

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152520	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  10/11/2023
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NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE NEPHROLOGY MISHAWAKA	STREET ADDRESS, CITY, STATE, ZIP CODE 710 PARK PL MISHAWAKA, IN 46545
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V 0000  Bldg. 00	<p>This visit was a post-condition revisit survey for an ESRD certification survey conducted dated 8/29/2023.</p> <p>Survey dates: 10/10/2023 and 10/11/2023</p> <p>Census by Service Type:</p> <p>In-Center Hemodialysis: 89</p> <p>Total Census: 89</p> <p>Isolation Room / Waiver: No</p> <p>During this post condition revisit survey, Fresenius Medical Care Mishawaka was found to have corrected three (3) condition level deficiencies, at Cfc 494.30 Infection Control, 494.80 Patient Assessment, and 494.90 Plan of care, 22 standard level deficiencies were found to be corrected, and 5 standard level deficiencies were recited.</p> <p>QR: A 2 10/24/23</p>	V 0000	<p>Fresenius Medical Care Nephrology Mishawaka Dialysis plan of correction Date of Survey 10/11/2023</p> <p>Provider 15-2520 V111 On 10/30/2023, the Facility Administration held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure:</p> <p>General Cleanliness and Infection Control Guidelines Clinic Audit Checklist Emphasis was placed on: Importance of ensuring that a sanitary environment is maintained in all areas of the treatment floor.</p> <p>Effective 11/1/23, Facility Administrator or Charge Nurse will conduct 3 days per week audits with focus on ensuring staff maintain a sanitary environment per policy, as required, utilizing Plan of Correction Monitoring Tool for 2 weeks and then weekly for an additional 2 weeks or until 90% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring</p>	
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Nathan Laskowski	Director of Operations	11/04/2023

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 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>will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator 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 QAI 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 QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing 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>	

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			<p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 11/10/2023.</p> <p><b>V503</b></p> <p>On 10/30/2023, the Facility Administration held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:</p> <p style="padding-left: 40px;">Patient Assessment and Monitoring Nursing Supervision and Delegation Volume Management on ESRD Patients on Hemodialysis</p> <p>Emphasis was placed on: Direct patient care staff may collect data such as weight, BP, pulse, respirations, temperature, general observations, access, and complaints reported by the patient. If the PCT/LPN note any changes or abnormal findings in the patient's condition or vascular access are observed or reported by the patient, or the patient was hospitalized, the registered nurse must assess the patient.</p> <p>- Fluid balance is an integral component of the HD treatment to prevent patient hyper- or</p>	

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			<p>hypovolemia both of which have been demonstrated to influence mortality and cardiovascular complications in ESRD patients on HD. Registered nurse should complete a fluid assessment on all ESRD patients receiving HD treatments. Assessment should evaluate patients for hypo- and hypervolemia.</p> <p>Post Weight comparison to EDW</p> <p>Pre/Post Blood Pressure</p> <p>Lowest Intradialytic Blood Pressure</p> <p>The RN is accountable for delivering care within the framework of the nursing process. The RN uses clinical findings to formulate nursing diagnoses and prioritize problems according to patient need.</p> <p>The registered nurse must evaluate each patient preferably within an hour or according to state requirements to:</p> <p>Confirm identity.</p> <p>Review the patient's condition.</p> <p>Review accuracy and completeness of treatment and patient data</p> <p>Review patient treatment prescription and equipment parameters to verify correct settings, and if dialysis prescription is being followed.</p> <p>Confirm that the correct vascular access is being used, and that the access is visible. Observe patient's response to treatment.</p>	

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			<p>Verify machine safety checks have been completed.</p> <p>Talk to the patient to elicit information such as changes in condition, response to treatment, new injuries, information/education needs or complaints, satisfaction with care.</p> <p><u>The RN will notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instruction.</u></p> <p>The Registered Nurse will assess/reassess any findings addressed pre or during treatment as needed.</p> <p>Effective 11/1/23, Facility Administrator or Charge Nurse will conduct 10 treatment sheets 3 days per week, alternating shifts, with focus on ensuring the physician is notified of changes in the patient's condition as well as ensuring the appropriateness of the dialysis prescription utilizing Plan of Correction Monitoring Tool for 2 weeks and then will complete weekly treatment audits on 10% of completed treatments for an additional 2 weeks or until 90% 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.</p>	

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			<p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator 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 QAI 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 QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing 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 QAI and Governing Body</p>	

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			<p>minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 11/10/23.</p> <p><b>V 504</b></p> <p>On 10/30/2023, the Facility Administration held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:</p> <p style="padding-left: 40px;">Patient Assessment and Monitoring Nursing Supervision and Delegation Volume Management on ESRD Patients on Hemodialysis version 1 Comprehensive Interdisciplinary Assessment and Plan of Care</p> <p>Emphasis was placed on:</p> <p>RN assessment pre, during, and post treatment should accurately reflect the findings. Direct patient care staff may collect data such as weight, BP, pulse, respirations, temperature, general observations, access, and complaints reported by the patient. If the PCT/LPN note any changes or abnormal findings in</p>	

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			<p>the patient's condition or vascular access are observed or reported by the patient, or the patient was hospitalized, the registered nurse must assess the patient.</p> <p><u>Report to the nurse:</u>  <u>Systolic blood pressures greater than 180 mm/Hg</u>  <u>Diastolic blood pressure greater than 100 mm/Hg</u>  <u>Blood Pressure less than or equal to 100 mm/hg systolic</u></p> <p>Any complaints by the patient before, during, or after treatment (i.e., nausea, vomiting, cramping)</p> <p>Fluid balance is an integral component of the HD treatment to prevent patient hyper- or hypovolemia both of which have been demonstrated to influence mortality and cardiovascular complications in ESRD patients on HD. Registered nurse should complete a fluid assessment on all ESRD patients receiving HD treatments. Assessment should evaluate patients for hypo- and hypervolemia.</p> <p>At a minimum, fluid assessment will include review of the following clinical indicators:</p> <ul style="list-style-type: none"> <li>EDW</li> <li>Pre/Post Weight</li> <li>Post Weight comparison to EDW</li> <li>Pre/Post Blood Pressure</li> <li>Lowest Intradialytic Blood Pressure</li> <li>Signs/symptoms of fluid overload</li> </ul>	

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			<p>Physical examination including lung assessment, cardiovascular (i.e., heart sounds) and peripheral vascular assessment (edema)</p> <p>If any of the following patient clinical conditions occur refer to the volume algorithm if applicable or consult with provider for appropriate fluid interventions:</p> <p>Pre-treatment signs or symptoms of hypervolemia Pre-treatment sitting systolic BP is greater than 160 mmHg and prior treatment post dialysis sitting systolic BP is greater than 140 mmHg.</p> <p>Pre-treatment signs or symptoms of hypovolemia Unable to achieve EDW due to UF intolerance.</p> <p>New to dialysis within 13 treatments Post-hospitalization Pre-treatment weight is less than or equal to EDW. Prior treatment was shortened by more than 15 minutes. Prior missed treatment Treatment adjustments based on fluid assessment, symptoms, and blood pressure are critical to improve a patient's volume status. EDW order should be updated post treatment to reflect treatment adjustments and patient fluid status.</p> <p>The RN is accountable for delivering care within the framework of the nursing process.</p>	

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			<p>The RN uses clinical findings to formulate nursing diagnoses and prioritize problems according to patient need.</p> <p>The registered nurse must evaluate each patient preferably within an hour or according to state requirements to:</p> <ul style="list-style-type: none"> <li>Confirm identity.</li> <li>Review the patient's condition.</li> <li>Review accuracy and completeness of treatment and patient data</li> <li>Review patient treatment prescription and equipment parameters to verify correct settings, and if dialysis prescription is being followed.</li> <li>Confirm that the correct vascular access is being used, and that the access is visible. Observe patient's response to treatment.</li> <li>Verify machine safety checks have been completed.</li> <li>Talk to the patient to elicit information such as changes in condition, response to treatment, new injuries, information/education needs or complaints, satisfaction with care.</li> </ul> <p><u>The RN will notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instruction.</u></p> <p>The Registered Nurse will assess/reassess any findings addressed pre or during treatment as needed.</p> <p>Prior to discharge, the RN must</p>	

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			<p>confirm the patient is stable for discharge and review the treatment record for:</p> <ul style="list-style-type: none"> <li>Slow/fast/irregular heart rate</li> <li>Low or high blood pressures</li> <li>Whether patient is achieving dry weight and identifying reason for patient not achieving dry weight</li> <li>Heart rate &lt;50 or &gt;120</li> </ul> <p>addressed by the registered nurse with documentation present.</p> <ul style="list-style-type: none"> <li>Blood pressures &lt; 100 systolic or greater than 180 systolic</li> </ul> <p>addressed by the registered nurse with or documentation present.</p> <ul style="list-style-type: none"> <li>Reported fall, and if heparin was held and MD notified.</li> <li>Correct dialysate prescription was delivered.</li> </ul> <p>Effective 11/1/23, Facility Administrator or Charge Nurse will conduct 10 treatment sheets 3 days per week, alternating shifts, with focus on ensuring patient pre/post and intradialytic blood pressures are being assessed/ managed and physician order followed utilizing Plan of Correction Monitoring Tool for 2 weeks and then will complete weekly treatment audits on 10% of completed treatments for an additional 2 weeks or until 90% 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</p>	

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			<p>Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator 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 QAI 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 QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing 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>	

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			<p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 11/10/2023.</p> <p><b>V 543</b></p> <p>On 10/30/2023, the Facility Administration held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:</p> <p style="padding-left: 40px;">Nursing Supervision and Delegation Patient Assessment and Monitoring Volume Management on ESRD Patients on Hemodialysis</p> <p>Emphasis was placed on: Direct patient care staff may collect data such as weight, BP, pulse, respirations, temperature, general observations, access, and complaints reported by the patient.</p> <p>If the PCT/LPN note any changes or abnormal findings in the patient's condition or vascular access are observed or reported by the patient, or the patient was hospitalized, the registered nurse must assess the patient.</p> <p><u>The RN will notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical</u></p>	

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			<p><u>judgment for additional instruction.</u></p> <p>Fluid balance is an integral component of the HD treatment to prevent patient hyper- or hypovolemia both of which have been demonstrated to influence mortality and cardiovascular complications in ESRD patients on HD. <u>Registered nurse should complete a fluid assessment on all ESRD patients receiving HD treatments.</u> Assessment should evaluate patients for hypo- and hypervolemia.</p> <p>At a minimum, fluid assessment will include review of the following clinical indicators:</p> <ul style="list-style-type: none"> <li>EDW</li> <li>Pre/Post Weight</li> <li>Post Weight comparison to EDW</li> <li>Pre/Post Blood Pressure</li> <li>Lowest Intradialytic Blood Pressure</li> <li>Signs/symptoms of fluid overload</li> <li>Physical examination including lung assessment, cardiovascular (i.e., heart sounds) and peripheral vascular assessment (edema)</li> </ul> <p>If any of the following patient clinical conditions occur refer to the volume algorithm if applicable or consult with provider for appropriate fluid interventions:</p> <ul style="list-style-type: none"> <li>Pre-treatment signs or symptoms of hypervolemia</li> <li>Pre-treatment sitting systolic BP is greater than 160 mmHg and prior treatment post dialysis sitting</li> </ul>	

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			<p>systolic BP is greater than 140 mmHg.</p> <p>Pre-treatment signs or symptoms of hypovolemia <u>Unable to achieve EDW due to UF intolerance.</u></p> <p>New to dialysis within 13 treatments Post-hospitalization <u>Pre-treatment weight is less than or equal to EDW.</u></p> <p>Prior treatment was shortened by more than 15 minutes. Prior missed treatment Treatment adjustments based on fluid assessment, symptoms, and blood pressure are critical to improve a patient's volume status. EDW order should be updated post treatment to reflect treatment adjustments and patient fluid status.</p> <p>The RN is accountable for delivering care within the framework of the nursing process. The RN uses clinical findings to formulate nursing diagnoses and prioritize problems according to patient need.</p> <p>The registered nurse must evaluate each patient preferably within an hour or according to state requirements to:</p> <p>Confirm identity. Review the patient's condition. Review accuracy and completeness of treatment and patient data Review patient treatment prescription and equipment</p>	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152520	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  10/11/2023
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NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE NEPHROLOGY MISHAWAKA	STREET ADDRESS, CITY, STATE, ZIP COD 710 PARK PL MISHAWAKA, IN 46545
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			<p>parameters to verify correct settings, and if dialysis prescription is being followed.</p> <p>Confirm that the correct vascular access is being used, and that the access is visible. Observe patient's response to treatment.</p> <p>Verify machine safety checks have been completed.</p> <p>Talk to the patient to elicit information such as changes in condition, response to treatment, new injuries, information/education needs or complaints, satisfaction with care.</p> <p>The RN will notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instruction.</p> <p>The Registered Nurse will assess/reassess any findings addressed pre or during treatment as needed.</p> <p>Prior to discharge, the RN must confirm the patient is stable for discharge and review the treatment record for:</p> <p>Slow/fast/irregular heart rate</p> <p>Low or high blood pressures</p> <p><u>Whether patient is achieving dry weight and identifying reason for patient not achieving dry weight</u></p> <p>Heart rate &lt;50 or &gt;120</p> <p>addressed by the registered nurse with documentation present.</p> <p>Blood pressures &lt; 100 systolic or greater than 180 systolic addressed by the registered nurse with or documentation present.</p>	

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			<p>Reported fall, and if heparin was held and MD notified. Correct dialysate prescription was delivered.</p> <p>Effective 11/1/23, Facility Administrator or Charge Nurse will conduct 10 treatment sheets 3 days per week, alternating shifts, with focus on ensuring the physician is aware of patients below their dry weight prior to treatment, inability of the patient to achieve their dry weight, as well as, ensuring the physician is notified when the post treatment weight is greater than/less than 1 kilogram of the ordered dry weight utilizing Plan of Correction Monitoring Tool for 2 weeks and then will complete weekly treatment audits on 10% of completed treatments for an additional 2 weeks or until 90% 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.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit</p>	

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			<p>results as related to this Plan of Correction prior to presenting to the QAI 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 QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing 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 QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 11/10/2023.</p> <p>- <b>V544</b> On 10/30/2023, the Facility Administration held a staff meeting</p>	

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			<p>and reinforced the expectations and responsibilities of the facility staff on policy:</p> <p>Patient Assessment and Monitoring Emphasis was placed on:</p> <p>Document machine parameters and safety checks every 30 minutes or more often as needed but not to exceed 45 minutes or per state regulations. Check machine settings and measurements:</p> <p>Check prescribed blood flow rate is being achieved or reason is documented in medical record if unable to meet prescribed blood flow rate.</p> <p>Check dialysate flow rate setting is correct, and the prescribed flow is being delivered.</p> <p>Registered Nurse will document in medical record if physician order not followed as prescribed to include but not limited to treatment time as ordered and notify physician.</p> <p>Effective 11/1/23, Facility Administrator or Charge Nurse will conduct 10 treatment sheets 3 days per week, alternating shifts, with focus on ensuring patient dialysis prescription orders are verified and adhered to, to achieve and sustain the prescribed dose of dialysis to meet the adequacy of dialysis utilizing Plan of Correction Monitoring Tool for 2 weeks and then will complete weekly</p>	

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			<p>treatment audits on 10% of completed treatments for an additional 2 weeks or until 90% 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.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator 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 QAI 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 QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p>	

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V 0111 Bldg. 00	<p>494.30 IC-SANITARY ENVIRONMENT</p> <p>The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.</p> <p>Based on observation, record review, and interview, the dialysis facility failed to ensure it provided and monitored a sanitary environment for 1 of 1 observation period conducted on 10/10/23.</p> <p>The findings include:</p> <p>1. Review of a facility policy dated 2/07/2022, titled "General Cleanliness and Infection Control Guidelines," indicated supplies or patient belongings should not be kept or stored behind the machine at patient treatment station, and sharps containers should be replaced on a regularly scheduled basis, or when no more than 2/3 to 3/4 full.</p>	V 0111	<p>The Governing Body is responsible for providing 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 QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 11/10/2023.</p> <p>V111 On 10/30/2023, the Facility Administration held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure:</p> <p>General Cleanliness and Infection Control Guidelines Clinic Audit Checklist Emphasis was placed on: Importance of ensuring that a sanitary environment is maintained in all areas of the treatment floor.</p> <p>Effective 11/1/23, Facility</p>	11/10/2023

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	<p>2. Observation of the treatment area on 10/10/2023, beginning at 10:35 AM revealed the following:</p> <p>A. At 10:38 AM, observed at station 8, a quarter size drop of blood was observed on the floor in front of the dialysis machine, used earbuds were on the right chair-side foldable table, litter was on the floor by the chair, two used cannulation needles / tubing sat on the left chair-side table, and the sharps container (a container used to safely dispose of contaminated / used needles) which was attached to the side of the dialysis machine, was full (a black line on the container evidenced when the container was considered full).</p> <p>B. During this observation, Registered Nurse (RN) indicated the needles were engaged (safety covers over the needles to prevent accidental needle sticks) and the PCT was probably getting ready to throw them away. The RN failed to dispose of the used needles.</p> <p>C. At 10:44 AM, observed the sharps container at stations 5 and 12 were full, and the sharps container at station 15 was over 3/4 full.</p> <p>D. At 10:47 AM, observed the Patient Care Technician (PCT) clean station 8, post treatment. The PCT failed to sanitize the shelf behind the station and placed the sanitized arm cushion and used earbuds on the same shelf behind the station; litter remained on the floor.</p> <p>E. At 10:52 AM, observed the sharps container at station 9 was full and a PCT prepared station 8 with clean supplies, in preparation for the next Patient for dialysis treatment. The used earbuds</p>		<p>Administrator or Charge Nurse will conduct 3 days per week audits with focus on ensuring staff maintain a sanitary environment per policy, as required, utilizing Plan of Correction Monitoring Tool for 2 weeks and then weekly for an additional 2 weeks or until 90% 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.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator 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 QAI 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 QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as</p>	

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V 0503 Bldg. 00	<p>and litter remained as observed at 10:38 AM.</p> <p>F. At 11:30 AM, the used earbuds at station 8, remained on the shelf behind the treatment chair.</p> <p>G. At 11:40 AM, a patient was assisted into the treatment chair at station 8, where the used earbuds remained.</p> <p>H. At 12:09 PM, observed the sharps container at station 7 was full, and the sharps container at station 8 remained full.</p> <p>3. During an interview on 10/10/2023 at 3:34 PM, the Clinical Manager indicated they provided disposable earbuds to the patients, when sharps containers were 3/4 full, they would be replaced and disposed of properly, and it was not a typical practice to leave used needles on the chair-side tables, post treatment. The Administrator indicated sharps containers were typically replaced when 3/4 full.</p> <p>494.80(a)(2) PA-APPROPRIATENESS OF DIALYSIS RX The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>(2) Evaluation of the appropriateness of the dialysis prescription, Based on observation, record review, and interview the agency failed to ensure the physician was notified of changes in conditions and failed to ensure the appropriateness of the patient's dialysis prescriptions in 1 of 1 clinical records reviewed with Patients experiencing nausea and cramping during treatment. (Patient #23)</p>	V 0503	<p>appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing 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 QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p><b>V503</b></p> <p>On 10/30/2023, the Facility Administration held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:</p> <p>Patient Assessment and</p>	11/10/2023
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	<p>The findings include:</p> <p>1. An agency document titled "Patient Assessment and Monitoring," published 5/1/2023, stated, " ... If the PCT/LPN [patient care technician/licensed practical nurse] notes any changes or abnormal findings in the patient's condition, the patient care technician must report the findings to the registered nurse [RN] who will further assess the patient ... During nursing rounds will assess the following parameters ... auscultate lung sounds ... assess for edema ... contact the Physician as needed for additional orders based on assessment findings and clinical judgment ...."</p> <p>2. A clinical record review, on 10/11/2023 for Patient #23, with start of care 9/21/2023, included a review of the dialysis treatment sheets from 9/29/2023 through 10/10/2023 and evidenced the following:</p> <p>The flowsheets dated 10/3/2023 and 10/5/2023 documented Patient #23 had complaints of nausea during treatment. The documentation failed to evidence the Physician was notified of the Patient's complaints of nausea.</p> <p>The flowsheets dated 10/3/2023 and 10/10/2023 documented Patient #23 had complaints of cramping during treatment. The documentation failed to evidence the Physician was notified of the Patient's complaints of nausea.</p> <p>During an interview on 10/11/2023 at 2:33 PM, the Facility Administrator indicated the Patient Care Technician should alert the nurse of any patient complaints and the nurse will evaluate the Patient to determine if the Physician should be notified.</p>		<p>Monitoring Nursing Supervision and Delegation Volume Management on ESRD Patients on Hemodialysis Emphasis was placed on: Direct patient care staff may collect data such as weight, BP, pulse, respirations, temperature, general observations, access, and complaints reported by the patient. If the PCT/LPN note any changes or abnormal findings in the patient's condition or vascular access are observed or reported by the patient, or the patient was hospitalized, the registered nurse must assess the patient.</p> <p>- Fluid balance is an integral component of the HD treatment to prevent patient hyper- or hypovolemia both of which have been demonstrated to influence mortality and cardiovascular complications in ESRD patients on HD. Registered nurse should complete a fluid assessment on all ESRD patients receiving HD treatments. Assessment should evaluate patients for hypo- and hypervolemia. Post Weight comparison to EDW Pre/Post Blood Pressure Lowest Intradialytic Blood Pressure The RN is accountable for delivering care within the</p>	
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			<p>framework of the nursing process. The RN uses clinical findings to formulate nursing diagnoses and prioritize problems according to patient need.</p> <p>The registered nurse must evaluate each patient preferably within an hour or according to state requirements to:</p> <ul style="list-style-type: none"> <li>Confirm identity.</li> <li>Review the patient's condition.</li> <li>Review accuracy and completeness of treatment and patient data</li> <li>Review patient treatment prescription and equipment parameters to verify correct settings, and if dialysis prescription is being followed.</li> <li>Confirm that the correct vascular access is being used, and that the access is visible. Observe patient's response to treatment.</li> <li>Verify machine safety checks have been completed.</li> <li>Talk to the patient to elicit information such as changes in condition, response to treatment, new injuries, information/education needs or complaints, satisfaction with care.</li> </ul> <p><u>The RN will notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instruction.</u></p> <p>The Registered Nurse will assess/reassess any findings addressed pre or during treatment as needed.</p>	

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			<p>Effective 11/1/23, Facility Administrator or Charge Nurse will conduct 10 treatment sheets 3 days per week, alternating shifts, with focus on ensuring the physician is notified of changes in the patient's condition as well as ensuring the appropriateness of the dialysis prescription utilizing Plan of Correction Monitoring Tool for 2 weeks and then will complete weekly treatment audits on 10% of completed treatments for an additional 2 weeks or until 90% 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.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator 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 QAI 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</p>	

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V 0504 Bldg. 00	<p>494.80(a)(2) PA-ASSESS B/P, FLUID MANAGEMENT NEEDS</p> <p>The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>Blood pressure, and fluid management needs.</p> <p>Based on observation, record review, and interview the dialysis facility failed to ensure patient pre/post and intradialytic blood pressure were being assessed and managed in 2 of 2</p>	V 0504	<p>each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing 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 QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p>	11/10/2023

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	<p>in-center hemodialysis records reviewed of patients experiencing hypertension during treatment. (Patient #23, #24)</p> <p>1. An agency document titled "Patient Assessment and Monitoring," published 5/1/2023, stated, " ... If the PCT/LPN [patient care technician/licensed practical nurse] notes any changes or abnormal findings in the patient's condition, the registered nurse [RN] must assess the patient ... Report to the nurse systolic blood pressures greater than 180 diastolic blood pressures greater than 100 systolic pressures less than or equal to 100 during treatment ... Report to the nurse patients whose heart rates have dropped below 60 or have risen above 100 ... An abnormal finding confirmed by the RN will be reported to the attending physician if necessary ...."</p> <p>2. An agency policy titled "Volume Management in ESRD [End Stage Renal Disease] Patients on Hemodialysis" published 9/7/2021 stated, "If any of the following patient clinical conditions occur refer to the volume algorithm if applicable or consult with the physician for appropriate fluid interventions: Pre-treatment sitting systolic BP is greater than 160 mmHg...."</p> <p>3. An agency policy titled "Nursing Supervision and Delegation," published 5/1/2023, stated, " ... The following can be used as a guideline for the PCT/ LPN or RN to refer the patient to the charge nurse for further assessment The charge nurse will determine any clinical interventions needed ... A systolic blood pressure greater than 180 and/or diastolic blood pressure greater than 100 at any time before, during or after the treatment. If B/P [blood pressure] less than 100 systolic during treatment A systolic blood pressure less than 100</p>		<p>and responsibilities of the facility staff on policies:</p> <p>Patient Assessment and Monitoring Nursing Supervision and Delegation Volume Management on ESRD Patients on Hemodialysis version 1 Comprehensive Interdisciplinary Assessment and Plan of Care</p> <p>Emphasis was placed on:</p> <p>RN assessment pre, during, and post treatment should accurately reflect the findings. Direct patient care staff may collect data such as weight, BP, pulse, respirations, temperature, general observations, access, and complaints reported by the patient. If the PCT/LPN note any changes or abnormal findings in the patient's condition or vascular access are observed or reported by the patient, or the patient was hospitalized, the registered nurse must assess the patient. <u>Report to the nurse:</u> <u>Systolic blood pressures greater than 180 mm/Hg</u> <u>Diastolic blood pressure greater than 100 mm/Hg</u> <u>Blood Pressure less than or equal to 100 mm/hg systolic</u> Any complaints by the patient</p>	

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NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE NEPHROLOGY MISHAWAKA	STREET ADDRESS, CITY, STATE, ZIP COD 710 PARK PL MISHAWAKA, IN 46545
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	<p>post-treatment when standing. A drop in systolic BP of 20 between sitting and standing ...."</p> <p>4. Clinical record review on 10/11/2023 for Patient #23, start of care 9/21/2023, included a review of the dialysis treatment sheets from 9/28/2023 through 10/7/2023 and evidenced the following:</p> <p>The Flowsheet dated 9/28/2023 documented Patient #23's blood pressure (BP) was 171/103, at 3:06 PM and 176/109 at 3:45 PM.</p> <p>The Flowsheet dated 10/3/2023 documented Patient #23's BP was 155/102, at 1:00 PM and 168/108 at 3:42 PM.</p> <p>The Flowsheet dated 10/5/2023 documented Patient #23's BP was 160/100, at 1:02 PM and 169/102 at 3:00 PM.</p> <p>The providers documentation failed evidence staff followed policies and procedures and failed to notify the Nurse of Patient #23's blood pressure.</p> <p>5. Clinical record review on 10/11/2023 for Patient #24, start of care 12/21/2021, included a review of the dialysis treatment sheets from 9/28/2023 through 10/7/2023 and evidenced the following:</p> <p>The Flowsheet dated 9/29/2023 documented Patient #24's BP was 164/117 at 12:50 PM; the BP was 160/114 at 1:01 PM; BP was 147/105 at 1:34 PM; BP was 137/100 at 2:04 PM; BP was 167/100 at 2:33 PM; BP was 144/103 at 3:07 PM, and BP was 140/109 at 3:37 PM.</p> <p>The Flowsheet dated 10/2/2023 documented Patient #24's BP was 172/122, at 12:54 PM, BP was 189/132 at 1:01 PM, BP was 177/120 at 1:32 PM, BP was 172/117 at 2:01 PM, BP was 162/110 at 2:31</p>		<p>before, during, or after treatment (i.e., nausea, vomiting, cramping)</p> <p>Fluid balance is an integral component of the HD treatment to prevent patient hyper- or hypovolemia both of which have been demonstrated to influence mortality and cardiovascular complications in ESRD patients on HD. Registered nurse should complete a fluid assessment on all ESRD patients receiving HD treatments. Assessment should evaluate patients for hypo- and hypervolemia.</p> <p>At a minimum, fluid assessment will include review of the following clinical indicators:</p> <ul style="list-style-type: none"> <li>EDW</li> <li>Pre/Post Weight</li> <li>Post Weight comparison to EDW</li> <li>Pre/Post Blood Pressure</li> <li>Lowest Intradialytic Blood Pressure</li> <li>Signs/symptoms of fluid overload</li> <li>Physical examination including lung assessment, cardiovascular (i.e., heart sounds) and peripheral vascular assessment (edema)</li> </ul> <p>If any of the following patient clinical conditions occur refer to the volume algorithm if applicable or consult with provider for appropriate fluid interventions:</p> <ul style="list-style-type: none"> <li>Pre-treatment signs or symptoms of hypervolemia</li> <li>Pre-treatment sitting systolic BP</li> </ul>	

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NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE NEPHROLOGY MISHAWAKA			STREET ADDRESS, CITY, STATE, ZIP COD 710 PARK PL MISHAWAKA, IN 46545		
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	<p>PM, BP was 161/119 at 3:06 PM, and BP was 195/126 at 3:51 PM.</p> <p>The Flowsheet dated 10/4/2023 documented Patient #24's BP was 171/115, at 12:35 PM, BP was 178/121 at 1:04 PM, BP was 165/117 at 1:31 PM, BP was 167/120 at 2:01 PM, BP was 156/103 at 2:34 PM, BP was 163/108 at 3:02 PM, and BP was 173/114 at 3:33 PM.</p> <p>The Flowsheet dated 10/6/2023 documented Patient #24's BP was 164/115, at 12:29 PM, BP was 167/106 at 2:32 PM, BP was 158/112 at 1:11 PM, BP was 155/110 at 1:32 PM, BP was 149/1 at 2:04 PM, and BP was 142/102 at 2:39 PM.</p> <p>The Flowsheet dated 10/9/2023 documented Patient #24's BP was 162/105, at 1:34 PM, BP was 159/109 at 2:03 PM, BP was 159/103 at 2:34 PM, BP was 165/109 at 3:02 PM, and BP was 168/108 at 3:31 PM.</p> <p>The providers documentation failed to evidence staff followed policies and procedures and failed to notify the Nurse of Patient #24's blood pressure.</p> <p>6. During an interview on 10/11/2023 at 2:41 PM, the Facility Administrator indicated any systolic BP over 180 or under 100 should be reported to the Nurse.</p>		<p>is greater than 160 mmHg and prior treatment post dialysis sitting systolic BP is greater than 140 mmHg.</p> <p>Pre-treatment signs or symptoms of hypovolemia Unable to achieve EDW due to UF intolerance. New to dialysis within 13 treatments Post-hospitalization Pre-treatment weight is less than or equal to EDW. Prior treatment was shortened by more than 15 minutes. Prior missed treatment Treatment adjustments based on fluid assessment, symptoms, and blood pressure are critical to improve a patient's volume status. EDW order should be updated post treatment to reflect treatment adjustments and patient fluid status.</p> <p>The RN is accountable for delivering care within the framework of the nursing process. The RN uses clinical findings to formulate nursing diagnoses and prioritize problems according to patient need.</p> <p>The registered nurse must evaluate each patient preferably within an hour or according to state requirements to: Confirm identity. Review the patient's condition. Review accuracy and completeness of treatment and patient data</p>		

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			<p>Review patient treatment prescription and equipment parameters to verify correct settings, and if dialysis prescription is being followed.</p> <p>Confirm that the correct vascular access is being used, and that the access is visible. Observe patient's response to treatment.</p> <p>Verify machine safety checks have been completed.</p> <p>Talk to the patient to elicit information such as changes in condition, response to treatment, new injuries, information/education needs or complaints, satisfaction with care.</p> <p><u>The RN will notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instruction.</u></p> <p>The Registered Nurse will assess/reassess any findings addressed pre or during treatment as needed.</p> <p>Prior to discharge, the RN must confirm the patient is stable for discharge and review the treatment record for:</p> <p>Slow/fast/irregular heart rate Low or high blood pressures Whether patient is achieving dry weight and identifying reason for patient not achieving dry weight Heart rate &lt;50 or &gt;120 addressed by the registered nurse with documentation present.</p> <p>Blood pressures &lt; 100 systolic or greater than 180 systolic</p>	

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			<p>addressed by the registered nurse with or documentation present. Reported fall, and if heparin was held and MD notified. Correct dialysate prescription was delivered.</p> <p>Effective 11/1/23, Facility Administrator or Charge Nurse will conduct 10 treatment sheets 3 days per week, alternating shifts, with focus on ensuring patient pre/post and intradialytic blood pressures are being assessed/ managed and physician order followed utilizing Plan of Correction Monitoring Tool for 2 weeks and then will complete weekly treatment audits on 10% of completed treatments for an additional 2 weeks or until 90% 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.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator 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 QAI Committee monthly.</p>	

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V 0543  Bldg. 00	494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status;		<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 QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing 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 QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p>	

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	<p>Based on record review and interview the facility failed to ensure the physician was notified of patients who were below their estimated dry weight prior to treatment, the inability of the patient to achieve their dry weight to establish the appropriateness of the dialysis prescriptions, and failed to evidence physician notification when post-treatment weight was greater than / less than 1 kilogram of the ordered dry weight for 2 of 6 hemodialysis records reviewed. (Patient #22, #23)</p> <p>The findings include:</p> <p>1. An agency policy titled "Volume Management in ESRD [End Stage Renal Disease] Patients on Hemodialysis" published 9/7/2021 stated "If any of the following patient clinical conditions occur refer to the volume algorithm if applicable or consult with the physician for appropriate fluid interventions:... Pre-treatment weight is less than or equal to EDW ... EDW order should be updated post-treatment adjustments and patient fluid status ... the clinical care team must be diligent in determining the EDW and routinely assess and adjust this metric ... EDW order should be updated post-treatment to reflect treatment adjustments and patient fluid status ... The assessment of EDW remains a clinical judgment of a clinical judgment of a clinician and clinical care team ... Obtain blood pressure and pulse at least every 30 minutes or more often as needed .... "</p> <p>2. An agency policy titled "Patient Assessment and Monitoring" published 5/1/2023 stated, "If the PCT/LPN notes any changes or abnormal findings in the patient's condition or vascular access are observed or reported by the patient, or if the patient was hospitalized, the patient care</p>	V 0543	<p><b>V 543</b></p> <p>On 10/30/2023, the Facility Administration held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:</p> <p style="padding-left: 40px;">Nursing Supervision and Delegation Patient Assessment and Monitoring Volume Management on ESRD Patients on Hemodialysis</p> <p>Emphasis was placed on: Direct patient care staff may collect data such as weight, BP, pulse, respirations, temperature, general observations, access, and complaints reported by the patient. If the PCT/LPN note any changes or abnormal findings in the patient's condition or vascular access are observed or reported by the patient, or the patient was hospitalized, the registered nurse must assess the patient. <u>The RN will notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instruction.</u> Fluid balance is an integral component of the HD treatment to prevent patient hyper- or hypovolemia both of which have been demonstrated to influence mortality and cardiovascular complications in ESRD patients</p>	11/10/2023

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	<p>technician MUST report the changes to a registered nurse Any abnormal finding confirmed by the RN [registered nurse] will be reported to the attending physician ... Maintain the patient post-treatment weight and ensure the post weight is consistent with the goal set of the machine ... Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes per state regulations ... The Registered Nurse will assess/reassess post-treatment as indicated ...."</p> <p>3. An agency policy titled "Nursing Supervision and Delegation," published 5/1/2023, stated, " ... the following task may not be delegated: assessment of each patient preferably within one hour (or according to state requirements) of treatment initiation in the clinic setting...."</p> <p>4. The clinical record for Patient # 22, with start of care 8/9/2022, included a review of the dialysis treatment sheets from 9/28/2023 through 10/7/2023 and evidenced the following:</p> <p>The flowsheet dated 9/28/2023 documented Patient #22's Estimated dry weight (EDW) was 68 kilograms (kg) and his post-treatment weight was 69.8 kg.</p> <p>The flowsheet dated 9/30/2023, documented Patient #22's EDW was 68 kg and his post-treatment weight was 69.7 kg.</p> <p>The flowsheet dated 10/3/2023 documented Patient #22's EDW was 68 kg, his pretreatment weight was 74.4 kg, and his post-treatment weight was 70.8 kg.</p> <p>The record failed to evidence the physician was notified of Patient's post treatment weight and</p>		<p>on HD. <u>Registered nurse should complete a fluid assessment on all ESRD patients receiving HD treatments.</u> Assessment should evaluate patients for hypo- and hypervolemia.</p> <p>At a minimum, fluid assessment will include review of the following clinical indicators:</p> <p>EDW Pre/Post Weight Post Weight comparison to EDW Pre/Post Blood Pressure Lowest Intradialytic Blood Pressure Signs/symptoms of fluid overload Physical examination including lung assessment, cardiovascular (i.e., heart sounds) and peripheral vascular assessment (edema)</p> <p>If any of the following patient clinical conditions occur refer to the volume algorithm if applicable or consult with provider for appropriate fluid interventions:</p> <p>Pre-treatment signs or symptoms of hypervolemia Pre-treatment sitting systolic BP is greater than 160 mmHg and prior treatment post dialysis sitting systolic BP is greater than 140 mmHg. Pre-treatment signs or symptoms of hypovolemia <u>Unable to achieve EDW due to UF intolerance.</u> New to dialysis within 13 treatments</p>	
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	<p>that their goal was not achieved.</p> <p>5. The clinical record for Patient #23, start of care 9/21/2023, included a review of the dialysis treatment sheets from 9/28/2023 through 10/7/2023 and evidenced the following:</p> <p>The flowsheet dated 9/30/2023 documented Patient #23's EDW was 105 kg and his post-treatment weight was 116 kg.</p> <p>The flowsheet dated 10/3/2023 documented Patient #23's EDW was 105 kg and his post-treatment weight was 115.8 kg.</p> <p>The record failed to evidence the physician was notified of Patient's post treatment weight and that their goal was not achieved.</p> <p>6. During an interview on 10/11/2023 at 3:14 PM, the Facility Administrator indicated weights are checked weekly to see if they need to be adjusted.</p>		<p>Post-hospitalization <u>Pre-treatment weight is less than or equal to EDW.</u> Prior treatment was shortened by more than 15 minutes. Prior missed treatment Treatment adjustments based on fluid assessment, symptoms, and blood pressure are critical to improve a patient's volume status. EDW order should be updated post treatment to reflect treatment adjustments and patient fluid status. The RN is accountable for delivering care within the framework of the nursing process. The RN uses clinical findings to formulate nursing diagnoses and prioritize problems according to patient need. The registered nurse must evaluate each patient preferably within an hour or according to state requirements to: Confirm identity. Review the patient's condition. Review accuracy and completeness of treatment and patient data Review patient treatment prescription and equipment parameters to verify correct settings, and if dialysis prescription is being followed. Confirm that the correct vascular access is being used, and that the access is visible. Observe patient's response to treatment. Verify machine safety checks</p>	

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			<p>have been completed.</p> <p>Talk to the patient to elicit information such as changes in condition, response to treatment, new injuries, information/education needs or complaints, satisfaction with care.</p> <p>The RN will notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instruction.</p> <p>The Registered Nurse will assess/reassess any findings addressed pre or during treatment as needed.</p> <p>Prior to discharge, the RN must confirm the patient is stable for discharge and review the treatment record for:</p> <p>Slow/fast/irregular heart rate Low or high blood pressures <u>Whether patient is achieving dry weight and identifying reason for patient not achieving dry weight</u> Heart rate &lt;50 or &gt;120 addressed by the registered nurse with documentation present.</p> <p>Blood pressures &lt; 100 systolic or greater than 180 systolic addressed by the registered nurse with or documentation present.</p> <p>Reported fall, and if heparin was held and MD notified.</p> <p>Correct dialysate prescription was delivered.</p> <p>Effective 11/1/23, Facility Administrator or Charge Nurse will conduct 10 treatment sheets 3</p>	

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			<p>days per week, alternating shifts, with focus on ensuring the physician is aware of patients below their dry weight prior to treatment, inability of the patient to achieve their dry weight, as well as, ensuring the physician is notified when the post treatment weight is greater than/less than 1 kilogram of the ordered dry weight utilizing Plan of Correction Monitoring Tool for 2 weeks and then will complete weekly treatment audits on 10% of completed treatments for an additional 2 weeks or until 90% 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.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator 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 QAI 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</p>	

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V 0544 Bldg. 00	<p>494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.</p> <p>Based on record review and interview, the facility failed to ensure patient dialysis prescription orders were verified and adhered to in order to achieve and sustain the prescribed dose of</p>	V 0544	<p>resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing 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 QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p>	11/10/2023

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152520	X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	X3) DATE SURVEY COMPLETED  10/11/2023
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NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE NEPHROLOGY MISHAWAKA	STREET ADDRESS, CITY, STATE, ZIP COD 710 PARK PL MISHAWAKA, IN 46545
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	<p>dialysis to meet the adequacy of dialysis in 5 out of 6 hemodialysis records reviewed (Patient #22, #23, #24, #26, and #28)</p> <p>The findings include:</p> <p>1. An agency policy titled "Patient Assessment and Monitoring, " published 5/1/2023, stated " ... Check the machine settings and measurements, check the prescribed blood flow is being achieved or reason is documented in the medical record if unable to meet the prescribed flow rate. Check dialysate flow rate setting is correct the prescribed flow is being delivered...."</p> <p>2. A review of the clinical record for Patient #22, start of care 8/9/2022, included a review of the dialysis treatment sheets from 9/28/2023 through 10/7/2023 and evidenced the following:</p> <p>The flowsheet dated 9/28/2023 documented Patient #22's prescribed blood flow rate (BFR) was 500 ml/min (milliliter/minute) and dialysate flow rate (DFR) was autoflow 1.5 (1.5 times the BFR). Patient #23's DFR during treatment was 500 ml/min. The documentation failed to evidence why Patient #23 failed to receive their prescribed dialysate flow rate.</p> <p>3. A review of the clinical record for Patient #23, start of care 9/21/2023, included a review of the dialysis treatment sheets from 9/28/2023 through 10/7/2023 and evidenced the following:</p> <p>The flowsheet dated 9/28/2023 documented Patient #23's prescribed BFR was 400 ml/min. During treatment, Patient's BFR was reduced to 250 ml/min, The review failed to evidence why Patient #24 failed to receive the prescribed blood flow rate.</p>		<p>staff on policy:</p> <p>Patient Assessment and Monitoring Emphasis was placed on:</p> <p>Document machine parameters and safety checks every 30 minutes or more often as needed but not to exceed 45 minutes or per state regulations.</p> <p>Check machine settings and measurements:</p> <p>Check prescribed blood flow rate is being achieved or reason is documented in medical record if unable to meet prescribed blood flow rate.</p> <p>Check dialysate flow rate setting is correct, and the prescribed flow is being delivered.</p> <p>Registered Nurse will document in medical record if physician order not followed as prescribed to include but not limited to treatment time as ordered and notify physician.</p> <p>Effective 11/1/23, Facility Administrator or Charge Nurse will conduct 10 treatment sheets 3 days per week, alternating shifts, with focus on ensuring patient dialysis prescription orders are verified and adhered to, to achieve and sustain the prescribed dose of dialysis to meet the adequacy of dialysis utilizing Plan of Correction Monitoring Tool for 2 weeks and then will complete weekly treatment audits on 10% of completed treatments for an</p>	

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	<p>The flowsheet dated 10/3/2023 documented Patient #23's prescribed BFR was 400 ml/min. During treatment, Patient's BFR was reduced to 350 ml/min, The review failed to evidence why Patient #24 failed to receive the prescribed blood flow rate.</p> <p>4. A clinical record review on 10/11/2023 for Patient #24, start of care 12/21/2021, included a review of the dialysis treatment sheets from 9/28/2023 through 10/7/2023 and evidenced the following:</p> <p>The flowsheet dated 10/2/2023 documented Patient #24's prescribed BFR was 300 ml/min. During treatment, the patient's BFR was reduced to 250 ml/min, The review failed to evidence why Patient #24 failed to receive the prescribed blood flow rate.</p> <p>During an interview on 10/11/2023 at 2:12 PM, the Facility Administrator indicated that if the BFR and/or DFR are not as prescribed, staff should have documented the reason for the change in the prescription.</p> <p>5. The clinical record for Patient 26 included a review of the treatment sheet dated 9/28/2023. Patient's prescribed Blood Flow Rate (BFR) was 400 and the Dialysate Flow Rate (DFR) was autoflow 2.0 (800). Dialysis treatment was initiated at 6:11 AM. At 8:32 AM, the BFR was decreased due to high arterial pressure (AP). Post-dialysis evaluation indicated the average BFR/DFR provided was 360 / 720, below the prescribed rate respectively.</p> <p>The dialysis treatment sheet dated 10/05/2023 was reviewed and evidenced Patient's prescribed BFR was 400 and the DFR was autoflow 2.0. Dialysis</p>		<p>additional 2 weeks or until 90% 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.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator 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 QAI 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 QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible</p>	

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	<p>treatment was initiated at 6:13 AM; the BFR was decreased at 7:31 AM due to high AP. Post-dialysis evaluation indicated the average BFR/DFR was 330 / 650, and below the prescribed rate.</p> <p>During an interview on 10/11/2023 at 3:29 PM, the Clinical Manager indicated the BFR and DFR should not have been adjusted.</p> <p>6. A review of the treatment records for Patient #28, evidenced dialysis treatment sheets dated 10/02/2023 and 10/06/2023. Patient's prescribed DFR was 500. Patient's DFR for both treatments was administered at a rate of 800.</p> <p>During an interview on 10/11/2023 at 3:43 PM, the Clinical Manager indicated the treatment was not administered per the prescribed rate.</p>		<p>for providing 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 QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p>		