

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152542	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 06/13/2025
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY BLACKTHORN	STREET ADDRESS, CITY, STATE, ZIP COD 6201 NIMTZ PKWY SOUTH BEND, IN 46628
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E 0000 Bldg. 00	An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62. Survey Dates: June 11, 12, and 13, 2025 Active Census: 63 At this Emergency Preparedness survey, Fresenius Medical Care Nephrology Blackthorn was found not in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62. Abbreviations: EP Emergency Preparedness	E 0000		
E 0028 Bldg. 00	494.62(b)(9) Dialysis Emergency Equipment Based on observation, record review, and interview, the dialysis facility failed to ensure all supplies in the crash cart were unexpired for 1 of 1 crash cart contents observed. Findings include: 1. Review of the Guidelines for Emergency Preparedness policy, revised 07/03/2023, indicated " ... The following minimum emergency supplies and equipment must be on the premises at all times, clean, functional, accessible, and immediately available ... IV solutions and administration sets ..."	E 0028	E028 Dialysis Emergency Equipment CFR(s): 494.62(b)(9) On 6/30/2025, the Clinical Manager (CM) held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Guidelines for Emergency Preparedness Emphasis will be placed on: The following minimum emergency supplies and equipment must be on the	07/13/2025

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

TITLE

(X6) DATE

Nathan Laskowski

Director of Operations/ Administrator

07/25/2025

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 disclosed 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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	<p>2. During an observation of the crash cart on 06/13/2025 at 2:52 PM, observed all IV tubing in the crash cart expired as of April 2025.</p> <p>3. During an interview on 06/13/2025 at 2:52 PM, the Interim CM indicated the IV tubing in the crash cart was expired.</p>		<p>premises at all times, clean, functional, accessible and immediately available: IV solutions and administration sets Effective 6/30/2025, the CM will conduct 3 days per week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring IV solutions an administration sets are kept in the emergency cart at all times and is not expired. The audits will then go to weekly for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The CM is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI Committee monthly.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting</p>	

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E 0039 Bldg. 00	<p>403.748(d)(2), 416.54(d)(2), 418.113(d)(EP Testing Requirements</p> <p>Based on record review and interview, the dialysis facility failed to ensure a full-scale community-based or facility-based exercise was conducted for 1 of 1 dialysis facility.</p> <p>Findings include:</p> <p>1. Review of the Guidelines for Emergency Preparedness policy, revised 07/03/2023, indicated " ... Annually, each facility MUST participate in a community-based disaster drill. If unable to participate, document who you contacted in the</p>	E 0039	<p>through to the sustained resolution of all identified issues.</p> <p>The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly.</p> <p>The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>E039 EP Testing Requirements CFR(s): 494.62(d)(2)</p> <p>On 6/30/2025, the Clinical Manager (CM) held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Guidelines for Emergency Preparedness Emphasis will be placed on:</p>	07/13/2025

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	<p>community and why the clinic was unable to participate on the Facility Specific Disaster Safety Plan form. If the EOC [Emergency Operations Center] or similar agency has not performed a community-based drill, or it was missed for a particular year, the DO [Director of Operations] should coordinate a dialysis facility area-based drill ..."</p> <p>2. Review of the EP materials included tabletop exercises completed 03/20/2023 and 04/25/2025 but failed to include a full-scale community-based or facility-based exercise for 2024.</p> <p>3. During an interview on 06/13/2025 at 4:22 PM, the Interim CM indicated there had not been any full-scale community-based exercises because there were none held in the county.</p> <p>4. During an interview on 06/13/2025 at 6:11 PM, the Alternate Administrator indicated that while he had attended a full-scale community-based exercise in 2024, he was unable to provide documentation of the contents of the exercise and had not completed a post-exercise analysis and response.</p>		<p>Annually, each facility MUST participate in a community-based disaster drill. If unable to participate, document who you contacted in the community and why the clinic was unable to participate on the Facility Specific Disaster Safety Plan form. If the EOC or similar agency has not performed a community-based drill, or it was missed for a particular year, the DO should coordinate a dialysis facility area-based drill.</p> <p>The Governing Body will: Review and approve the Facility Specific Disaster Safety plan initially and annually. Review the FKC Facility Emergency Information Directory is complete and current. Effective, 6/30/2025 the CM will conduct weekly week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring the facility participates in a community-based disaster drill and completes an after-action review. The audits will then go to Monthly for an additional 2 months or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Medical Director will review the results of audits each month</p>	

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			<p>at the QAPI Committee meeting monthly.</p> <p>The CM is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI Committee monthly.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly.</p> <p>The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p>	

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V 0000 Bldg. 00	<p>This visit was for a CORE Federal recertification survey of an ESRD provider.</p> <p>Survey dates: June 11, 12, and 13, 2025</p> <p>Census by Service Type:</p> <p>In-Center Hemodialysis: 63</p> <p>Total Active Census: 63</p> <p>Isolation Room/Waiver: Waiver not required because the facility was constructed prior to 02/09/2009.</p> <p>Abbreviations:</p> <p>RN-Registered Nurse, CM-Clinical Manager, PCT-Patient Care Technician, ICHD-In-Center Hemodialysis, IV-Intravenous</p> <p>QR 6/19/25 A2</p>	V 0000		
V 0111 Bldg. 00	<p>494.30 IC-SANITARY ENVIRONMENT</p> <p>Based on observation, record review, and interview, the dialysis facility failed to ensure the ten-percent bleach solution was correctly prepared for 1 of 1 observation of ten-percent bleach solution preparation.</p> <p>Findings include:</p> <p>1. Review of the Mixing Bleach policy, revised 02/03/2025, indicated " ... Pour the measured</p>	V 0111	<p>V111 IC-SANITARY ENVIRONMENT CFR(s): 494.30</p> <p>On 6/30/2025, the Clinical Manager (CM) held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Mixing Bleach</p>	07/13/2025

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	<p>amount of water needed into a labeled opaque container. Measuring ensures proper concentration ... Slowly pour the measured amount of bleach into measured water in opaque container. Mix solution ... Test mixed solution for presence of bleach [greater than or equal to 500 parts per million] using approved test strips and document in the electronic documentation system ..."</p> <p>2. During an observation of the water room opening on 06/12/2025 beginning at 5:33 AM, observed PCT 4 prepare the ten-percent bleach solution. PCT 4 put 100 milliliters of bleach into the ten-percent bleach bottle and filled with unmeasured water up to the top of the bend at the top of the bottle. No visible fill line or graduated lines were observed on the bottle. When asked if there was a line on the bottle to show how much water to add, PCT 4 indicated she did not see one.</p> <p>3. On 06/13/2025 at 2:54 PM, observed the prepared ten-percent bleach solution from the treatment floor. Observed a visible black line lower than the bend at the top of the bottle.</p> <p>4. During an interview on 06/12/2025 at 4:59 PM, the Interim CM indicated the procedure for mixing the ten-percent bleach solution included the PCTs have a measuring container, so they measure out for that and fill the container to the marked area. The Interim CM further indicated the ten-percent bleach solution bottle had graduated lines.</p>		<p>Emphasis will be placed on: Diluting a bleach solution to: 1:100 = 1 part bleach to 99 parts water 1:10 = 1 part bleach to 9 parts water.</p> <p>Pour the measured amount of water needed into a labeled opaque container. Measuring ensures proper concentration: · 1:100 = 1-part bleach + 99 parts water · 1:10 = 1-part bleach + 9 parts water.</p> <p>Slowly pour the measured amount of bleach into measured water in opaque container. Mix solution. Mixing slowly decreases fumes.</p> <p>Label opaque container with "Bleach Solution", strength of solution, date and time prepared, and preparer's initials.</p> <p>Cover opaque container with lid.</p> <p>Test mixed solution for presence of bleach (= 500ppm) using approved test strips and document in the electronic documentation system.</p> <p>Effective 6/30/2025 the CM will conduct 3 days per week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring the 1:10 and 1:100 bleach solution are properly measure by staff when mixing and properly labeled. The audits will then go to weekly for an additional 2 weeks or until 100% compliance is achieved.</p>		

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			<p>The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The CM is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI Committee monthly.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly.</p> <p>The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by</p>	

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V 0113 Bldg. 00	<p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE</p> <p>Based on observation, record review, and interview, the dialysis facility failed to ensure infection control policies and procedures were followed related to hand hygiene for 1 of 5 PCTs observed on the ICHD treatment floor.</p> <p>Findings include:</p> <ol style="list-style-type: none"> Review of the Hand Hygiene policy, revised 11/06/2023, indicated " ... Hands Will Be ... Decontaminated using alcohol-based hand rub or by washing hands with soap and water ... Immediately after removing gloves ..." During an ICHD treatment floor observation on 06/11/2025 at 2:18 PM, PCT 1 removed her gloves and failed to perform hand hygiene. At 2:22 PM PCT 1 put on new gloves and failed to first perform hand hygiene. During an interview on 06/11/2025 at 3:08 PM, PCT 1 indicated hand hygiene should be performed between glove changes. During an interview on 06/12/2025 at 4:59 PM, the Interim CM indicated hand hygiene should be performed before putting on gloves and after taking off gloves. 	V 0113	<p>the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>V113 IC-WEAR GLOVES/HAND HYGIENE CFR(s): 494.30(a)(1)</p> <p>On 6/30/2025, the Clinical Manager (CM) held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.</p> <p>Hand Hygiene Emphasis will be placed on: Hand hygiene includes either washing hands with soap and water or using a waterless alcohol-based antiseptic hand rub with 60-90% alcohol content when: Hands are visibly dirty or contaminated with proteinaceous material, blood, or other body fluids Before and after direct contact with patients Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medication</p>	07/13/2025
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			<p>Immediately after removing gloves</p> <p>After contact with body fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly soiled</p> <p>After contact with inanimate objects near the patient</p> <p>When moving from a contaminated body site to a clean body site of the same patient</p> <p>Effective 6/30/2025, the CM will conduct 3 days per week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring hand hygiene is performed when removing gloves and also as listed above. The audits will then go to weekly for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The CM is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI Committee monthly.</p>	

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V 0715 Bldg. 00	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P Based on record review and interview, the medical director failed to ensure the dialysis facility's policies and procedures related to patient assessment and monitoring and determination of blood pressure for 5 of 5 patient records reviewed	V 0715	The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. V715 MD RESP-ENSURE ALL ADHERE TO P&P CFR(s): 494.150(c)(2)(i)	07/13/2025

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	<p>(Patient #9, 10, 11, 12, 13); hypertension for 3 of 5 patient records reviewed; and blood flow rate for 3 of 5 patient records reviewed (Patient #10, 11, 13).</p> <p>Findings include:</p> <ol style="list-style-type: none"> Review of the Medical Director Compliance Guidelines policy, revised 01/01/2007, indicated " ... The Medical Director of the facility is designated in writing to be responsible for the execution of patient care policies ..." Review of the Patient Assessment and Monitoring policy, revised 05/01/2023, indicated " ... During Treatment ... Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulations ... Document machine parameters and safety checks every 30 minutes or more often as needed but not to exceed 45 minutes or per state regulations ... Report to the nurse ... Systolic blood pressures greater than 180 mm/Hg [millimeters of mercury] ... Diastolic blood pressure greater than 100 mm/Hg ... Blood Pressure less than or equal to 100 mm/Hg systolic ... Check machine settings and measurements ... Check prescribed blood flow is being achieved or document in medical record if unable to meet prescribed blood flow ... Document any findings and interventions in the medical record ..." Review of the Hypertension policy, dated 09/07/2021, indicated " ... Staff will recognize, report, and immediately address systolic blood pressures greater than 180 mm/Hg [millimeters of mercury] and/or diastolic blood pressures greater than 100 mm/Hg ..." Review of the Determination of Blood Pressure policy, revised 02/07/2022, indicated " ... Incenter 		<p>On 6/30/2025, the Clinical Manager (CM) held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.</p> <p>Patient assessment and monitoring</p> <p>Medical Director compliance guidelines</p> <p>Hypertension</p> <p>Determination of blood pressure</p> <p>Emphasis will be placed on:</p> <p>The Medical Director of the facility is designated in writing to be responsible for the execution of patient care policies. If the responsibility for day-to-day execution of patient care policies has been delegated to a registered nurse, the Medical Director provides guidance in such matters.</p> <p>Patient Assessment and Monitoring</p> <p>Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulations.</p> <p>Document machine parameters and safety checks every 30 or more often as needed but not to exceed 45 minutes or per state regulations.</p> <p>Report to the nurse:</p> <p>Systolic blood pressures greater than 180 mm/Hg</p> <p>Diastolic blood pressure greater</p>	

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	<p>patients ... Obtain blood pressure readings pre- and post-dialysis sitting and standing (if applicable) and every 30 minutes or more during hemodialysis treatments as indicated ..."</p> <p>5. Review of Patient #9's treatment sheets dated 05/24/2025 to 06/10/2025 included the following: 05/27/2025 Blood pressure, pulse rate, and access checks were conducted at 1:03 PM with follow-up blood pressure, pulse rate, and access checks at 2:02 PM (59 minutes later). Staff failed to conduct blood pressure, pulse rate, and access checks every 30 minutes during ICHD treatment.</p> <p>05/29/2025 Blood pressure, pulse rate, and access checks were conducted at 12:31 PM with follow-up blood pressure, pulse rate, and access checks at 1:31 PM (one hour later). Staff failed to conduct blood pressure, pulse rate, and access checks every 30 minutes during ICHD treatment.</p> <p>05/31/2025 Blood pressure and pulse rate checks were conducted at 12:04 PM with follow-up blood pressure and pulse rate checks at 1:08 PM (one hour and four minutes later). An access check was conducted at 12:05 PM with a follow-up access check at 1:08 PM (one hour and three minutes later). Staff failed to conduct blood pressure, pulse rate, and access checks every 30 minutes during ICHD treatment.</p> <p>06/05/2025 Blood pressure, pulse rate, and access checks were conducted at 1:05 PM with follow-up blood pressure, pulse rate, and access checks at 2:03 PM (58 minutes later). Staff failed to conduct blood pressure, pulse rate, and access checks every 30 minutes during ICHD treatment.</p> <p>06/10/2025 A pre-treatment sitting blood pressure of 211/99 was recorded by PCT 3. The record</p>		<p>than 100 mm/Hg Blood Pressure less than or equal to 100 mm/hg systolic Check machine settings and measurements: Check prescribed blood flow is being achieved or reason is documented in medical record if unable to meet prescribed blood flow. Document any findings and interventions in the medical record. Hypertension Staff will recognize, report, and immediately address systolic blood pressures greater than 180 mm/Hg and/or diastolic blood pressures greater than 100 mm/Hg. Determination of Blood Pressure Incenter patients: Obtain blood pressure readings pre- and post-dialysis sitting and standing (if applicable) and every 30 minutes or more during hemodialysis treatments as indicated.</p> <p>Effective 6/30/2025, the CM will conduct 3 days per week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring blood pressure and machine checks are completed and documented every 30 minutes not to exceed 45. The focus will be on ensuring that the above listed out of range blood pressures</p>	

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	<p>failed to evidence the RN was notified of the systolic blood pressure greater than 180.</p> <p>During an interview on 06/13/2025 at 3:20 PM, PCT 6 indicated blood pressure, pulse, and access checks should be performed at the beginning of treatment, every 30 minutes, and at the end of treatment.</p> <p>During an interview on 06/13/2025 at 3:14 PM, PCT 5 indicated blood pressures over 180 systolic should be reported to the nurse.</p> <p>6. Review of Patient #10's treatment sheets dated 05/24/2025 to 06/10/2025 included the following: 05/24/2025 Blood pressure and pulse rate checks were conducted at 10:03 AM with follow-up blood pressure and pulse rate checks at 11:02 AM (59 minutes later). Staff failed to conduct blood pressure and pulse rate checks every 30 minutes during ICHD treatment.</p> <p>Patient #10's prescribed blood flow rate was 500. The treatment was started at 8:25 AM with the first machine settings check recorded at 8:27 AM with a blood flow rate of 400, and Patient #10 ran at 400 until 11:02 AM when it was lowered to 350. The Patient then ran at a blood flow rate of 350 until the end of the treatment. The treatment run sheet failed to evidence the reason the blood flow rate was not set as prescribed by the physician.</p> <p>Patient #10 had an order to receive Midodrine (a medication used to treat low blood pressure) 5 milligrams by mouth as needed for systolic blood pressures below 100. At 11:02 AM, Patient #10 had a blood pressure of 86/45, and had a blood pressure of 90/32 at 11:32 AM. The treatment record failed to evidence Patient #10 received Midodrine after a blood pressure less than 100</p>		<p>will be reported to the nurse and documented as well as any interventions. The focus will also be on ensuring machine checks including but not limited to BFR's are documented on every 30 minutes and any change or intervention will be documented in the medical record. The focus will be on ensuring blood pre and post standing blood pressures are obtained on all ambulatory patients. The audits will then go to weekly for an additional 2 weeks or until 100% compliance is achieved.</p> <p>The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The CM is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI Committee monthly.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting</p>	

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	<p>systolic.</p> <p>06/05/2025 Patient #10's prescribed blood flow rate was 500. The treatment was started at 8:04 AM with the first machine settings check recorded at 8:07 AM with a blood flow rate of 400, and Patient #10 ran at 400 until 10:02 AM when it was lowered to 350. The Patient then ran at a blood flow rate of 350 until the end of the treatment. The treatment run sheet failed to evidence the reason the blood flow rate was not set as prescribed by the physician.</p> <p>Patient #10 had an order to receive Midodrine 5 milligrams by mouth as needed for systolic blood pressures below 100. At 9:37 AM, Patient #10 had a blood pressure of 96/47, 85/66 at 10:02 AM, 98/60 at 10:34 AM, 82/43 at 11:06 AM, 86/53 at 11:31 AM, and 82/42 at 12:01 PM. The treatment record failed to evidence Patient #10 received Midodrine after a blood pressure less than 100 systolic.</p> <p>Patient #10's prescribed blood flow rate was 500. The treatment on 6/10/2025 was started at 8:46 AM with the first machine settings check recorded at 9:01 AM with a blood flow rate of 450, and Patient #10 ran at 450 until 12:04 PM when it was lowered to 400. The Patient then ran at a blood flow rate of 400 until the end of the treatment. The treatment run sheet failed to evidence the reason the blood flow rate was not set as prescribed by the physician.</p> <p>Patient #10 had a blood pressure of 93/33 at 11:04 AM and 95/52 at 11:05 AM recorded by PCT. The treatment record failed to evidence the RN was notified of the systolic blood pressures less than 100.</p>		<p>through to the sustained resolution of all identified issues.</p> <p>The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly.</p> <p>The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p>	

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	<p>During an interview on 06/13/2025 at 3:14 PM, PCT 5 indicated blood pressures under 100 systolic should be reported to the nurse.</p> <p>During an interview on 06/13/2025 at 3:20 PM, PCT 6 indicated patients should be started at a blood flow rate of 50 and gradually increased until the prescribed blood flow rate is reached. PCT 6 further indicated Patient #10 was a catheter patient who usually can't run at 500 due to venous pressure. PCT 6 indicated he was told to inform the RN when the blood flow rate could not be run as prescribed but did not document that because he assumed the RNs would document it.</p> <p>During an interview on 06/13/2025 at 2:57 PM, RN 1 indicated treatments should begin with the prescribed blood flow rate and indicated the reason for lowering it should be documented on the treatment run sheet.</p> <p>7. Review of Patient #11's treatment sheets dated 05/26/2025 to 06/11/2025 included the following:</p> <p>05/26/2025 The treatment record indicated Patient #11 had a pre-treatment standing blood pressure recorded but failed to include a post-treatment standing blood pressure. The treatment record failed to indicate a reason the post-treatment standing blood pressure could not be assessed.</p> <p>06/09/2025 Blood pressure, pulse rate, and access checks were conducted at 11:35 AM with follow-up blood pressure, pulse rate, and access checks at 12:34 PM (59 minutes later). The next follow-up blood pressure, pulse rates, and access checks were conducted at 1:31PM (57 minutes later). Staff failed to conduct blood pressure, pulse rate, and access checks every 30 minutes during ICHD treatment.</p>			

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	<p>Patient #11 had a prescribed blood flow rate of 500. Treatment began at 9:49 AM with the first blood flow rate recording of 410 at 10:02 AM. Patient #11 ran at a blood flow rate of 410 for the entire treatment. The treatment run sheet failed to evidence the reason the blood flow rate was not set as prescribed by the physician.</p> <p>06/11/2025 Patient #11 had an RN assessment at 10:12 AM which indicated the Patient was ambulatory with a steady gait. The treatment record failed to include a pre-treatment standing blood pressure nor a reason the standing blood pressure could not be assessed.</p> <p>During an interview on 06/13/2025 at 3:08 PM, PCT 4 indicated standing blood pressure checks should be performed before and after treatment. PCT 4 indicated she did not know why Patient #11 did not have a pre-treatment standing blood pressure on 06/11/2025 and indicated the Patient sometimes refuses. PCT 4 indicated the reason for not performing a standing blood pressure is documented on the treatment sheet in the notes section.</p> <p>During an interview on 06/13/2025 at 3:06 PM, PCT 2 indicated blood pressures, pulse rates, and accesses should be checked every 30 minutes during ICHD.</p> <p>During an interview on 06/13/2025 at 3:39 PM, the Interim CM indicated she did not see a reason why Patient #11 was not started and run at the prescribed blood flow rate on 06/09/2025.</p> <p>8. Review of Patient #12's treatment sheets dated 05/23/2025 to 06/09/2025 included the following: 05/30/2025 An RN assessment was conducted at</p>			

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	<p>12:30 PM in which Patient #12 was described as ambulatory with a steady gait. The treatment record failed to include a pre-treatment standing blood pressure nor a reason the standing blood pressure could not be assessed.</p> <p>PCT 5 recorded a blood pressure of 126/104 at 3:08 PM for Patient #12. The treatment record failed to evidence PCT 5 informed the RN of the diastolic blood pressure greater than 100.</p> <p>06/06/2025 Blood pressure, pulse rate, and access checks were conducted at 1:33 PM with follow-up blood pressure, pulse rate, and access checks at 2:30 PM (57 minutes later). Staff failed to conduct blood pressure and pulse rate checks every 30 minutes during ICHD treatment.</p> <p>06/09/2025 An RN assessment was conducted at 12:30 PM in which Patient #12 was described as ambulatory with a steady gait. The treatment record failed to include a pre-treatment standing blood pressure nor a reason the standing blood pressure could not be assessed.</p> <p>During an interview on 06/13/2025, PCT 5 indicated she did not know what the parameters were for reporting diastolic blood pressures to the RN. PCT 5 also indicated she documents RN notification by checking the box that says, "RN notified" and sometimes also puts in a note. PCT 5 also indicated she wasn't sure why she didn't get Patient #12's pre-treatment standing blood pressures on 05/30/2025 and 06/09/2025 because she usually gets it unless the patient is already in the chair.</p> <p>9. Review of Patient #13's treatment sheets dated 05/26/2025 to 06/11/2025 included the following:</p>			

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

PRINTED: 07/28/2025

FORM APPROVED

OMB NO. 0938-039

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	<p>05/26/2025 RN assessments were conducted at 10:47 AM and 2:10 PM in which Patient #13 was described as ambulatory with a steady gait. The treatment record failed to include a pre-treatment or post-treatment standing blood pressure nor a reason the standing blood pressures could not be assessed.</p> <p>05/28/2025 RN assessments were conducted at 10:37 AM and 2:03 PM in which Patient #13 was described as ambulatory with a steady gait. The treatment record failed to include a pre-treatment or post-treatment standing blood pressure nor a reason the standing blood pressures could not be assessed.</p> <p>05/30/2025 RN assessments were conducted at 8:05 AM and 11:57 AM in which Patient #13 was described as ambulatory with a steady gait. The treatment record failed to include a pre-treatment or post-treatment standing blood pressure nor a reason the standing blood pressures could not be assessed.</p> <p>Patient #13 had a prescribed blood flow rate of 500. Treatment began at 8:18 AM with a blood flow rate of 400. Patient #13 ran at a blood flow rate of 400 for the entire treatment. The treatment run sheet failed to evidence the reason the blood flow rate was not set as prescribed by the physician.</p> <p>During an interview on 06/13/2023 at 3:14 PM, PCT 5 indicated standing blood pressure checks should be performed before and after ICHD treatment. PCT 5 indicated Patient #13 refused standing blood pressure checks on 05/28/2025, but there was no choice for "patient refuses" in the system. PCT 5 indicated she could add a note in.</p>			

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	<p>During an interview on 06/13/2025 at 2:57 PM, RN 1 indicated Patient #13 has refused standing blood pressure checks. RN 1 further indicated it should probably be documented when the patient refuses standing blood pressure checks. RN 1 also indicated treatments should be started at the patient's prescribed blood flow rate, and the reason should be documented somewhere if the blood flow rate was lowered. RN 1 indicated she did not see a reason documented by the PCT or herself why Patient #13 was not started at the prescribed blood flow rate.</p> <p>10. During an interview on 06/13/2025 at 3:39 PM, the Interim CM indicated blood pressure, pulse rate, and access checks are to be performed every 30 minutes during treatment and that blood pressures over 180 systolic should be reported to the nurse. The Interim CM indicated that information should be documented somewhere on the treatment run sheet. The Interim CM indicated she would have to check the policy regarding the parameters for reporting diastolic blood pressures to the RN. The Interim CM also indicated patient treatment should be started at the prescribed blood flow rate whenever possible and further indicated changes from the prescribed blood flow rate should be noted in the treatment record.</p> <p>11. During an interview on 06/13/2025 at 4:43 PM, the Medical Director indicated he is responsible for everything that happens in the facility and that policies are followed.</p>			