

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  155618	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  05/19/2023
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NAME OF PROVIDER OR SUPPLIER  MAJESTIC CARE OF CARMEL	STREET ADDRESS, CITY, STATE, ZIP CODE 12999 N PENNSYLVANIA ST CARMEL, IN 46032
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F 0000  Bldg. 00	<p>This visit was for a Recertification and State Licensure Survey. This visit included a State Residential Licensure Survey. This visit also included the Investigation of Residential Complaints IN00406339, IN00404866, IN00404606 and IN00403105.</p> <p>Complaint IN00406339 - No deficiencies related to the allegations are cited.</p> <p>Complaint IN00404866 - State deficiencies related to the allegations are cited at R0148.</p> <p>Complaint IN00404606 - State deficiencies related to the allegations are cited at R0148.</p> <p>Complaint IN00403105 - No deficiencies related to the allegations are cited.</p> <p>Survey dates: May 15, 16, 17, 18, and 19, 2023</p> <p>Facility Number: 001149 Provider Number: 155618 AIM Number: 200145500</p> <p>Census Bed Type: SNF/NF: 29 SNF: 24 Residential: 75 Total: 128</p> <p>Census Payor Type: Medicare: 8 Medicaid: 29 Other: 16 Total: 53</p>	F 0000	The Creation and submission of this plan of correction does not constitute an admission by this provider of any conclusion set forth in the statement of deficiencies or of an violation of regulation. This provider respectfully requests the 2567 Plan of Correction be the letter of credible allegation and REQUESTS DESK REVIEW IN LIEU OF POST SURVEY REVISIT on or after June 7, 2023.	
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
John Seib	Executive Director	06/07/2023

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 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 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 0582 SS=D Bldg. 00	<p>These deficiencies reflect State Findings cited in accordance with 410 IAC 16.2-3.1.</p> <p>Quality review was completed on May 26, 2023.</p> <p>483.10(g)(17)(18)(i)-(v) Medicaid/Medicare Coverage/Liability Notice §483.10(g)(17) The facility must-- (i) Inform each Medicaid-eligible resident, in writing, at the time of admission to the nursing facility and when the resident becomes eligible for Medicaid of-- (A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged; (B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and (ii) Inform each Medicaid-eligible resident when changes are made to the items and services specified in §483.10(g)(17)(i)(A) and (B) of this section.</p> <p>§483.10(g)(18) The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare/ Medicaid or by the facility's per diem rate. (i) Where changes in coverage are made to items and services covered by Medicare and/or by the Medicaid State plan, the facility must provide notice to residents of the change as soon as is reasonably possible. (ii) Where changes are made to charges for other items and services that the facility</p>			

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	<p>offers, the facility must inform the resident in writing at least 60 days prior to implementation of the change.</p> <p>(iii) If a resident dies or is hospitalized or is transferred and does not return to the facility, the facility must refund to the resident, resident representative, or estate, as applicable, any deposit or charges already paid, less the facility's per diem rate, for the days the resident actually resided or reserved or retained a bed in the facility, regardless of any minimum stay or discharge notice requirements.</p> <p>(iv) The facility must refund to the resident or resident representative any and all refunds due the resident within 30 days from the resident's date of discharge from the facility.</p> <p>(v) The terms of an admission contract by or on behalf of an individual seeking admission to the facility must not conflict with the requirements of these regulations.</p> <p>Based on interview and record review, the facility failed to ensure notices were given 48 hours prior to the Medicare benefits ending date and to ensure the residents chose an option for ongoing services for 3 of 3 residents reviewed for beneficiary notices. (Resident 153, 17 and 45)</p> <p>Findings include:</p> <p>1. The NOMC (Notice of Medicare Non-Coverage) form for Resident 153 indicated the coverage of Medicare Part A services would end on 2/7/23. The daughter was telephoned, on 2/6/2 at 3:20 p.m., to notify her of the end of coverage date.</p> <p>During an interview, on 5/18/23 at 2:42 p.m., the BOM (Business Office Manager) indicated the Social Services Director was in charge of giving notices to the resident or resident representative.</p>	F 0582	<p><b>F 582 Medicaid / Medicare Coverage / Liability Notice</b></p> <p><b>1. What corrective actions will be accomplished for those residents found to have been affected by the alleged deficient practice?</b></p> <ul style="list-style-type: none"> <li>- Resident 153 had discharged from the facility at the time of this plan of correction. Facility reached out to resident/designee to clarify options and inform them of the error.</li> <li>- Resident 17 resides in the facility on Medicaid. Resident 17 / designee was informed in writing of (A) The items and services that are included in the nursing facility</li> </ul>	06/07/2023
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	<p>The notice should have been given on 2/5/23 for the required 48-hour notice.</p> <p>2. A Skilled Nursing Facility Advance Beneficiary Notice of Non-Coverage (SNFABN) for Resident 17 indicated beginning on 2/2/23 the resident may have to pay out of pocket for care if there was no other insurance to cover the costs. The form included 3 options: 1. The resident wanted the care and wanted Medicare billed. 2. The resident wanted the care and did not want Medicare billed. 3. The resident did not want the care.</p> <p>The resident signed the form on 1/30/23 and did not check which option was chosen.</p> <p>During an interview, on 5/18/23 at 2:40 p.m., the BOM indicated the staff should ensure an option was chosen by the resident or representative and included in the documentation.</p> <p>3. An SNFABN form for Resident 45 indicated on 3/15/23 the resident may have to pay out of pocket for care if there was no other insurance to cover the costs. The form included 3 options: 1. The resident wanted the care and wanted Medicare billed. 2. The resident wanted the care and did not want Medicare billed. 3. The resident did not want the care.</p> <p>The verbal consent from the resident's representative was documented on 3/10/23. The documentation did not include which option the representative chose.</p> <p>During an interview, on 5/18/23 at 2:44 p.m., the BOM indicated the facility documentation should have included which option the family representative chose.</p>		<p>under the state plan for which the resident may not be charged; (B) Those other items and services that the facility offers and or which the resident may be charged, and the amount of charges for those services; AND Resident was also informed of services available in the facility and of charges for those services, including any changes for services not covered under Medicare/Medicaid or by the facilities per diem rate. Resident 17 by their designee were assisted to document a current option for ongoing services under the SNFABN including the three options: 1. Their resident wanted the care and wanted Medicare billed. 2. The resident wanted care and did not want Medicare billed. 3. The resident did not want the care.</p> <p>- Resident 45 had discharged from the facility at the time of this plan of correction. Facility reached out to resident/designee to clarify options and inform them of the error.</p> <p><b>2. How other residents having the potential to be affected by the same deficient practice will be identified and what corrective action will be taken?</b></p> <p>- All residents who received Medicare benefits at the facility and discharged with benefit days remaining have the potential to be</p>	

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	The facility had not provided a policy for beneficiary notices at time of exit from the facility.  3.1-4(f)(3)		<p>affected by the alleged deficient practice.</p> <ul style="list-style-type: none"> <li>- A complete review of all residents who discharged from Medicare Part A stay with benefit days remaining in the last six months was completed to identify any affected parties.</li> <li>- Social Services director will be in-serviced on Beneficiary Notice Guidelines and specifically the timelines and proper completion of NOMNC and SNFABN by ED/Designee by 6/7/2023 to ensure All residents who receive Medicare benefits at the facility and are discharged with benefit days remaining receive adequate notice and appropriately choose an option in the event that there is no insurance to cover the cost. i.e. 1. Their resident wanted the care and wanted Medicare billed. 2. The resident wanted care and did not want Medicare billed. 3. The resident did not want the care.</li> </ul> <p><b>3. What measures will be put into place or what systemic changes will be made to ensure that the deficient practice will not recur?</b></p> <ul style="list-style-type: none"> <li>- It is the responsibility of the facility and All IDT members to ensure residents are given proper notices including but not limited to NOMNC and SNFABN. IDT staff will be in-serviced on provision of NOMNC and SNFABN by the</li> </ul>		

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F 0657 SS=D Bldg. 00	483.21(b)(2)(i)-(iii) Care Plan Timing and Revision §483.21(b) Comprehensive Care Plans §483.21(b)(2) A comprehensive care plan		ED/Designee on or before 6/7/2023. - Audit Tool NOMNC / SNFABN / Care Plan / Discharge Tracking Tool will be utilized by the IDT and monitored by the Executive Director, Director of Nursing and/or designee to ensure compliance.  <b>4. How corrective actions will be monitored to ensure the deficient practice will not recur i.e., what quality assurance program will be put into place?</b> - Audit Tool NOMNC / SNFABN / Care Plan / Discharge Tracking Tool will be utilized by the IDT and monitored by the Executive Director, Director of Nursing and/or designee to ensure compliance. - Results of audit tool will be presented to the QAPI Committee Monthly to review for compliance and follow-up. Identified noncompliance may result in staff reeducation and/or disciplinary action. - If 100% threshold is not achieved an action plan will be developed to achieve desired threshold. Data will be submitted to the QAPI committee overseen by the ED for review and follow-up.		

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	<p>must be-</p> <p>(i) Developed within 7 days after completion of the comprehensive assessment.</p> <p>(ii) Prepared by an interdisciplinary team, that includes but is not limited to--</p> <p>(A) The attending physician.</p> <p>(B) A registered nurse with responsibility for the resident.</p> <p>(C) A nurse aide with responsibility for the resident.</p> <p>(D) A member of food and nutrition services staff.</p> <p>(E) To the extent practicable, the participation of the resident and the resident's representative(s). An explanation must be included in a resident's medical record if the participation of the resident and their resident representative is determined not practicable for the development of the resident's care plan.</p> <p>(F) Other appropriate staff or professionals in disciplines as determined by the resident's needs or as requested by the resident.</p> <p>(iii) Reviewed and revised by the interdisciplinary team after each assessment, including both the comprehensive and quarterly review assessments.</p> <p>Based on observation, interview and record review, the facility failed to offer a care plan meeting and to initiate a care plan for a urinary tract infection for 2 of 2 residents reviewed for care plans. (Resident 4 and 35)</p> <p>Findings include:</p> <p>1. During an interview, on 5/15/23 at 12:45 p.m., Resident 4 indicated she had not been invited to a care plan meeting since she had been admitted to the facility.</p>	F 0657	<p><b>F 657 Care Plan Timing and Revision</b></p> <p><b>1. What corrective actions will be accomplished for those residents found to have been affected by the alleged deficient practice?</b></p> <ul style="list-style-type: none"> <li>- Facility has held care plan review with resident 4 and invited their representative.</li> <li>- Facility has initiated a care plan for urinary tract infection for resident 35 on date of discovery.</li> </ul>	06/07/2023
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	<p>The record for Resident 4 was reviewed on 5/16/23 at 4:25 p.m. Diagnoses included, but were not limited to, congestive heart failure, anxiety disorder, depression, hypertension, post traumatic disorder, and chronic pain.</p> <p>A facility document, titled "Interdisciplinary Team Care Plan Conference Summary," dated 9/22/22, indicated the form was not completed and the resident did not have a care plan conference.</p> <p>A progress note, dated 2/17/23 at 11:51 p.m., indicated the care plan was reviewed. The staff in attendance were the Minimum Data Set Coordinator (MDSC), Social Service Director (SSD), Unit Manager (UM), Registered Dietician (RD), and the Director of Nursing Services (DNS). The resident was being reviewed for accuracy of her plan of care, all parties reviewed and were satisfied with the plan of care.</p> <p>During an interview, on 5/19/23 at 2:46 p.m., the Regional Support Nurse indicated the resident was admitted on 9/21/22. The facility should arrange a care plan meeting with the resident and resident's family within the first 72 hours of being admitted. He was not sure why the resident or resident's family was not included for the 2/17/23 care plan review.2. During an observation, on 05/16/23 at 12:01 p.m., Resident 35 was on contact isolation for Escherichia Coli (E. coli) and ESBL (Extended Spectrum Beta-Lactamase, a bacteria that could not be killed by many antibiotics which made it harder to treat) in the urine.</p> <p>The record for Resident 35 was reviewed on 05/17/2023 at 11:13 a.m. Diagnosis included, but were not limited to, schizophrenia, anxiety, essential hypertension, ischemic cardiomyopathy, bipolar disorder, heart failure, asthma, allergic</p>		<p>UTI has resolved at this time and care plan discontinued. Resident 35 has a new guardian. Resident 35 and their new guardian have been invited to a Care Plan review, but guardian representative has declined invite at this time.</p> <p><b>2. How other residents having the potential to be affected by the same deficient practice will be identified and what corrective action will be taken?</b></p> <ul style="list-style-type: none"> <li>- All residents have the potential to be affected by the alleged deficient practice.</li> <li>- A complete IDT review of all resident care plans was completed on or before 6/7/2023. Resident Care Plans were updated as needed.</li> <li>- IDT staff will be in-serviced on Care Plan Timing and Revision by ED/Designee on or before 6/7/2023 including the inclusion of resident and their representatives to the extent practicable.</li> <li>- All residents and their representatives SHALL be invited on or before 6/7/2023 to schedule a care plan review and participate in the development of the comprehensive care plan to the extent practicable by social services upon admission and upon review. An explanation SHALL be included in the residents medical record if the participation of the resident and their representative is</li> </ul>	

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	<p>rhinitis, personal history of covid-19, and sleep disorder.</p> <p>The facility matrix indicated the resident was in transmission-based precautions for ESBL.</p> <p>A physician's order, dated 05/07/23, indicated Amoxicillin-Pot Clavulanate (an antibiotic) tablet 875-125 mg (milligram) was started on 05/07/2023 and to give 1 tablet by mouth two times a day due to a UTI bacterial infection for 28 days.</p> <p>During an interview, on 05/18/23 at 2:47 p.m., the Regional Support indicated there was not a care plan for the UTI and there should have been one.</p> <p>A current policy, titled "Care Planning- Interdisciplinary Team," dated as revised on 09/28/17 and received from the DNS on 05/19/23 at 3:31 p.m., indicated "...Our facility's Care Planning/Interdisciplinary Team is responsible for the development of an individualized care plan for each resident...The care plan will be read aloud to the resident, family and IDT team. A written summary or copy of the baseline care plan will be given to the resident and/or representative...Every effort will be made to schedule care plan meetings at the best time of the day for the resident and family...The summary of the baseline and comprehensive care plan will be given to the resident and/or representative within 7 days of completion..."</p> <p>3.1-35(d)(2)(B)</p>		<p>determined not practicable.</p> <ul style="list-style-type: none"> <li>- All residents progress notes and order changes are reviewed daily to ensure care plans are up to 6/7/2023 and reflect the residents current status and needs.</li> </ul> <p><b>3. What measures will be put into place or what systemic changes will be made to ensure that the deficient practice will not recur?</b></p> <ul style="list-style-type: none"> <li>- It is the responsibility of the facility and All IDT to be engaged in care planning. IDT staff will be in-serviced on Care Plan Timing and Revision by the ED/Designee on or before 6/7/2023 including the inclusion of resident and their representatives to the extent practicable.</li> <li>- A complete IDT review of all resident care plans was completed on or before 6/7/2023. Resident Care Plans were updated as needed and documentation of recent participation of resident and their Representative was assessed.</li> <li>- All residents and representatives have been invited to schedule a care plan review and revision.</li> <li>- Audit Tool Care Plan Timing and Revision Tracking tool will be utilized by the Executive Director, Director of Nursing and/or designee to monitor compliance. Audits will be completed upon admission, significant change</li> </ul>		

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			<p>and/or at least quarterly via care plan review meeting to mirror the MDS schedule.</p> <p><b>4. How corrective actions will be monitored to ensure the deficient practice will not recur i.e., what quality assurance program will be put into place?</b></p> <ul style="list-style-type: none"> <li>- Audit Tool Care Plan Timing and Revision Tracking Tool will be utilized by the IDT and supervised by the Executive Director, Director of Nursing and/or designee to monitor compliance. Care plan reviews are completed upon admission, significant change and/or at least quarterly via care plan review meeting to mirror the MDS schedule. MDS shall notify Social Services Director of the upcoming MDS schedule so that resident and their representative can participate to the extent practicable.</li> <li>- Results of audit tool will be presented to the QAPI Committee Monthly to review for compliance and follow-up. Identified noncompliance may result in staff reeducation and/or disciplinary action.</li> <li>- If 90% threshold is not achieved an action plan will be developed to achieve desired threshold. Data will be submitted to the QAPI committee overseen by the ED for review and follow-up.</li> </ul>	

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F 0679 SS=D Bldg. 00	<p>483.24(c)(1) Activities Meet Interest/Needs Each Resident §483.24(c) Activities. §483.24(c)(1) The facility must provide, based on the comprehensive assessment and care plan and the preferences of each resident, an ongoing program to support residents in their choice of activities, both facility-sponsored group and individual activities and independent activities, designed to meet the interests of and support the physical, mental, and psychosocial well-being of each resident, encouraging both independence and interaction in the community.</p> <p>Based on observation, interview and record review, the facility failed to ensure a resident received twice weekly activities and a resident received the identified preference for the activity of their choice for 2 of 5 residents for activities. (Resident 3 and 253)</p> <p>Findings include:</p> <p>1. During an observation, on 5/15/23 at 2:56 p.m., Resident 3 was in his room, lying in his bed, and the television (TV) was on.</p> <p>During an observation, on 5/16/23 at 11:12 a.m., the resident was in his room, lying in his bed, and the TV was on. Other residents were observed in the common area playing bingo.</p> <p>During an observation, 5/17/23 at 10:57 a.m., the resident was in his room, lying in his bed, and the TV was on. Other residents were observed in the dining room listening to live music.</p> <p>During an observation, on 5/18/23 at 3:09 p.m., the resident was in his room, lying in bed, and the TV was on. Other residents were observed in the</p>	F 0679	<p><b>F 679 Activities Meet Interest/Needs Each Resident</b></p> <p><b>1. What corrective actions will be accomplished for those residents found to have been affected by the alleged deficient practice?</b></p> <ul style="list-style-type: none"> <li>- Resident 3 Activity Care Plan reviewed and up to date and a schedule of his 1:1 activities was presented to IDT for tracking and review.</li> <li>- Resident 253 activity care plan has been implemented and up to date with his preferences. Resident was provided a selection of books in accordance with his preferences on 5/18 by the Executive Director.</li> </ul> <p><b>2. How other residents having the potential to be affected by the same deficient practice will be identified and what corrective action will be taken?</b></p>	06/07/2023	

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	<p>common area.</p> <p>The record for Resident 3 was reviewed on 5/17/23 at 10:03 a.m. Diagnosis included, but were not limited to, persistent vegetative state, unspecified intercranial injury, cerebrovascular disease, paralytic syndrome, and chronic pain.</p> <p>An activity care plan, dated 1/13/2016 and revised on 9/16/2022, indicated the goal included the resident would attempt to respond with eye tracking and head movement during activities with staff, family, or community at least 2 times a week. The interventions included, but were not limited to, coordinate and display items in the room sent by his sister for visual stimulation and comfort, provide sensory stimulation with 1:1 visits, read family stories to him, and play music.</p> <p>An activity log, dated 4/03/23 through 5/15/23, indicated there were five (5) one to one activities completed. Three of the five one to one activities included watching TV.</p> <p>The resident did not receive twice weekly activities as indicated by the care plan.</p> <p>During an interview, on 5/18/23 at 2:35 p.m., Anonymous Staff 4 indicated the resident liked music and sometimes the staff would read to him.2. During an interview, on 5/15/23 at 2:57 p.m., Resident 253 indicated he spoke to the Activity Director and told her he liked books about ghost stories, but he had not received any at this time. He could not get out of his room for activities because of his wounds and weakness.</p> <p>During an observation, on 5/17/23 at 2:00 p.m., the resident was lying in bed with the head of the bed elevated. The resident was watching television.</p>		<ul style="list-style-type: none"> <li>- All residents who require 1:1 activities have the potential to be affected by the alleged deficient practice.</li> <li>- All Resident new admissions require an activity care plan have the potential to be affected by the alleged deficient practice.</li> <li>- An audit of all residents activity care plans was completed on or before 6/7/2023 to ensure their activity care is in place.</li> <li>- Activity Director has been provided education and counseling including but not limited to a Performance Improvement Plan on or before 6/7/2023.</li> <li>- Facility Activity staff will be in-serviced on documentation of resident activities, including 1:1 activity schedules by ED/Designee by 6/7/2023 to ensure residents receive services per their care plan.</li> </ul> <p><b>3. What measures will be put into place or what systemic changes will be made to ensure that the deficient practice will not recur?</b></p> <ul style="list-style-type: none"> <li>- Activity Director has been provided education and counseling including but not limited to a Performance Improvement Plan on or before 6/7/2023. The PIP includes validation and completion of care plans in a timely manner as well as documented completion of a 1:1 schedule for those</li> </ul>		

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	<p>During an observation, on 5/18/23 at 2:26 p.m., the resident was lying in bed talking on the telephone. The television was on and there were no books in his room.</p> <p>The record for Resident 253 was reviewed on 5/16/23 at 4:33 p.m. Diagnoses included, but were not limited to, spina bifida, pressure ulcer of right buttock unstageable, pressure ulcer of left buttock unstageable, morbid obesity, sepsis, type 2 diabetes, bacteremia, and left BKA (below the knee amputation).</p> <p>There was no activity care plan in the electronic medical record.</p> <p>During an interview, on 05/18/23 at 3:15 p.m., Anonymous Staff 4 indicated the resident had been signed up for the library at home project. He would be able to pick the library books he wanted, but they would not come until June. She was not sure if he would be in the facility until June. He received the daily chronicles (a daily newsletter from the facility) and a monthly calendar, but he was not able to get out of his room. She had not given him in room activities.</p> <p>A current policy, titled "Activity Programs," dated as revised on 7/2018 and received from the Director of Nursing on 05/19/23 at 5:35 p.m., indicated "...Individualized and group activities are provided that: reflect the schedules, choices, and rights of the resident, are offered at hours of convenient to the residents, including evenings, holidays, and weekends, reflect the cultural and religious interests, hobbies, life experience, and personal preferences of the residents, appeal to men and women as well as those of various age groups residing in the facility..."</p>		<p>indicated on their care plan.</p> <p>Resident activity schedule, 1:1 schedule and outstanding CP will be reviewed on all weekdays. Weekends to be reviewed on Monday.</p> <ul style="list-style-type: none"> <li>- Facility Activity staff will be in-serviced on documentation of resident activities, including 1:1 activity schedules by ED/Designee by 6/7/2023 to ensure residents receive services per their care plan.</li> <li>- A complete review of all resident activity care plans was completed on or before 6/7/2023 by activities consultant Courtney and Associates. Resident Care Plans were to updated as needed.</li> <li>- Audit Tool Resident Activities audit tool will be utilized by the Executive Director, Director of Nursing and/or designee to monitor compliance. Audits will be completed daily X5days, weekly X4 weeks, monthly X2 months, and quarterly thereafter until compliance is maintained for at least two consecutive quarters.</li> </ul> <p><b>4. How corrective actions will be monitored to ensure the deficient practice will not recur i.e., what quality assurance program will be put into place?</b></p> <ul style="list-style-type: none"> <li>- Activity Director has been provided education and counseling including but not limited to a Performance Improvement Plan on or before 6/7/2023. The PIP includes validation and completion</li> </ul>	

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F 0684 SS=D Bldg. 00	483.25 Quality of Care § 483.25 Quality of care Quality of care is a fundamental principle that applies to all treatment and care provided to facility residents. Based on the comprehensive assessment of a resident, the		of care plans in a timely manner as well as documented completion of a 1:1 schedule for those indicated on their care plan. Resident activity schedule, 1:1 schedule and outstanding CP will be reviewed on all weekdays. Weekends to be reviewed on Monday. - Audit Tool Resident Activities audit tool will be utilized by the Executive Director, Director of Nursing and/or designee to monitor compliance. Audits will be completed daily X5days, weekly X4 weeks, monthly X2 months, and quarterly thereafter until compliance is maintained for at least two consecutive quarters. - Results of audit will be presented to the QAPI Committee Monthly for compliance and follow-up. Identified noncompliance may result in staff reeducation and/or disciplinary action. - If 90% threshold is not achieved an action plan will be developed to achieve desired threshold. Data will be submitted to the QAPI committee overseen by the ED for review and follow-up.	

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	<p>facility must ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the residents' choices.</p> <p>Based on observation, interview and record review, the facility failed to ensure the physician was notified of a weight gain as ordered for a resident who was diagnosed with congestive heart failure for 1 of 1 resident reviewed for edema. (Resident 41)</p> <p>Finding includes:</p> <p>During an observation, on 5/15/23 at 12:52 p.m., Resident 41 was sitting in her recliner with both legs elevated. The resident's bilateral legs and ankles were swollen.</p> <p>The record for Resident 41 was reviewed on 5/16/23 at 4:42 p.m. Diagnosis included, but were not limited to, congestive heart failure, hypertension, urine retention, and depressive disorder.</p> <p>A physician's order, dated 10/25/22, indicated daily weight and to notify the provider of a 3-pound weight gain in two days or a 5-pound weight gain in a week and to weigh before breakfast related to congestive heart failure.</p> <p>A physician's order, dated 1/4/23, indicated furosemide (a diuretic) 20 mg (milligrams) tablet give two tablets daily related to edema.</p> <p>During a record review, the physician was not notified for the following weight gains:</p> <p>a. 3/9/23 to 3/11/23, the resident had a 5-pound weight gain.</p> <p>b. 3/25/23 to 3/26/23, the resident had a 6-pound</p>	F 0684	<p><b>F 684 Quality of Care</b></p> <p><b>1. What corrective actions will be accomplished for those residents found to have been affected by the alleged deficient practice?</b></p> <ul style="list-style-type: none"> <li>- Resident 41 assessed for change of condition. Resident 41 orders reviewed and tracked for reporting and accuracy by DNS/designee. Resident assessed by MD. The orders for resident 41 were reviewed and updated as necessary.</li> <li>- New Daily weight tracker implemented specifying call parameters.</li> <li>- Facility audited all residents to ensure all residents with orders for daily weight were being tracked and call parameters were being followed per MD orders.</li> </ul> <p><b>2. How other residents having the potential to be affected by the same deficient practice will be identified and what corrective action will be taken?</b></p> <ul style="list-style-type: none"> <li>- All residents who require daily weights to monitor for signs and symptoms of Congestive Heart Failure have the potential to be affected by the alleged deficient practice.</li> </ul>	06/07/2023

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	<p>weight gain.</p> <p>c. 4/9/23 to 4/10/23, the resident had a 4.8-pound weight gain.</p> <p>d. 4/18/23 to 4/19/23, the resident had an 8-pound weight gain.</p> <p>e. 5/14/23 to 5/15/23, the resident had a 4-pound weight gain.</p> <p>A care plan, revised 3/16/23, indicated the resident was at risk for impaired cardiac output. The interventions included, but were not limited to, the resident would be observed for signs and symptoms of cardiac dysfunction, shortness of breath, and edema.</p> <p>During an interview, on 5/17/23 at 1:15 p.m., Anonymous Staff 2 indicated the resident's legs were swollen and the resident was weighed daily. The resident had a physician's order if the resident had a weight gain of more than 3 pounds in a day the Nurse Practitioner (NP) would be notified and asked if additional Lasix (a diuretic) would be needed.</p> <p>During an interview, on 5/20/23 at 4:15 p.m., the Regional Support Nurse indicated he did not know why the physician was not notified of the weight gains and did not find documentation the physician was notified of the weight gains.</p> <p>A current facility policy, titled "Heart Failure - Clinical Protocol," dated as revised 11/2018 and provided by the Regional Support Nurse on 5/19/23 at 5:00 p.m., indicated "...The physician will review and make recommendations for relevant aspects of the nursing care plan; for example, what symptoms to expect, how often and what (weights...etc.) to monitor, when to report findings to the physician, etc...The physician will document information related to the individual's</p>		<ul style="list-style-type: none"> <li>- A complete review of residents with orders for daily weights was conducted on or before <b>6/7/2023</b>.</li> <li>- A complete review of residents with Congestive Heart Failure was conducted on or before 6/7/2023.</li> <li>- Direct Care Staff will be in-serviced on "Daily Weight Monitoring" by DNS/Designee on or before 6/7/2023 to ensure compliance monitoring and reporting program.</li> </ul> <p><b>3. What measures will be put into place or what systemic changes will be made to ensure that the deficient practice will not recur?</b></p> <ul style="list-style-type: none"> <li>- Direct Care Staff will be in-serviced on "Daily Weight Monitoring" by DNS/Designee on or before 6/7/2023 to ensure compliance monitoring and reporting program.</li> <li>- New Daily Weight Monitoring Tool will be used daily by staff for all residents with orders for daily weights.</li> </ul> <p><b>4. How corrective actions will be monitored to ensure the deficient practice will not recur i.e., what quality assurance program will be put into place?</b></p> <ul style="list-style-type: none"> <li>- Audit Tool Daily Weight Monitoring Tool will be utilized by the Executive Director, Director of Nursing and/or designee to monitor compliance. Daily Weight</li> </ul>		

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F 0688 SS=D Bldg. 00	<p>prognosis and current signs and symptoms...the presence of edema...."</p> <p>A current facility policy, titled "Resident Weight Monitoring," dated 10/2018 and provided by the Director of Nursing on 5/18/23 at 3:38 p.m., indicated "...Daily Weights: Orders for daily weights should include Physician call parameters such as +/- 3 lbs in 24 hours. Should be recorded on MAR or TAR using decimal point numeration such as 152.6 lbs. MAR and TAR should indicate if Physician was notified of parameter change...."</p> <p>3.1-37(a)</p> <p>483.25(c)(1)-(3) Increase/Prevent Decrease in ROM/Mobility §483.25(c) Mobility. §483.25(c)(1) The facility must ensure that a resident who enters the facility without limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable; and</p> <p>§483.25(c)(2) A resident with limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion.</p> <p>§483.25(c)(3) A resident with limited mobility receives appropriate services, equipment, and assistance to maintain or improve mobility</p>		<p>Monitoring tool will be completed daily as part of regular clinical review.</p> <ul style="list-style-type: none"> <li>- Results of audit tool will be presented at morning clinical meeting and verified at stand down.</li> <li>- DNS will present results of weight program to the QAPI Committee Monthly to review for compliance and follow-up. Identified noncompliance may result in staff reeducation and/or disciplinary action.</li> <li>- If 100% threshold is not achieved an action plan will be developed to achieve desired threshold. Data will be submitted to the QAPI committee overseen by the ED for review and follow-up.</li> </ul>	

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	<p>with the maximum practicable independence unless a reduction in mobility is demonstrably unavoidable.</p> <p>Based on observation, interview and record review, the facility failed to ensure a resident was re-assessed for interventions to treat and prevent further contracture for 1 of 2 residents reviewed for limited range of motion. (Resident 3)</p> <p>Finding includes:</p> <p>During an observation, on 05/15/23 at 3:00 p.m., the resident was in his room lying in bed. The resident had contractures of both hands.</p> <p>During an observation, on 05/17/23 at 11:03 a.m., the resident was in his room lying in bed with rolled up washcloths in both hands.</p> <p>During an observation, on 05/18/23 at 12:23 p.m., the resident was in his room lying in bed with rolled up washcloths in both hands.</p> <p>The resident did not have elbow splints or hand splints during the observations.</p> <p>The record for Resident 3 was reviewed on 05/17/23 at 10:03 am. Diagnoses included, but were not limited to, persistent vegetative state, unspecified intracranial injury, cerebrovascular disease, paralytic syndrome, and chronic pain.</p> <p>A physician's order, dated 03/31/2016, indicated hand splints to be worn daily from 8:00 a.m. through 5:00 p.m.</p> <p>A physician's order, dated 07/28/2016, indicated elbow splints to be worn daily from 8:00 a.m. until bedtime.</p>	F 0688	<p><b>F 688 Increase / Prevent Decrease in ROM</b></p> <p><b>1. What corrective actions will be accomplished for those residents found to have been affected by the alleged deficient practice?</b></p> <ul style="list-style-type: none"> <li>- Resident 3 assessed and placed on therapy caseload to determine interventions to treat and prevent further contracture. Orders and care plan updated as needed.</li> </ul> <p><b>2. How other residents having the potential to be affected by the same deficient practice will be identified and what corrective action will be taken?</b></p> <ul style="list-style-type: none"> <li>- All residents who are at risk for contracture have the potential to be affected by the alleged deficient practice.</li> <li>- All residents audited for risk of potential contractures on or before 6/7/2023. Residents with existing contractures care plans reviewed and updated as needed.</li> <li>- Direct Care Staff will be in-serviced on identifying residents at risk for contracture and therapy referral tool by 6/7/2023 to ensure timely intervention and treatment.</li> </ul> <p><b>3. What measures will be put into place or what systemic changes will be made to ensure that the deficient</b></p>	06/07/2023

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	<p>A physical therapy plan of treatment, dated 07/27/2021-09/24/2021, indicated the short-term goal included resident and caregivers would be able to demonstrate ROM safely 85% of the time in order to prevent further joint contractures. Another goal was for the resident and the caregivers to demonstrate 100% of the time safely performing ROM and proper positioning of the resident in bed in order to limit joint deformities.</p> <p>A contracture care plan, dated 04/24/2018 and revised on 02/02/2023, indicated the resident was at risk for further contractures due to immobility, muscle spasms, neuropathy, vegetative state, and cognition impairment. The goals included the resident would be free of any discomfort or adverse side effects from pain medication. The interventions included, but were not limited to, administer medication as ordered, monitor for increased risk for falls, monitor for altered mental status, anxiety, constipation, depression, dizziness, lack of appetite, nausea, vomiting, pruritus, respiratory distress, sedation, urinary, passive range of motion and non-pharmacologic pain interventions: positioning, quiet environment, distraction, enjoy watching tv at times, and check for incontinence.</p> <p>The care plan was not updated to include the goals of physical therapy to prevent further joint contracture and to limit joint deformity.</p> <p>A care plan, dated 01/02/2011 and revised 02/02/2023, indicated the resident was at a risk for alteration in skin integrity. Goals indicated the resident would have decrease/minimize skin breakdown risk. Interventions included, but were not limited to, pressure redistributing device on bed/chair, provide preventative skin care routinely and prn, and turn and reposition every 2 hours.</p>		<p><b>practice will not recur?</b></p> <ul style="list-style-type: none"> <li>- Direct Care Staff will be in-serviced on identifying residents at risk for contracture and therapy referral tool by 6/7/2023 to ensure timely intervention and treatment.</li> <li>- Audit Tool Therapy at risk will be utilized by the Executive Director, Director of Nursing and/or designee to monitor compliance. Audits will be completed daily X5days, weekly X4 weeks, monthly X2 months, and quarterly thereafter until compliance is maintained for at least two consecutive quarters.</li> <li>- Daily Walking Rounds by management staff to assess residents for change of condition in conjunction with monitoring therapy referral tool.</li> </ul> <p><b>4. How corrective actions will be monitored to ensure the deficient practice will not recur i.e., what quality assurance program will be put into place?</b></p> <ul style="list-style-type: none"> <li>- Audit Tool Therapy At Risk will be utilized by the Executive Director, Director of Nursing and/or designee to monitor compliance. Audits will be completed daily X5days, weekly X4 weeks, monthly X2 months, and quarterly thereafter until compliance is maintained for at least two consecutive quarters.</li> <li>- Results of audit tool will be presented to the QAPI Committee Monthly to review for compliance and follow-up. Identified</li> </ul>		

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	<p>The care plan was not updated to include the goals of physical therapy to prevent further joint contracture and to limit joint deformity.</p> <p>The resident's census indicated hospice services were stopped on 01/22/2023.</p> <p>There were no orders for contracture prevention or recent therapy assessment following discharge from hospice.</p> <p>During an interview, on 05/18/23 at 12:14 p.m., Anonymous Staff 3 indicated the CNAs would do range of motion when changing him. They would put rolled washcloths in both hands. He was on hospice until a few months ago. He no longer qualified for hospice.</p> <p>During an interview, dated 05/18/23 at 12:23 p.m., Anonymous Staff 6 indicated staff would put washcloths in the resident's hands since the hands were contracted.</p> <p>During an interview, dated 05/19/23 at 2:30 p.m., the Director of Nursing indicated they did not do an assessment for contractures following the resident's release from hospice. The facility did not have a restorative program.</p> <p>A current policy, titled "Repositioning," dated as revised May 2013 and received from the Regional Support Nurse on 05/19/2023 at 5:00 p.m., indicated "...The purpose of this procedure is to provide guidelines for evaluation of resident repositioning needs, to aid in the development of the individualized care plan for repositioning to promote comfort for all bed or chair-bound residents and to prevent skin breakdown, promote circulation and provide pressure relief for</p>		<p>noncompliance may result in staff reeducation and/or disciplinary action.</p> <p>- If 90% threshold is not achieved an action plan will be developed to achieve desired threshold. Data will be submitted to the QAPI committee overseen by the ED for review and follow-up.</p>	

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F 0689 SS=D Bldg. 00	<p>residents...Review the resident's care plan to evaluate for any special needs of the resident...A turning/repositioning program includes a continuous consistent program for changing for the resident's position and realigning the body. A program is defined as a specific approach that is organized, planned, documented, monitored and evaluated...Steps in the procedure...Check the care plan, assignment sheet or the communication system to determine resident's specific positioning needs including special equipment, resident level of participation and the number of staff required to complete procedure...."</p> <p>3.1-42(a)(2)</p> <p>483.25(d)(1)(2) Free of Accident Hazards/Supervision/Devices §483.25(d) Accidents. The facility must ensure that - §483.25(d)(1) The resident environment remains as free of accident hazards as is possible; and</p> <p>§483.25(d)(2)Each resident receives adequate supervision and assistance devices to prevent accidents. Based on observation, interview and record review, the facility failed to ensure a resident who was at risk for falls had their bed in the lowest position for 1 of 4 residents reviewed for falls. (Resident 3)</p> <p>Finding includes:  During an observation, on 05/15/23 at 3:00 p.m., Resident 3 was lying in bed with the bed in a high position.</p>	F 0689	<p><b>F 689 Free of Accidents and Hazards/Supervision</b></p> <p><b>1. What corrective actions will be accomplished for those residents found to have been affected by the alleged deficient practice?</b></p> <ul style="list-style-type: none"> <li>- Resident 3 care plan updated to reflect resident preference to see outside of the window. Care Plan updated.</li> <li>- Direct Care Staff was</li> </ul>	06/07/2023			

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	<p>During an observation, on 05/17/23 at 11:03 a.m., Resident 3 was lying in bed with the bed in a high position.</p> <p>During an observation, on 05/15/23 at 12:14 p.m., Resident 3 was lying in bed with the bed in a high position.</p> <p>During an observation, at 05/18/23 at 3:09 p.m., with the Regional Support Nurse, the resident's bed was in the high position.</p> <p>The record for Resident 3 was reviewed on 05/17/23 at 10:03 a.m. Diagnoses included, but were not limited to, persistent vegetative state, unspecified intracranial injury, cerebrovascular disease, paralytic syndrome, and chronic pain.</p> <p>A care plan, dated 12/28/20 and last revised on 02/02/23, indicated the resident was at risk for falls due to involuntary movements, current medical comorbidities, vegetative state, impaired gait, impaired cognition, and bed/chair fast.</p> <p>During an interview, on 05/18/23 at 12:14 p.m., Anonymous Staff 3 indicated the resident's bed was in the high position because the resident was not a fall risk. The bed was kept waist high for the CNAs to provide care.</p> <p>During an interview, on 05/18/23 at 2:47 p.m., the Regional Support Nurse indicated the resident's bed should not be left up in the high position. The staff should raise it up for care and put it back down.</p> <p>A current policy, titled "Fall Management," dated as last revised in January 2023 and received from the Director on Nursing on 05/19/23 at 5:35 p.m., indicated "...Fall risk will be assessed upon</p>		<p>in-serviced on bed positioning as a fall intervention including but not limited to bed height.</p> <p><b>2. How other residents having the potential to be affected by the same deficient practice will be identified and what corrective action will be taken?</b></p> <ul style="list-style-type: none"> <li>- All residents who are totally dependent have the potential to be affected by the alleged deficient practice.</li> <li>- A complete audit of all residents to identify any residents who could benefit from bed positioning as a fall intervention / safety measure on 6/7/2023.</li> <li>- Direct Care Staff will be in-serviced on bed positioning as a fall intervention/safety measure by ED/Designee by 6/7/2023 including but not limited to bed height.</li> </ul> <p><b>3. What measures will be put into place or what systemic changes will be made to ensure that the deficient practice will not recur?</b></p> <ul style="list-style-type: none"> <li>- Direct Care Staff will be in-serviced on bed positioning as a fall intervention/safety measure by ED/Designee by 6/7/2023 including but not limited to bed height.</li> <li>- Daily Walking rounds on SNF to assess bed positioning.</li> <li>- Magic Ambassador to assess bed positioning as part of</li> </ul>	

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	<p>admission, quarterly and with significant change...a care plan will be developed at time of admission with specific care plan interventions to address each resident's fall risk factors...."</p> <p>3.1-45 (a)(1)</p>		<p>normal rounds on all days worked.</p> <ul style="list-style-type: none"> <li>- Audit Tool "Bed Safety" will be utilized by the Executive Director, Director of Nursing and/or designee to monitor compliance. Audits will be completed daily X5days, weekly X4 weeks, monthly X2 months, and quarterly thereafter until compliance is maintained for at least two consecutive quarters.</li> </ul> <p><b>4. How corrective actions will be monitored to ensure the deficient practice will not recur i.e., what quality assurance program will be put into place?</b></p> <ul style="list-style-type: none"> <li>- Audit Tool "Bed Safety" will be utilized by the Executive Director, Director of Nursing and/or designee to monitor compliance. Audits will be completed daily X5days, weekly X4 weeks, monthly X2 months, and quarterly thereafter until compliance is maintained for at least two consecutive quarters.</li> <li>- Results of audit tool will be presented to the QAPI Committee Monthly to review for compliance and follow-up. Identified noncompliance may result in staff reeducation and/or disciplinary action.</li> <li>- If 90% threshold is not achieved an action plan will be developed to achieve desired threshold. Data will be submitted to the QAPI committee overseen by the ED for review and follow-up.</li> </ul>	

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F 0700 SS=D Bldg. 00	<p>483.25(n)(1)-(4) Bedrails §483.25(n) Bed Rails. The facility must attempt to use appropriate alternatives prior to installing a side or bed rail. If a bed or side rail is used, the facility must ensure correct installation, use, and maintenance of bed rails, including but not limited to the following elements.</p> <p>§483.25(n)(1) Assess the resident for risk of entrapment from bed rails prior to installation.</p> <p>§483.25(n)(2) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to installation.</p> <p>§483.25(n)(3) Ensure that the bed's dimensions are appropriate for the resident's size and weight.</p> <p>§483.25(n)(4) Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails. Based on observation, interview and record review, the facility failed to ensure an informed consent was completed for the use of side rails for 1 of 2 residents reviewed for accident hazards. (Resident 3)</p> <p>Finding includes:  During an observation, on 5/18/23 at 12:18 p.m., the resident's bed had two quarter side rails in the raised position.  The record for Resident 3 was reviewed on 5/17/23 at 10:03 a.m. Diagnoses included, but were not limited to, persistent vegetative state, unspecified</p>	F 0700	<p><b>F 700 Bedrails</b> <b>1. What corrective actions will be accomplished for those residents found to have been affected by the alleged deficient practice?</b></p> <ul style="list-style-type: none"> <li>- Assist rails were removed from bed for Resident 3. On 5/18/23 by IDT.</li> <li>- All residents reviewed for assist rail placement on or before 6/7/2023.</li> <li>- All residents reviewed for side rail consents on or before 6/7/2023.</li> </ul>	06/07/2023	

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	<p>intracranial injury, cerebrovascular disease, paralytic syndrome, and chronic pain.</p> <p>An Adaptive Device Review, dated 4/25/23, indicated the resident had an "other" type of device in use to promote independence. There was not a consent form signed.</p> <p>The Adaptive Device Review did not state what type of device was utilized.</p> <p>A Resident Care sheet, dated 5/18/23, indicated the resident had assist rails to enhance bed mobility.</p> <p>During an interview, on 5/18/23 at 2:47 p.m., the Regional Support Nurse indicated there was no consent for the side rails in the electronic health record.</p> <p>A current policy, titled "Bed Safety," dated as revised in December 2007 and received from the Regional Support Nurse on 5/19/23 at 5:00 p.m., indicated "...The staff shall obtain consent for the use of side rails from the resident or the resident's legal representative prior to their use...Before using side rails for any reason, the staff shall inform the resident and family about the benefits and potential hazards associated with side rails...."</p> <p>3.1-45(a)(1)</p>		<p><b>2. How other residents having the potential to be affected by the same deficient practice will be identified and what corrective action will be taken?</b></p> <ul style="list-style-type: none"> <li>- All residents who have side rails have the potential to be affected by the alleged deficient practice.</li> <li>- All residents reviewed for assist rail placement and appropriateness on or before 6/7/2023.</li> <li>- All residents reviewed for side rail consents on or before 6/7/2023.</li> </ul> <p><b>3. What measures will be put into place or what systemic changes will be made to ensure that the deficient practice will not recur?</b></p> <ul style="list-style-type: none"> <li>- IDT will be in-serviced on "Bed Safety" policy specifically how it pertains to the use of assist rails and necessary consents on or before 6/7/2023</li> <li>- Consents will be kept with the Bed safety assessment book and in the clinical record.</li> <li>- Resident Assist rails will be care planned for appropriate use.</li> <li>- Magic Ambassador to monitor use of assist rails in accordance with resident care plan.</li> <li>- Audit Tool Bed Safety will be utilized by the Executive</li> </ul>		

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			<p>Director, Director of Nursing and/or designee to monitor compliance. Audits will be completed daily X5days, weekly X4 weeks, monthly X2 months, and quarterly thereafter until compliance is maintained for at least two consecutive quarters.</p> <p><b>4. How corrective actions will be monitored to ensure the deficient practice will not recur i.e., what quality assurance program will be put into place?</b></p> <ul style="list-style-type: none"> <li>- Audit Tool Bed Safety will be utilized by the Executive Director, Director of Nursing and/or designee to monitor compliance. Audits will be completed daily X5days, weekly X4 weeks, monthly X2 months, and quarterly thereafter until compliance is maintained for at least two consecutive quarters.</li> <li>- Results of audit tool will be presented to the QAPI Committee Monthly to review for compliance and follow-up. Identified noncompliance may result in staff reeducation and/or disciplinary action.</li> <li>- Bed Rail Assessment book will be reviewed by the safety committee monthly to assure compliance with maintenance and consents. Results will be presented to the QAPI committee.</li> <li>- If 100% threshold is not achieved an action plan will be developed to achieve desired</li> </ul>	

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F 0758 SS=D Bldg. 00	<p>483.45(c)(3)(e)(1)-(5) Free from Unnec Psychotropic Meds/PRN Use</p> <p>§483.45(e) Psychotropic Drugs. §483.45(c)(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories: (i) Anti-psychotic; (ii) Anti-depressant; (iii) Anti-anxiety; and (iv) Hypnotic</p> <p>Based on a comprehensive assessment of a resident, the facility must ensure that---</p> <p>§483.45(e)(1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;</p> <p>§483.45(e)(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;</p> <p>§483.45(e)(3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and</p> <p>§483.45(e)(4) PRN orders for psychotropic</p>		threshold. Data will be submitted to the QAPI committee overseen by the ED for review and follow-up.				

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	<p>drugs are limited to 14 days. Except as provided in §483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.</p> <p>§483.45(e)(5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication. Based on interview and record review, the facility failed to clarify the diagnoses for the use of an antipsychotic medication and to ensure PRN (as needed) psychotropic medications were only ordered and re-evaluated after 14 days for 2 of 5 residents reviewed for unnecessary medications. (Residents 12 and 45)</p> <p>Findings include:</p> <p>1. The record for Resident 12 was reviewed on 05/16/23 at 4:42 p.m. Diagnoses included, but were not limited to, dementia without behavioral disturbances, psychotic disturbance, and depressive disorder.</p> <p>A care plan, revised 12/12/21, indicated the resident was at risk for exhibiting behavior symptoms due to diagnosis of delusional disorder, dementia, and depression. The interventions included, but were not limited to, administer medication as ordered, approach the resident in a calm and friendly manor, document behaviors per behavior management program, and psychiatry services.</p>	F 0758	<p><b>F 758 Drug Regimen is Free From Unnecessary Psychotropic Medications</b></p> <p><b>1. What corrective actions will be accomplished for those residents found to have been affected by the alleged deficient practice?</b></p> <ul style="list-style-type: none"> <li>- The orders and diagnosis for Resident 12 have been clarified with MD. Resident 12 treatment plan, care plan, and orders were reviewed and updated as needed. GDR process ongoing for Resident 12.</li> <li>- Resident 45 PRN medication order was reviewed per policy. Resident 45 has discharged from the facility at the time of this plan of correction.</li> </ul> <p><b>2. How other residents having the potential to be affected by the same deficient practice will be identified and what corrective action will be</b></p>	06/07/2023
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	<p>A pharmacy note to the attending physician or prescriber, dated 3/14/23, indicated Resident 12 was on Risperidone (an antipsychotic) 1 mg (milligram) twice a day. The active psychotic diagnosis was agitation. Agitation was not an approved indication for antipsychotic therapy. Recommend a review of the resident's condition and update to an approved indication listed in the active diagnosis list to avoid CMS (Center for Medicare &amp; Medicaid Services) regulatory tags. Antipsychotic therapy was contraindicated in the elderly dementia population unless other compelling indications for use exist.</p> <p>A Psychiatry Progress note, dated 3/16/23, indicated the diagnosis for Risperidone was for psychotic disorder with delusion.</p> <p>A physician's order, dated 4/18/23, indicated Risperdal 1 mg twice daily was ordered for agitation.</p> <p>A behavioral note, dated 4/19/23, indicated the resident was seen for a recent event in which he was agitated and intentionally getting on the floor. The resident's antipsychotic medication was just increased due to the increased behavioral activity.</p> <p>During an interview, on 5/20/23 at 4:15 p.m., the Clinical Support Nurse did not know why the diagnoses for the medication was for agitation. The diagnosis of agitation was not an appropriate diagnosis for the medication the resident was on.2. The record for Resident 45 was reviewed on 05/16/23 at 4:44 p.m. Diagnoses included, but were not limited to, Parkinson's disease, anxiety, and insomnia.</p> <p>A physician's order, dated 2/18/23, indicated</p>		<p><b>taken?</b></p> <ul style="list-style-type: none"> <li>- All residents are prescribed anti-psychotic medication and psychotropic medications have the potential to be affected by the alleged deficient practice.</li> <li>- Consultant Pharmacist completed an Audit of all residents receiving PRN psychotropic medication to ensure that these medications were only ordered for 14 days and reevaluated accordingly on or before 6/7/2023.</li> <li>- Facility audited all residents receiving antipsychotic medication, antidepressant medication, and anti-anxiety medication to ensure diagnosis and indication for use are appropriate on or before 6/7/2023.</li> </ul> <p><b>3. What measures will be put into place or what systemic changes will be made to ensure that the deficient practice will not recur?</b></p> <ul style="list-style-type: none"> <li>- Direct Care staff will be in-serviced on facility policy "Use of Psychotropic Medication" by DNS/Designee on or before 6/7/2023 to ensure procedures are being followed, diagnosis are appropriate, assessments/monitoring completed, and orders in place.</li> <li>- The IDT will be in-serviced on "Use of Psychotropic Medication" by DNS/Designee on or before 6/7/2023 to ensure Diagnosis are appropriate,</li> </ul>		

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	<p>lorazepam (a medication for anxiety) 0.25 mg (milligrams) every 12 hour as needed.</p> <p>A physician's order, dated 3/21/23, indicated lorazepam 0.25 mg every 12 hours as needed.</p> <p>A physician's order, dated 5/10/23, indicated lorazepam 0.25 ml every 4 hours as needed.</p> <p>During an interview, on 05/19/23 at 4:03 p.m., Anonymous Staff 5 indicated the resident was frequently restless and they tried to keep her occupied. The staff member was not aware the PRN order for the lorazepam needed reviewed every 14 days.</p> <p>A recent publication of "PDR.net" indicated "...risperidone (Risperdal) was indicated for the treatment of schizophrenia...the black box warning indicated antipsychotics are not approved for the treatment of dementia-related psychosis in geriatric patients and the use of risperidone in this population should be avoided if possible due to an increase in morbidity and mortality...."</p> <p>A current policy, titled "Medication Utilization and Prescribing-Clinical Protocol," received from the Regional Support Nurse on 05/19/23 at 3:35 p.m., indicated "...a diagnosis by itself may not be sufficient justification for prescribing a medication. The existence of a condition or risk does not necessarily require a treatment and the treatment may be something besides medication, or in addition to, medication...the consultant pharmacist can help by reviewing facility medication usage patterns and trends and by intensifying medication reviews of individuals taking medications that present clinically significant risks...the consultant pharmacist should use the monthly and interim drug regimen</p>		<p>procedures are being followed, assessments/monitoring completed, and orders in place.</p> <ul style="list-style-type: none"> <li>- Roster of all residents prescribed PRN psychotropic medications Shall be kept and consulted as part of regular daily clinical oversight.</li> <li>- A copy of the regulations regarding use of unnecessary drugs/ unnecessary psychotropic medications and the facility policy regarding use of psychotropic medication were provided to the physician as a resource, including but not limited to all Hospice physicians operating in the facility.</li> <li>- DNS/Designee will review all residents receiving antipsychotic medication, antidepressant medication, and antianxiety medication at least monthly and upon order changes as part of its monthly Behavior Monitoring meeting to ensure each resident has a behavior monitoring program.</li> <li>- Audit Tool Antipsychotic Medications Monitoring will be utilized by the Executive Director, Director of Nursing and/or designee to monitor compliance. Audits will be completed weekly X6 weeks, monthly thereafter as part of the Behavior monitoring program / GDR meeting.</li> </ul> <p><b>4. How corrective actions will be monitored to ensure the deficient practice will not recur</b></p>	

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F 0921 SS=D Bldg. 00	<p>review to help identify potentially problematic medications, including medication regimens that are not supported based on clinical signs or symptoms...."</p> <p>A current policy, titled "Antipsychotic Medication Use," received from the Regional Support Nurse on 5/19/23 at 4:03 p.m., indicated "...diagnosis of a specific condition for which antipsychotic medications are necessary to treat will be based on comprehensive assessment of the resident...antipsychotic medications will not be used if the only symptoms are on or more of the following...restlessness...fidgeting...the need to continue PRN (as needed) orders for psychotropic medications beyond 14 days requires that the practitioner document the rationale for the extended order. The duration of the PRN order will be indicated in the order...PRN orders for antipsychotic medications will not be renewed beyond 14 days unless the healthcare practitioner has evaluated the resident for the appropriateness of that medication...."</p> <p>3.1-48(a)(2) 3.1-48(a)(4)</p> <p>483.90(i) Safe/Functional/Sanitary/Comfortable Environ §483.90(i) Other Environmental Conditions The facility must provide a safe, functional, sanitary, and comfortable environment for</p>		<p><b>i.e., what quality assurance program will be put into place?</b></p> <ul style="list-style-type: none"> <li>- DNS/Designee will review all residents receiving antipsychotic medication, antidepressant medication, and antianxiety medication upon admission, monthly, and upon order changes as part of its monthly Behavior Monitoring meeting to ensure each resident has a behavior monitoring program.</li> <li>- Audit Tool Antipsychotic Medications Monitoring will be utilized by the Executive Director, Director of Nursing and/or designee to monitor compliance. Audits will be completed weekly X6 weeks, monthly thereafter as part of the Behavior monitoring program / GDR meeting.</li> <li>- Results of audit tools will be presented to the QAPI Committee Monthly to review for compliance and follow-up. Identified noncompliance may result in staff reeducation and/or disciplinary action.</li> <li>- If 100% threshold is not achieved an action plan will be developed to achieve desired threshold. Data will be submitted to the QAPI committee overseen by the ED for review and follow-up.</li> </ul>	

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	<p>residents, staff and the public.</p> <p>Based on observation and interview, the facility failed to ensure ceilings panels were free from stains, rooms were free from flying insects and garbage, loose baseboard trim and paint on a bathroom floor, and failed to ensure the second-floor dining room was free from scuff marks and gouges on the walls for 8 of 36 rooms observed. (Room 218, 219, 220, 222, 238, 239, 240, 245 and the second-floor dining room)</p> <p>Findings include:</p> <p>During an observation, beginning at 3:12 p.m., on 5/17/23 with the Executive Director, Director of Nursing (DON), Administrator in Training (AIT), Housekeeping Director, and the Maintenance Director the following were observed:</p> <ol style="list-style-type: none"> <li>Room 218 had one ceiling panel by the window with a large brown stain and two smaller brown stains.</li> <li>Room 219 had seven ceiling panels by the window with eight brown stains.</li> <li>Room 220 had little flying insects around the room and on the bedside table.</li> <li>Room 222 had little flying insects around her food sitting on the resident's bedside table and one ceiling panel above the bed with a large brown stain.</li> <li>Room 238 had a linen closet with black marks and missing paint with gauges above the handrail</li> <li>Room 239's bathroom had baseboard trim hanging off the wall underneath the sink.</li> </ol>	F 0921	<p>F921 Safe/Functional/ Sanitary/Comfortable Environment</p> <p><b>1. What corrective actions will be accomplished for those residents found to have been affected by the alleged deficient practice?</b></p> <ul style="list-style-type: none"> <li>- Ceiling Panel in room 218 has been replaced.</li> <li>- Ceiling panels in room 219 have been replaced.</li> <li>- Facility pest control services were notified of flying insects on May 17th and performed pest control services in facility and room 220 on May 18th.</li> <li>- Facility pest control services were notified of flying insects on May 17th and performed pest control services in facility and room 222 on May 18th.</li> <li>- Ceiling panel in room 222 has been replaced.</li> <li>- Linen closet in room 238 was addressed specifically the black marks and missing paint with gauges above the handrail were fixed.</li> <li>- Baseboard trim in room 239 was fixed.</li> <li>- Alleged White stain on floor in the bathroom of 240 was not present upon walkthrough and was not able to be identified by surveyor or administrator upon investigation which was acknowledged by the surveyor during the walkthrough. Facility environmental staff cleaned the</li> </ul>	06/07/2023

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	<p>7. Room 240 had a white stain on the floor in the bathroom. The paint on the door frame was missing.</p> <p>8. Room 245 had a used syringe on the floor and a pair of dirty gloves under the bed.</p> <p>9. The dining room on the second floor had black scuff marks on the four walls. The wall by the first window had a large gouge between the windows.</p> <p>During an interview, on 5/17/23 at 3:12 p.m., the Maintenance Director indicated she was unaware of the stained ceiling panels and the flying bugs.</p> <p>During an interview, on 5/17/23 at 3:13 p.m., the Executive Director indicated they had the roof fixed due to leaking last week.</p> <p>A current facility policy, dated 2/2021, titled "Pest Control Policy," provided by the Clinical Support Nurse on 5/19/23 at 3:14 p.m., indicated "...Purpose: to provide a safe and limited pest environment...the facility will strive to maintain a pest free environment, administration will contact the pest control agency as needed should pest control services be needed between routine pest control treatments...residents, family members and visitors should alert facility administration in the event of a pest control concern for follow up as indicated...."</p> <p>The facility did not have an Environmental Policy.</p> <p>3.1-19(f)</p>		<p>floor in room 240 no white stain is present.</p> <ul style="list-style-type: none"> <li>- "Missing paint" on Door frame in room 240 was touched up based upon surveyor observation.</li> <li>- The alleged "used syringe and dirty gloves under bed" in room 245 were not present in room 245 during environmental walkthrough on may 17th. Surveyor acknowledged that they were not present at the walkthrough. Environmental supervisor indicated she had cleaned the room and that a catheter syringe for bolus feeding had fallen off the side table and was pushed up against the wall and she had disposed of the same as part of normal housekeeping.</li> <li>- The second floor dining room was repainted to address scuff marks and all walls were patched and sanded prior to painting to address the gouge.</li> </ul> <p><b>2. How other residents having the potential to be affected by the same deficient practice will be identified and what corrective action will be taken?</b></p> <ul style="list-style-type: none"> <li>- All residents have the potential to be affected by the alleged deficient practice.</li> <li>- Facility maintenance and environmental supervisor completed a thorough evaluation of resident rooms to determine if ceiling tiles needed replaced,</li> </ul>	

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			<p>doors needed touched up and scuff marks were present on or before 6/7/2023. Any Items identified on the evaluation were addressed.</p> <ul style="list-style-type: none"> <li>- Environmental supervisor addressed housekeeping staff cleaning procedures including deep cleans and normal housekeeping.</li> <li>- Direct care staff will be in-serviced on tels system to create work orders for maintenance as items are needing maintenance and touch up by ED/Designee on or before 6/7/2023.</li> <li>- IDT will be in-serviced on tels system to create work orders for maintenance as items are needing maintenance and touch up by ED/Designee on or before 6/7/2023.</li> <li>- ED/Environmental Supervisor / Maintenance and or designee shall complete a visual walkthrough of Skilled nursing facility at least daily.</li> </ul> <p><b>3. What measures will be put into place or what systemic changes will be made to ensure that the deficient practice will not recur?</b></p> <ul style="list-style-type: none"> <li>- Environmental supervisor addressed housekeeping staff cleaning procedures including deep cleans and normal housekeeping.</li> <li>- Direct care staff will be in-serviced on tels system to</li> </ul>	

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			<p>create work orders for maintenance as items are needing maintenance and touch up by ED/Designee on or before 6/7/2023.</p> <ul style="list-style-type: none"> <li>- IDT will be in-serviced on tels system to create work orders for maintenance as items are needing maintenance and touch up by ED/Designee on or before 6/7/2023.</li> <li>- ED/Environmental Supervisor / Maintenance and or designee shall complete a visual walkthrough of Skilled nursing facility at least daily to inspect for environmental concerns including but not limited to a safe and limited pest environment. Any issues will be reported to pest control agency for service.</li> <li>- Audit Tool Environment will be utilized by the Executive Director, Director of Maintenance and/or designee weekly to monitor compliance.</li> <li>- Maintenance Director / Designee shall at random thoroughly inspect five rooms per week for maintenance needs using room audit sheet.</li> </ul> <p><b>4. How corrective actions will be monitored to ensure the deficient practice will not recur i.e., what quality assurance program will be put into place?</b></p> <ul style="list-style-type: none"> <li>- ED/Environmental Supervisor / Maintenance and or designee shall complete a visual</li> </ul>	

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R 0000  Bldg. 00	This visit was for a State Residential Licensure	R 0000	<p>walkthrough of Skilled nursing facility at least daily to inspect for environmental concerns including but not limited to a safe and limited pest environment. Any issues will be reported to pest control agency for service.</p> <ul style="list-style-type: none"> <li>- Audit Tool Environment will be utilized by the Executive Director, Director of Maintenance and/or designee weekly to monitor compliance.</li> <li>- ED/ Designee and Maintenance director shall monitor Tels system for work orders weekly.</li> <li>- Maintenance Director / Designee shall thoroughly inspect five rooms per week for maintenance needs using room audit sheet. Any issues will be addressed through work orders.</li> <li>- Results of audit tool will be presented to the QAPI Committee Monthly to review for compliance and follow-up. Identified noncompliance may result in staff reeducation and/or disciplinary action.</li> <li>- If 90% threshold is not achieved an action plan will be developed to achieve desired threshold. Data will be submitted to the QAPI committee overseen by the ED for review and follow-up.</li> </ul> <p>The Creation and submission of</p>	

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R 0148 Bldg. 00	<p>Survey. This visit included the Investigation of Residential Complaints IN00406339, IN00404866, IN00404606 and IN00403105. This visit also included a Recertification and State Licensure Survey.</p> <p>Complaint IN00406339 - No deficiencies related to the allegations are cited.</p> <p>Complaint IN00404866 - State deficiencies related to the allegations are cited at R0148.</p> <p>Complaint IN00404606 - State deficiencies related to the allegations are cited at R0148.</p> <p>Complaint IN00403105 - No deficiencies related to the allegations are cited.</p> <p>Survey dates: May 15, 16, 17, 18, and 19, 2023</p> <p>Facility number: 001149</p> <p>Residential Census: 75</p> <p>This State Residential Finding is cited in accordance with 410 IAC 16.2-5.</p> <p>Quality review was completed on May 26, 2023.</p> <p>410 IAC 16.2-5-1.5(e)(1-4) Sanitation and Safety Standards - Deficiency (e) The facility shall maintain buildings, grounds, and equipment in a clean condition, in good repair, and free of hazards that may adversely affect the health and welfare of the residents or the public as follows: (1) Each facility shall establish and implement a written program for maintenance to ensure the continued upkeep of the facility. (2) The electrical system, including</p>		<p>this plan of correction does not constitute an admission by this provider of any conclusion set forth in the statement of deficiencies or of an violation of regulation. This provider respectfully requests the 2567 Plan of Correction be the letter of credible allegation and REQUESTS DESK REVIEW IN LIEU OF POST SURVEY REVISIT on or after June 7, 2023.</p>	

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	<p>appliances, cords, switches, alternate power sources, fire alarm and detection systems, shall be maintained to guarantee safe functioning and compliance with state electrical codes.</p> <p>(3) All plumbing shall function properly and comply with state plumbing codes.</p> <p>(4) At least yearly, heating and ventilating systems shall be inspected.</p> <p>Based on observation, interview and record review, the facility failed to maintain equipment in a clean condition and in good repair in 2 of 2 laundry rooms and 1 common area observed for environment. (Third floor laundry, Fourth floor laundry and Fourth floor common area)</p> <p>Findings include:</p> <p>1. During an observation, on 05/17/2023 at 8:42 a.m., in the fourth-floor laundry room, the floor beside #1 washing machine had deep, open gouges on the right side and to the rear right side of the washer. The top layer of the vinyl flooring was missing, and the bare floor was exposed. Approximately 4 feet of beige colored cove base was missing on the wall behind #1 washing machine, exposing the bare wall. Both #1 and #2 clothes dryers were observed to have approximately half an inch accumulation of lint in the lint-catcher. The lint accumulation retained its shape when pulled from the side of the lint screen. A large amount of lint was laying on the floor on the left side of the #2 clothes dryer.</p> <p>2. During an observation of the fourth-floor common area, on 05/17/2023 at 3:41 p.m., two exterior windows were open with no screens covering the opening. During an interview, with an anonymous staff member at this time, the staff member indicated the screens had been removed</p>	R 0148	<p>Residential</p> <p><b>1. What corrective actions will be accomplished for those residents found to have been affected by the alleged deficient practice?</b></p> <ul style="list-style-type: none"> <li>- Flooring on 4th floor Laundry Room has been replaced.</li> <li>- Cove Base identified in 4th Floor Laundry Room has been fixed.</li> <li>- Flooring on 3rd Floor Laundry Room has been replaced.</li> <li>- Cove Base in 3rd Floor Laundry Room was inspected and is intact.</li> <li>- Common Area windows have been sealed pending identification of suitable replacement screens.</li> <li>- 3rd and 4th floor laundry room have been deep cleaned.</li> </ul> <p><b>2. How other residents having the potential to be affected by the same deficient practice will be identified and what corrective action will be taken?</b></p> <ul style="list-style-type: none"> <li>- All residents have the potential to be affected by the</li> </ul>	06/07/2023

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	<p>when the exterior of the facility was painted and were never reinstalled. The staff member indicated the painting occurred "about a year ago."</p> <p>3. A tour of the environment was conducted, on 05/18/2023 at 10:00 a.m., with the Maintenance Director (MD). The following observations were seen:</p> <p>The third-floor laundry room: The exterior of #1 washer had a heavy buildup of a sticky substance. The washer was soiled with a blue colored liquid in the lid and interior of the washer. The exterior of #2 washer was sticky to the touch and blue liquid accumulation was observed in the seams on the front. The interior of the door was soiled with a white, filmy substance.</p> <p>The fourth-floor laundry room: The cove base behind #1 washer and gouges on the floor remained. The MD found the missing cove base across the room, folded in half, and placed under a table. When pulled out, by the MD, the cove base was covered with dust and lint.</p> <p>A current policy, titled "Safe and Homelike Environment," undated and received on 05/19/2023 at 3:47 p.m., indicated "...In accordance with the residents' rights, the facility will provide a safe, clean, comfortable and homelike environment...."</p> <p>This State finding relates to Complaints IN00404866 and IN00404606.</p>		<p>alleged deficient practice.</p> <ul style="list-style-type: none"> <li>- Environmental supervisor will supervise daily cleaning and review of 3rd and 4th floor Laundry Room.</li> <li>- Direct Care staff will inspect lint catcher Q shift.</li> <li>- ED/Environmental Supervisor / Maintenance and or designee shall complete a visual walkthrough of Laundry Rooms at least Daily.</li> <li>- ED/Environmental Supervisor / Maintenance and or designee shall complete a visual walkthrough of 3rd and 4th floor daily to ensure windows remain closed.</li> </ul> <p><b>3. What measures will be put into place or what systemic changes will be made to ensure that the deficient practice will not recur?</b></p> <ul style="list-style-type: none"> <li>- Environmental supervisor will supervise daily cleaning and review of 3rd and 4th floor Laundry Room.</li> <li>- Direct Care staff will inspect lint catcher Q shift.</li> <li>- ED/Environmental Supervisor / Maintenance and or designee shall complete a visual walkthrough of Laundry Rooms at least Daily.</li> <li>- Audit Tool Environment will be utilized by the Executive Director, Director of Maintenance and/or designee to monitor compliance daily X5days, weekly</li> </ul>	

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			<p>X4 weeks, monthly X2 months, and quarterly thereafter until compliance is maintained for at least two consecutive quarters.</p> <p><b>4. How corrective actions will be monitored to ensure the deficient practice will not recur i.e., what quality assurance program will be put into place?</b></p> <ul style="list-style-type: none"> <li>- Environmental supervisor will supervise daily cleaning and review of 3rd and 4th floor Laundry Room.</li> <li>- Direct Care staff will inspect lint catcher Q shift.</li> <li>- ED/Environmental Supervisor / Maintenance and or designee shall complete a visual walkthrough of Laundry Rooms at least Daily.</li> <li>- Audit Tool Environment will be utilized by the Executive Director, Director of Maintenance and/or designee to monitor compliance daily X5days, weekly X4 weeks, monthly X2 months, and quarterly thereafter until compliance is maintained for at least two consecutive quarters.</li> <li>- Results of audit tool will be presented to the Safety Committee Monthly to review for compliance and follow-up. Identified noncompliance may result in staff reeducation and/or disciplinary action.</li> <li>- If 100% threshold is not achieved an action plan will be</li> </ul>	

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

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  155618	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED  05/19/2023
NAME OF PROVIDER OR SUPPLIER  MAJESTIC CARE OF CARMEL			STREET ADDRESS, CITY, STATE, ZIP CODE 12999 N PENNSYLVANIA ST CARMEL, IN 46032		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCY (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	
			developed to achieve desired threshold. Data will be submitted to the Safety committee overseen by the ED for review and follow-up.		