcium antagonists
		• Elevated serum lithium level
		• Elevated serum sodium level
		• Diarrhea
		• Nausea/vomiting
		• Weakness/dizziness
		• Stomach pain\
		• Hand tremors or muscle twitches
		• Slurred speech
		• Abnormal ECG
		• Incoordination
		• Uncontrollable eye movements
		• Seizures
		• Coma
			• Stat order for ECG
			• Stat order for drug level
			• Stat order for IV hydration
			• Transfer to hospital
				• Is there evidence in the medical record for clinical indication?
				• Is there evidence of a system for ensuring therapeutic drug levels are drawn routinely?
				• Is there a system to ensure lab results are appropriately communicated to the physician including when panic values are obtained?
				• Is there evidence of a system to ensure changes in condition are identified and assessed promptly, including an assessment of medications?
				• For residents with risk factors for drug toxicity related to lithium use, does the care plan reflect interdisciplinary monitoring for signs/symptoms of adverse drug reactions to lithium?
				• Is there a system to ensure extended-release formulations are delivered correctly (e.g., medications not crushed)?

Drug toxicity related to valproic acid	• Existing liver disease • Impaired renal function • Concurrent	• Loss of appetite, • Nausea/vomiting • Confusion • Dizziness	• Stat order for drug level (VPA) • Order for brain CT (looking for edema)	• Is there evidence of a system for ensuring therapeutic drug levels are drawn routinely? • Is there a system to ensure lab results are appropriately communicated to the physician

Adverse Drug Event Trigger Tool

Adverse Drug Event (ADE)	**Risk Factors** - These increase the potential for ADEs. Multiple factors increase risk.	**Triggers: Signs and Symptoms (S/S)** - Any of these may indicate an ADE may have occurred.	**Triggers: Clinical Interventions** - These actions may indicate an ADE occurred.	**Surveyor Probes** - These questions are designed to assist in the investigation. A negative answer does not necessarily indicate noncompliance.
	administration: • Antidepressants • Benzodiazepines • Antibiotics	• Lethargy • Numbness, tingling, weakness, or involuntary muscle twitching, • Increased heart rate • Decreased respirations	• Order for ECG • Administration of Narcan, L-carnitine, or activated charcoal	including when panic values are obtained? • Is there evidence of a system to ensure changes in condition are identified and assessed promptly, including an assessment of medications? • For residents with risk factors for drug toxicity related to valproic acid use, does the care plan reflect interdisciplinary monitoring for signs/symptoms of adverse drug reactions to valproic acid? • Is there a system to ensure extended-release formulations are delivered correctly (e.g., medications not crushed)?

Drug toxicity related to antibiotics	• History of renal disease/insufficiency
	• Concurrent administration with:
	  • Medications that raise PT/INR or PTT
	  • Phenytoin
	  • Other antibiotics
		• Elevated kidney function tests
		• Elevated liver function tests
		• Elevated serum potassium
		• Decrease in platelets
		• Nausea/vomiting
		• Diarrhea
		• Loss of appetite
		• Flushing of skin
		• Lethargy
		• Dizziness
		• Hearing loss
		• Rash
		• Seizures
		• Ventricular arrhythmias
		• Peripheral neuropathy
			• Orders for abrupt discontinuation of medication
			• ECG order
			• Order for STAT lab work
				• Is there evidence in the medical record for clinical indication?
				• Is the order time limited?
				• Does the care plan and/or medication administration record (MAR) reflect special instructions related to antibiotic administration such as taking with food or water, infusing IV antibiotic over certain time period, monitoring of drug levels and other labs (as appropriate)?
				• Is there evidence of a system to ensure changes in condition are identified and assessed promptly, including an assessment of medications?
				• Is there a system to ensure lab results are appropriately communicated to the physician including when panic values are obtained?
				• For residents with liver or kidney disease, is there evidence of additional monitoring to ensure antibiotics do not adversely affect kidney

Adverse Drug Event Trigger Tool

Adverse Drug Event (ADE)	**Risk Factors** - These increase the potential for ADEs. Multiple factors increase risk.	**Triggers: Signs and Symptoms (S/S)** - Any of these may indicate an ADE may have occurred.	**Triggers: Clinical Interventions** - These actions may indicate an ADE occurred.	**Surveyor Probes** - These questions are designed to assist in the investigation. A negative answer does not necessarily indicate noncompliance.
		• Esophagitis • Symptoms of hypoglycemia • Phlebitis		or liver function, i.e., additional lab work, monitoring intake/output? • Is there evidence of a system to evaluate appropriate use of antibiotics, i.e. an antibiotic stewardship program? • For residents with risk factors for drug toxicity related to antibiotic use, does the care plan reflect interdisciplinary monitoring for signs/symptoms of adverse drug reactions to antibiotics? • Is there a system to ensure that dietary adjustments are made if needed when antibiotics are ordered? • Is there a system to ensure antibiotics are not given in conjunction with medications that impact their absorption (e.g., Milk of Magnesia)?
Altered cardiac output related to cardiac medications (blood pressure medications, beta blockers)	• Advanced age • History of heart attack, arrhythmia, cardiomyopathies, or CHF	• Fainting • Falls • Elevation/drop in BP • Bradycardia • Dizziness • Light-headedness • Nausea • Sweating • Weakness/fatigue • Visual disturbances • Clamminess • Loss of consciousness	• Abrupt stop of medication • IV fluids • Transfer to hospital	• Is there evidence of a system to ensure changes in condition are identified and assessed promptly, including an assessment of medications? • For residents with risk factors for altered cardiac input related to cardiac medications, does the care plan reflect interdisciplinary monitoring for signs/symptoms of altered cardiac output? • Is there a system to ensure routine monitoring of cardiac status for residents receiving blood pressure medications (e.g., blood pressure monitoring)?