

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 07/09/2024  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>155359</b>		(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____		(X3) DATE SURVEY COMPLETED  <b>C</b>  <b>07/05/2024</b>	
NAME OF PROVIDER OR SUPPLIER  <b>MAJESTIC CARE OF FORT WAYNE</b>				STREET ADDRESS, CITY, STATE, ZIP CODE <b>7519 WINCHESTER RD</b> <b>FORT WAYNE, IN 46819</b>			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		(X5) COMPLETION DATE
F 000	<p>INITIAL COMMENTS</p> <p>This visit was for the Investigation of Complaint IN00437523.</p> <p>Complaint IN00437523 - Federal/State deficiency related to the allegations are cited at F760.</p> <p>Survey date: July 5, 2024</p> <p>Facility number: 000250 Provider number: 155359 AIM number: 100289980</p> <p>Census Bed Type: SNF/NF: 69 Total: 69</p> <p>Census Payor Type: Medicare: 0 Medicaid: 65 Other: 4 Total: 69</p> <p>This deficiency reflects State Findings cited in accordance with 410 IAC 16.2-3.1.</p>			F 000			
F 760 SS=G	<p>Quality review completed July 8, 2024</p> <p>Residents are Free of Significant Med Errors CFR(s): 483.45(f)(2)</p> <p>The facility must ensure that its- §483.45(f)(2) Residents are free of any significant medication errors. This REQUIREMENT is not met as evidenced by: Based on interview and record review, the facility failed to ensure 1 of 3 residents reviewed were free from a significant medication error. This error</p>			F 760	<p>Past noncompliance: no plan of correction required.</p>		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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F 760	<p>Continued From page 1</p> <p>resulted in a change of condition and hospitalization (Resident K).</p> <p>Findings include:</p> <p>An anonymous complaint, submitted to the Indiana Department of Health, indicated Resident K had been administered a "double dose" of medication which was alleged to have contributed to his death.</p> <p>On 7/5/24 at 10:23 A.M., Resident K's record was reviewed. Diagnoses included Schizoaffective disorder, bipolar type, alcohol induced persisting dementia, moderate dementia with psychotic disturbance, generalized anxiety disorder, major depressive disorder, and chronic obstructive pulmonary disease (COPD) with current tobacco use. The resident was prescribed several psychotropic medications to treat his behavior symptoms. His behaviors included verbal fights with staff, verbal aggression with other residents, peer to peer altercations, and physical aggression towards staff.</p> <p>A nurse progress note, dated 6/3/24 at 2:11 p.m., indicated a call had been placed to the psychiatrist regarding Resident K's continued behaviors. Orders were given for Clozaril 150 mg (milligrams) by mouth-give 2 times per day and start weekly lab draws for complete blood counts.</p> <p>A physician order, dated 6/4/24, was for Clozaril 100 mg tablet by mouth-give 2 times per day along with Clozaril 50 mg tablet to equal Clozaril 150 mg by mouth, given 2 times per day.</p> <p>A timeline, provided by the Director of Nursing (DON) on 7/5/24 at 10:26 A.M., indicated:</p>	F 760			

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F 760	<p>Continued From page 2</p> <p>-On 6/5/24 at 2:29 p.m., Clozaril was delivered to the facility and one time order received to give the medication when it arrived. Clozaril 100 mg tablet and Clozaril 50 mg tablet equaled 150 mg was given by mouth to Resident K.</p> <p>-At 3:30 p.m., a second dose of Clozaril 100 mg tablet and Clozaril 50 mg tablet equaled 150 mg was given by mouth to Resident K.</p> <p>-At 4:00 p.m., the resident was observed to be lethargic. He was taken to his room and laid down in bed. Staff discovered the resident had erroneously been given 2 doses of Clozaril 150 mg which equaled 300 mg of Clozaril administered within an hour. A call was placed to the psychiatric Nurse Practitioner (NP) to notify of the medication error and resident's current condition.</p> <p>-At 4:17 p.m., the psychiatric NP returned call to the facility and indicated she would contact the Psychiatrist for further orders.</p> <p>-At 4:20 p.m., the psychiatric NP called back the facility with recommendations to monitor the resident's vital signs (blood pressure, pulse, respirations, temperature, and pulse oximetry) every 2 hours for 8 hours, then every 4 hours until the resident was awake.</p> <p>Vital signs on 6/5/24 were:  -4:00 p.m., Blood pressure (BP): 160/74 (normal-120/80); pulse (P): 77 (normal-60-100); respirations (R): 18 (normal-16-20); temperature (T): 96.4 (normal 98.6); Pulse oximetry (normal &gt;90%): 90% on room air.  -6:00 p.m., BP: 198/80, P: 81, R: 20, T: 96.5, Pulse oximetry: 92% on oxygen.  -8:00 p.m., BP: 166/76, P: 91, R: 20, T: 96, Pulse oximetry: 88% on oxygen.  -10:05 p.m., BP: 150/59, P: 79, R: 18, T: 96,</p>	F 760			

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F 760	<p>Continued From page 3</p> <p>Pulse oximetry: 83% on oxygen.</p> <p>Nurse progress notes indicated the following on 6/5/24:</p> <p>-5:12 p.m., the NP and doctor were updated on the resident receiving Clozaril. Staff were monitoring vital signs with no concerns.</p> <p>-9:08 p.m., the resident was sleeping without change in condition.</p> <p>-9:20 p.m., the resident was started on a new medication on this day; his vital signs were monitored closely; he was currently resting in bed with the head of the bed elevated; oxygen in place; would continue to monitor.</p> <p>-10:05 p.m., the resident was resting comfortably in bed with oxygen in place and no apparent distress. There was no adverse reaction to the new medication observed; would continue to monitor.</p> <p>-11:00 p.m., the resident continued to rest comfortably with no adverse reaction or distress noted.</p> <p>-11:15 p.m., the resident was observed with no pulse or respirations. CPR (Cardiopulmonary Resuscitation) initiated and 911 called. Once medics arrived, they continued with CPR and resident taken to the hospital.</p> <p>A hospital History and Physical and Consultation notes, dated 6/6/24 at 11:19 a.m., indicated the resident had increased behaviors at his nursing home and had been started on Clozaril. The resident had accidentally received 2 doses in a very short length of time which had occurred yesterday (6/5/24). Yesterday evening, the resident was found unresponsive, around 11:15-11:20 p.m., CPR was initiated and EMS called. The resident was asystole (no heartbeat)</p>	F 760			

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F 760	<p>Continued From page 4</p> <p>which required 4 rounds of epinephrine and intubation. While hospitalized he remained unresponsive, on the ventilator with questionable aspiration pneumonia (when food or liquid is breathed into the airways or lungs instead of being swallowed) and cardiac/respiratory arrest of unknown origin.</p> <p>On 7/5/24 at 1:40 P.M., the Psychiatrist was interviewed. He indicated he had been notified of the medication error and 2 doses of Clozaril 150 mg given within an hour of each other. He indicated there was no antidote to be given and the resident was to have his vital signs, including his oxygen saturation, monitored frequently. He indicated if there had been changes in his vital signs, the only intervention to have done was administer intravenous fluids until the resident's vitals stabilized.</p> <p>On 7/5/24 at 3:00 P.M., "Clozaril" information was obtained from the website, drugs.com. The website indicated Clozaril was an antipsychotic medication used to treat schizophrenia in adults after other treatments had failed. Clozaril came with a black box warning the medication could cause severe neutropenia (low white blood cell count), low blood pressure, slow heart rate, dizziness, seizures, inflammation of the heart and death in elderly patients with dementia related psychosis; side effects were dose related; starting dose was 12.5 mg one to two times per day which could be increased 25-50 mg per day if well tolerated; target dose of 300-450 mg in divided doses by the end of 2 weeks. Low blood pressure, slow heart rate, and cardiac arrest could occur with Clozaril treatment with the highest risk during the initial titration period, especially with rapid dose escalation. These</p>	F 760			

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F 760	<p>Continued From page 5</p> <p>reactions could occur with the first dose, at doses as low as 12.5 mg, which could be fatal.</p> <p>Overdosage: The most commonly reported signs and symptoms associated with Clozaril overdose were sedation, delirium, coma, fast heart rate, low blood pressure, respiratory failure, aspiration pneumonia, heart arrhythmias and seizures.</p> <p>The past non-compliance deficiency began on 6/5/24 and deficient practice corrected on 6/6/24 after the facility in-serviced all nurses and QMAs (Qualified Medication Aid) on safe medication administration, including signing out of the MAR immediately after administering a medication. All resident MAR (Medication Administration Record) were reviewed for completion the prior 30 days, resident charts audited for documentation accuracy, medication administration policy and procedures reviewed and medication pass competencies completed on all licensed nursing and QMA staff. The facility is monitoring by completing medication pass observations routinely for 6 months.</p> <p>This tag relates to Complaint IN00437523.</p> <p>3.1-48(c)(2)</p>			F 760			