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	IL6003560	A. BUILDING: _____ B. WING _____	C 09/26/2024

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S 000	Initial Comments Complaint Investigation 2467614/IL178311	S 000		
S9999	Final Observations Statement of Licensure Violations 300.610a) 300.1210b) 300.1610a)1) 300.1620a) 300.1630b) Section 300.610 Resident Care Policies a) The facility shall have written policies and procedures governing all services provided by the facility. The written policies and procedures shall be formulated by a Resident Care Policy Committee consisting of at least the administrator, the advisory physician or the medical advisory committee, and representatives of nursing and other services in the facility. The policies shall comply with the Act and this Part. The written policies shall be followed in operating the facility and shall be reviewed at least annually by this committee, documented by written, signed and dated minutes of the meeting. Section 300.1210 General Requirements for Nursing and Personal Care b) The facility shall provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychological well-being of the resident, in accordance with each resident's comprehensive resident care plan. Adequate and properly supervised nursing care and personal care shall be provided to each	S9999		

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resident to meet the total nursing and personal care needs of the resident.

Section 300.1610 Medication Policies and Procedures

a) Development of Medication Policies

1) Every facility shall adopt written policies and procedures for properly and promptly obtaining, dispensing, administering, returning, and disposing of drugs and medications. These policies and procedures shall be consistent with the Act and this Part and shall be followed by the facility. These policies and procedures shall be in compliance with all applicable federal, State and local laws.

Section 300.1620 Compliance with Licensed Prescriber's Orders

a) All medications shall be given only upon the written, facsimile, or electronic order of a licensed prescriber. The facsimile or electronic order of a licensed prescriber shall be authenticated by the licensed prescriber within 10 calendar days, in accordance with Section 300.1810. All orders shall have the handwritten signature (or unique identifier) of the licensed prescriber. (Rubber stamp signatures are not acceptable.) These medications shall be administered as ordered-by the licensed prescriber and at the designated time.

Section 300.1630 Administration of Medication

b) The facility shall have medication records that shall be used and checked against the licensed prescriber's orders to assure proper

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administration of medicine to each resident. Medication records shall include or be accompanied by recent photographs or other means of easy, accurate resident identification. Medication records shall contain the resident's name, diagnoses, known allergies, current medications, dosages, directions for use, and, if available , a history of prescription and non-prescription medications taken by the resident during the 30 days prior to admission to the facility.

These Requirements were not met as evidenced by:

Based on interview and record review the facility failed to follow physician orders for a resident's anticoagulant medication (Warfarin/Coumadin) resulting in the resident receiving an increased anticoagulant dosage for 24 days. The facility also failed to monitor the resident's anticoagulant medication as recommended by the drug manufacturer guidelines. These failures affect one (R1) resident reviewed for anticoagulation therapy on a sample list of three residents. These failures resulted in R1 experiencing internal bleeding and dying.

Findings include:

The undated Warfarin package insert documents, "The dosage and administration of warfarin sodium tables must be individualize for each patient according to the patient's (International Normalized Ratio) INR response to the drug. Adjust the dose based on the patient INR and the condition being treated. Monitoring: Obtain daily INR determinations upon initiation until stable in the therapeutic range. Obtain subsequent INR

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determination every 1-4 weeks.

The National Institute of Health (NIH) report on Warfarin (Coumadin) anticoagulant dated March 24, 2023 documents, "Close monitoring of a patient's INR is a strong recommendation when initiating Warfarin. The INR requires more frequent monitoring when starting Warfarin. More frequent monitoring is necessary for patients with supratherapeutic or subtherapeutic INR to evaluate safety and efficacy. Also, the INR requires assessment when initiating, discontinuing, or changing doses of medications known to interact with Warfarin. Patients also require close monitoring for signs and symptoms of active bleeding throughout their treatment. Close monitoring for signs and symptoms of bleeding, such as dark tarry stools, nosebleeds, and hematomas, is necessary.

R1's census report dated 1/25/24 documents admission to the facility.

R1's undated diagnoses sheet includes the following diagnoses: Transient Cerebral Ischemic Attack, Non-Rheumatic Aortic Valve Stenosis, Hypothyroidism, Hypertension, Chronic Respiratory Failure, Congestive Heart Failure, Chronic Obstructive Pulmonary Disease, Aneurysm of the Ascending Aorta Without Rupture, Depression, Dementia, Anxiety, and the Presence of a Prosthetic Heart Valve.

R1's January, February and March 2024 physician order sheet documents Plavix (antiplatelet) 75 milligrams (mg) to be given daily.

R1's April 5, 2024 medication administration record documents R1's Plavix was discontinued and Warfarin (anticoagulant), 4mg daily was

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started.

R1's Anticoagulant Monitoring Flow Sheets do not document target INRs.

R1's Prothrombin Time (PT) and International normalized ratio (INR) results sheet dated April 23, 2024 documents a target range PT of 9.1-10.7 and a target range INR of 2.0-3.0.

R1's first documented PT/INR in the medical record is dated 4/23/24 with PT results of 16.4 and INR results of 1.7 (Both out of range).

R1's next documented PT/INR in the medical record is dated 5/7/24 with PT results of 14.3 and INR results of 1.5 (Both out of range).

R1's next documented PT/INR in the medical record is dated 5/14/24 with PT results of 15 and INR results of 1.5 (Both out of range).

R1's next documented PT/INR in the medical record is dated 5/21/24 with PT results of 19.4 and INR results of 2.0 (PT results out of range).

R1's May 2024 physician orders document to administer Warfarin 2mg from 5/2/24-5/14/24 and to administer Warfarin 3mg from 5/15/24-5/31/24.

R1's next documented PT/INR in the medical record is dated 6/4/24 with PT results of 24.8 and INR results of 2.6 (PT results out of range).

R1's next documented PT/INR in the medical record is dated 6/13/24 with PT results of 51.3 and INR results of 5.4 (Both out of range).

R1's next documented PT/INR in the medical record is dated 6/18/24 with PT results of 35.8

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and INR results of 3.7 (Both out of range).

R1's June 2024 physician orders document Warfarin 3mg to administer from 6/1/24-6/12/24, 6/15/24-6/17/24 and from 6/19/24-6/26/24.

R1's next documented PT/INR in the medical record is dated 6/27/24 with PT results of 116 and an INR greater than 10 (Both critically out of range high results).

R1's physician orders dated 6/27/24 document to hold the Warfarin for three days, obtain two PT and INRs, the first on 6/28/24 and the second on 7/1/244 and to restart Warfarin at 2.5mg on 6/30/24.

R1's June and July 2024 medication administration records document that the facility continued to administer 3mg of Warfarin from June 30, 2024 until discharge on 7/23/24 (24 days) and that a PT/INR was not completed until 7/2/24, rather than as ordered on 6/28/24 and 7/1/24.

After the critical PT/INR value on 6/27/24 and the recheck on 7/2/24; the facility, the physician, nor the pharmacy requested another PT/INR until 7/23/24 when the results are documented as a PT of 120 and an INR of greater than 10 (critically high results). At this time R1 was sent to the local hospital.

R1's local hospital notes dated 7/23/24 document that R1 was sent to the local hospital with Warfarin toxicity and was admitted with lethal bleeding requiring frozen fresh plasma to reverse his INR and then R1 was sent to a tertiary care center for critical care.

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S9999	Continued From page 6 R1's tertiary care center notes dated 7/24/24 document a left hemothorax, right lung with alveolar hemorrhage, increased size of the ascending aortic aneurysm, and a subcutaneous right gluteal hematoma measuring 7.8 centimeters (cm) x 5.7cm x 7.9cm. R1's death certificate dated 7/29/24 documents R1's cause of death as cardiopulmonary arrest with acute respiratory failure and a left hemothorax. On 9/24/24 at 10:30AM, V2 Director of Nursing (DON) said that the facility was not administering the Warfarin as ordered and not monitoring R1's labs as they should have done. On 9/25/24 at 9:10AM, V13 Medical Director said that the facility should have followed the correct Warfarin order and that R1 was at risk for increased bleeding and that R1 clearly died from the hemothorax. On 9/25/24 at 10:30AM, V12 Consultant Pharmacist said that she was unaware that R1 had out of target range or critical Prothrombin (PT) and International normalized ratio (INR) times. On 9/24/24 at 1:15PM, V3 Pharmacist stated that collaboration with the pharmacy when PT/INRs are inconsistent is the standard of care and that given R1's inconsistent results, closer laboratory monitoring should have been done. Failure to do so could result in increased bleeding and possibly death. (AA)	S9999		