

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152526	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	(X3) DATE SURVEY COMPLETED 05/19/2025
NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE KOKOMO		STREET ADDRESS, CITY, STATE, ZIP COD 2350 S DIXON RD STE 450 KOKOMO, IN 46902		
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E 0000  Bldg. 00	<p>An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62.</p> <p>Survey Dates: May 12, 13, 14, 15, 16, 19, 2025</p> <p>Active Census: 107</p> <p>At this Emergency Preparedness survey, Fresenius Medical Care Kokomo was not found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62.</p>	E 0000		
E 0028  Bldg. 00	<p>494.62(b)(9) Dialysis Emergency Equipment</p> <p>Based on observation, policy review, and interview, the dialysis facility failed to implement its EP policies and procedures by failing to ensure all emergency drugs were on-site at all times, which had the potential to affect all 108 active patients.</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. The facility policy #46865 "Emergency Medications, Equipment and Supplies," dated 2/03/25, indicated the facility must maintain at least two doses of Calcium Chloride on-site "to manage emergency situations."</li> <li>2. An observation of the facility's emergency medications available on-site on 5/12/25 beginning at 9:17 AM failed to evidence the emergency drug Calcium Chloride.</li> </ol>	E 0028	<p>E028 DIALYSIS EQUIPMENT CFR(s): 494.62(b)(9) Immediately on 6/5/25, Administrative Assistant Susan placed an order for Calcium Chloride for the Emergency Cart. On 6/9/25, the FA held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the following Policy.</p> <ul style="list-style-type: none"> <li>• Emergency Medications, Equipment and Supplies Emphasis will be placed on:</li> <li>• The medications and supplies outlined in this policy must be maintained at the facility for emergency use.</li> <li>• Emergency Medications The</li> </ul>	06/19/2025

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

TITLE

(X6) DATE

Levi Alecu

Director of Operations

06/06/2025

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>3. During an interview on 5/12/25 beginning at 9:30 AM, Charge Nurse 1 reported the agency did not have Calcium Chloride on the premises.</p> <p>4. During an interview on 5/19/25 beginning at 4:16 PM, Administrator was unsure of the reason Calcium Chloride was not kept on-site.</p>		<p>Pharmacy and Therapeutics Committee and the Medical Advisory Board identified a reasonable selection of medications to manage emergency situations such as allergic reactions, hypoglycemia, and cardiac arrest pending arrival of EMS when the physician is present or under the direct order of the physician. These medications and recommended quantities must be maintained at the dialysis facility. Any requests by the Governing Body to modify the minimum required medications must be approved by the FKC Corporate Medical Office.</p> <ul style="list-style-type: none"> <li>o Cardiac Arrest (Physician must be present to administer)</li> <li>¿ Calcium Chloride 10% 10mL prefilled syringe or vial (must keep 2 vials on hand)</li> </ul> <p>Effective 6/9/25 FA will conduct 3 days per week audits, for 2 weeks utilizing the facility specific audit tool, with focus on ensuring 2 vials of Calcium Chloride are kept in the Emergency cart and then 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</p>	

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E 0031  Bldg. 00	403.748(c)(2), 416.54(c)(2), 418.113(c)( Emergency Officials Contact Information  Based on EP plan review, policy review, and	E 0031	<p>monthly.</p> <p>The FA 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 DO 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.</p> <p>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>Completion DATE: 6/19/2025</p>	06/19/2025

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	<p>interview, the dialysis facility failed to maintain and update its communication plan to include federal and state emergency preparedness staff and other sources of assistance, which had the potential to affect 108 active patients and all staff.</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. The facility policy #25907 "Guidelines for Emergency Preparedness," dated 7/03/23, indicated the facility "must develop a communication plan" which was to include "facility emergency information contact lists ...."</li> <li>2. The review of the facility's EP communication plan failed to evidence contact information for federal and state EP staff as well as other sources of assistance.</li> <li>3. During an interview on 5/19/25 beginning at 4:16 PM, Administrator was unsure of the reason a list of EP official contacts and other sources of assistance was not included in the EP communication plan.</li> </ol>		<p><b>CONTACT INFORMATION</b> CFR(s): 494.62(c)(2) Immediately on 6/9/25, the FA placed the list of Emergency Preparedness official contacts and other sources of assistance in the Emergency Preparedness Binder. On 6/9/25, the FA held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the following Policy.</p> <ul style="list-style-type: none"> <li>• Guidelines for Emergency Preparedness</li> </ul> <p>Emphasis will be placed on:</p> <ul style="list-style-type: none"> <li>• The facility must develop a communication plan for all patients (in-center and home). This plan includes the following:</li> <ul style="list-style-type: none"> <li>◦ Create and maintain staff, patient and facility emergency information contact lists:</li> <ul style="list-style-type: none"> <li>◦ Quarterly, the Director of Operations/Area Manager or designee will review and update:</li> <li>• The FKC Facility Emergency Information Directory</li> <li>◦ Quarterly, the CM will review and update:</li> <li>• The Emergency and Disaster Staff Contact Information Sheet</li> <li>• The Emergency and Disaster Patient Contact Information Sheet</li> <li>◦ A current copy of the emergency lists must:</li> <li>• Be kept locked in the emergency supply boxes, or cart.</li> </ul> </ul> <p>Effective 6/9/25 FA will conduct 3 days per week audits, for 2 weeks utilizing the facility specific audit</p> </ul>	

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			<p>tool, with focus on ensuring the EP official contacts and other sources of assistance is current and kept in the EP binder and then 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.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The FA 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 DO 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.</p> <p>The Plan of correction is reviewed in QAPI monthly.</p> <p>The Governing Body is responsible</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 EP review, policy review, and interview, the dialysis facility failed to revise and enact changes to the EP plan based on after-action reviews (AAR) of its EP testing, which had the potential to affect 108 active patients and staff.</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. The facility policy "Guidelines for Emergency Preparedness," dated 7/03/23, indicated if a facility activated its emergency plan for a disaster, an after-action review was to be completed, and the plan was to be revised as needed.</li> <li>2. The facility's EP documentation evidenced the home therapy division conducted a fire tabletop drill on 3/13/24. An AAR of the drill evidenced opportunities for improvement included "pull fire alarm to notify other tenants of [the building]," which would include the ICHD treatment floor, and "take emergency cart with evacuation." The facility's improvement plan included repeating the drill within six months. The EP documentation failed to evidence a repeat fire drill which included the home therapy division had been completed.</li> </ol>	E 0039	<p>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>Completion DATE: 6/19/2025</p> <p>E039 EP TESTING REQUIREMENTS CFR(s): 494.62(d)(2)</p> <p>On 6/9/25, the FA held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility DPC staff on the following Policies:</p> <ul style="list-style-type: none"> <li>• Guidelines for Emergency Preparedness</li> <li>• In addition to the community drills, facilities must select an event of high likelihood and conduct a table-top drill. It is recommended a different drill be completed annually.</li> <li>• Quarterly, all FKC patients must receive fire drill and emergency evacuation training.</li> <li>o Training must be documented in QAI and on the fire drill attendance form.</li> <li>o All drills: Fire, emergency evacuation, tabletop and</li> </ul>	06/19/2025

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	<p>During an interview on 5/19/25 beginning at 3:20 PM, Home Therapy Manager 4 reported he was not aware if a follow-up fire drill had been conducted.</p> <p>During an interview on 5/19/25 beginning at 4:16 PM, Administrator was not aware if a follow-up fire drill including the home therapy division had been conducted.</p> <p>3. The agency's EP documentation evidenced the facility activated its EP plan for a "blizzard" on 1/06/25. The AAR of the EPP activation identified "improvement plans or action steps needed to help [the facility] be more prepared in case of a disaster" was "Patient communication." The EP documentation failed to evidence further details regarding revisions to the EPP or action steps to be taken to improve the EPP based on the AAR.</p> <p>During an interview on 5/19/25 beginning at 4:16 PM, Administrator after the activation of the facility's EP plan on 1/06/25, the facility found many patients did not come for their scheduled ICHD treatment despite the facility remaining open, and the facility needed to improve its communication with patients by reach out via phone if there was advanced warning of severe weather. The EP documentation failed to evidence the recommended changes were revised in the EP plan and enacted.</p>		<p>community-based drill must be reviewed and documented in QAI.</p> <ul style="list-style-type: none"> <li>• When an emergency situation temporarily prevents the facility from continuing operations, the Clinical Manager, Program Manager, Facility Administrator or designee should: <ul style="list-style-type: none"> <li>o Develop an emergency treatment schedule, ensuring that all patients who have had shortened or missed treatments during the emergency are rescheduled.</li> <li>o Assign staff to notify patients that treatments are being rescheduled and provide new treatment times and/or days.</li> <li>o Notify all clinical staff of the emergency and any possible needs for additional staff.</li> </ul> </li> <li>• If facility is involved in an actual disaster, it can take the place of community-based drill or tabletop drill. The facility must have pictures and news articles to document the event. The DO must complete an after-action review and make any revision to the emergency plan as needed.</li> </ul> <p>On 7/25/25, the DO addressed the AAR and made all necessary changes to the facility emergency plan.</p> <p>Effective 6/9/25 FA will conduct weekly audits for 2 with a focus on ensuring table top drills will be completed annually and if in the AAR there is any revision needed to the EP plan those changes will</p>	

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			<p>be made, a focus will also be on ensuring that in the event that an actual disaster occurs the DO will conduct an AAR and make any necessary changes identified, 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 at the QAPI Committee meeting monthly.</p> <p>The FA 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 DO 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>	

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FORM APPROVED  
OMB NO. 0938-039

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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: May 12, 13, 14, 15, 16, 19, 2025</p> <p>Census by Service Type:</p> <p>In-Center Hemodialysis: 76</p> <p>Home Hemodialysis: 7</p> <p>Home Peritoneal Dialysis: 25</p> <p>Isolation: Waiver</p> <p>Abbreviations:</p> <p>RN - Registered Nurse</p> <p>LPN - Licensed Practical Nurse</p> <p>PCT - Patient Care Technician</p> <p>MD - Medical Director</p> <p>RD - Registered Dietician</p> <p>MSW - Masters Social Worker</p> <p>ICHD - In-Center Hemodialysis</p>	V 0000	<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>Completion DATE: 6/19/2025</p>	

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V 0111  Bldg. 00	<p>HHD - Home Hemodialysis PD - Peritoneal Dialysis CVC - Central Venous Catheter IV - Intravenous EP - Emergency Preparedness IDT - Interdisciplinary Team</p> <p>494.30 <b>IC-SANITARY ENVIRONMENT</b></p> <p>Based on observation, policy review, and interview, the dialysis facility failed to maintain a sanitary environment within the ICHD treatment area for 2 of 2 days of ICHD treatment area observations, which had the potential to affect 76 active ICHD patients.</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. The policy "Cleaning and Disinfecting the Dialysis Station," dated 9/05/23, indicated bleach solution would be stored in "covered opaque containers to prevent disintegration of the chemical (sodium hypochlorite) when exposed to sunlight and air."</li> <li>2. The policy "General Cleanliness and Infection Control Guidelines," dated 11/04/24, indicated "supplies ... should not be kept or stored behind the machine at the patient station."</li> <li>3. During an ICHD flash tour on 5/12/25 beginning at 8:38 AM - 9:35 AM, three containers with 1:100 concentration bleach solution were observed without a lid completely covering the solution on one occasion. One face shield was observed sitting on the chaise wall immediately behind Station 2 while a patient was dialyzing at the station.</li> </ol>	V 0111	<p>V111 IC-SANITARY ENVIRONMENT CFR(s): 494.30</p> <p>On 6/9/25, the FA held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility DPC staff on the following Policies:</p> <ul style="list-style-type: none"> <li>• Cleaning and Disinfecting the Dialysis Station</li> <li>• General Cleanliness and Infection Control</li> </ul> <p>Emphasis will be placed on:</p> <ul style="list-style-type: none"> <li>o Bleach solution will be stored in labeled, covered opaque containers to prevent disintegration of the chemical (sodium hypochlorite) when exposed to sunlight and air.</li> <li>o Supplies or patient's belongings should not be kept or stored behind the machine at the patient station.</li> </ul> <p>Effective 6/9/25, the FA will conduct 3 days per week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring Bleach solution is stored with a lid completely covering the top, a focus will also be on ensuring</p>	06/19/2025

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	<p>4. During an ICHD observation on 5/12/25 from 10:45 AM - 12:28 PM, two containers of 1:100 concentration bleach solution were observed without a lid completely covering the solution on four occasions.</p> <p>5. During an ICHD observation on 5/13/25 from 9:23 AM - 10:57 AM, two containers of 1:100 concentration bleach solution and one container of 1:10 concentration bleach solution were observed without a lid completely covering the solution on two occasions. At 9:43 AM, PCT 2 dipped gauze wipes into a container of 1:100 concentration bleach solution. After wetting the gauze, the technician failed to return the lid to where it completely covered the solution.</p> <p>At 9:23 AM, four face shields and staff binders used to prepare tape for fistula cannulation were observed stored on a counter behind Stations 19 and 20. Patient #25 was dialyzing in Station 19, directly in front of the stored supplies.</p> <p>At 10:50 AM, the face shields and staff binders remained on the counter behind Stations 19 and 20. Patient #30 was sitting in Station 20 preparing to begin dialysis treatment.</p> <p>6. During an interview on 5/12/25 beginning at 2:19 PM, PCT 4 reported bleach solution should be stored in containers with the lids on, as light would "dilute" the bleach concentration.</p> <p>7. During an interview on 5/12/25 beginning at 3:12 PM, PCT 6 reported bleach solution should be stored in containers with the lid on.</p> <p>8. During an interview on 5/12/25 beginning at 3:21 PM, PCT 5 reported bleach solution should be stored in containers with the lid on.</p>		<p>there are no supplies or patient belongings stored behind the machine at the patient station. The audits will then go to weekly for an additional 2 weeks or until 100% compliance is achieved. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The FA 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 DO 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</p>	

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152526	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING	(X3) DATE SURVEY COMPLETED 05/19/2025
NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE KOKOMO		STREET ADDRESS, CITY, STATE, ZIP COD 2350 S DIXON RD STE 450 KOKOMO, IN 46902		
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V 0113  Bldg. 00	<p>9. During an interview on 5/13/25 beginning at 9:47 AM, PCT 3 reported bleach solution should be stored in containers with the lid on.</p> <p>10. During an interview on 5/13/25 beginning at 3:19 PM, Charge Nurse 1 reported bleach solution should be stored in a container with the lid on. The nurse also reported face shields and staff binders should not be stored behind treatment stations.</p> <p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE</p> <p>Based on observation, policy review, and interview, the dialysis facility failed to ensure staff and patients followed facility infection control policies and procedures for 6 of 10 staff observed performing procedures on the ICHD treatment floor (PCT 1, PCT 2, PCT 4, PCT 7, RN 2, RN 3).</p> <p>Findings include:</p> <p>1. The facility policy "Hand Hygiene", dated 11/06/23, indicated hand hygiene should be performed "before and after direct contact with patients ... before performing any invasive procedure such as vascular access cannulation or administration of parenteral [administered through a non-oral route] medications. Immediately after removing gloves ... After contact with inanimate objects near the patient ... After contact with other objects within the patient station or treatment space." The policy also indicated patients should perform hand hygiene after each dialysis treatment "to help ensure the prevention of cross contamination to [patients'] family members or other patients. Gloves were to be</p>	V 0113	<p>minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>Completion DATE: 6/19/2025</p> <p>V113 IC WEAR GLOVES/HAND HYGIENE CFR(s): 494.3(A)(1)</p> <p>On 6/9/25, the FA held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility DPC staff on the following Policies:</p> <ul style="list-style-type: none"> <li>• Hand hygiene</li> <li>• Access Assessment and Cannulation</li> <li>• Termination of Treatment using a Central Venous Catheter</li> </ul> <p>Emphasis will be placed on:</p> <p>Hand hygiene</p> <ul style="list-style-type: none"> <li>• 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: <ul style="list-style-type: none"> <li>o Hands are visibly dirty or contaminated with proteinaceous material, blood, or other body fluids</li> <li>o Before and after direct contact</li> </ul> </li> </ul>	06/19/2025

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	<p>provided to patients "when performing procedures which risk exposure to blood or body fluids, such as ... holding [fistula or graft] access sites post treatment ...."</p> <p>2. The facility policy "Access Assessment and Cannulation," dated 5/05/25, indicated when cannulating a fistula, staff should evaluate the access area, remove gloves, perform hand hygiene, don new gloves, then apply antiseptic to each cannulation site.</p> <p>3. The facility policy "Termination of Treatment Using a Central Venous Catheter ...," dated 2/07/22, indicated after a patient's treatment was complete, staff were to return blood from the dialysis machine and tubing, obtain the patient's sitting and standing blood pressure, remove their gloves, perform hand hygiene, don new gloves, and disconnect the patient's dialysis lines from the CVC.</p> <p>4. During an ICHD treatment floor observation on 5/12/25 beginning at 10:50 AM, PCT 1 was in Station 1 preparing Patient #5 for their dialysis treatment. The technician left the station, picked up a thermometer sitting above a hand washing sink, re-entered the station, and obtained Patient's temperature. PCT 1 then left the station, returned the thermometer, re-entered Station 1, donned new gloves, and continued preparing Patient #5 for dialysis. The technician failed to perform hand hygiene prior to donning gloves.</p> <p>During an interview on 5/13/25 beginning at 3:16 PM, PCT 1 reported hand hygiene should be performed prior to donning gloves.</p> <p>5. During an ICHD treatment floor observation on 5/12/25 beginning at 11:19 AM, PCT 4 was in</p>		<p>with patients</p> <ul style="list-style-type: none"> <li>o Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medication</li> <li>o Immediately after removing gloves</li> <li>o After contact with body fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly soiled</li> <li>o After contact with inanimate objects near the patient</li> <li>o When moving from a contaminated body site to a clean body site of the same patient</li> <li>• Patients should perform hand hygiene if able, prior to and after each dialysis treatment.</li> <li>• As needed, direct patient care staff will demonstrate how to operate the sinks, demonstrate hand washing to patients who are able to perform hand washing, and explain risk of contamination with regard to their vascular access and hands to all patients.</li> <li>• Gloves must be provided to patients when performing procedures which risk exposure to blood or body fluids, such as when self-cannulating or holding access sites post treatment to achieve hemostasis.</li> <li>• To help ensure the prevention of cross contamination to their family members or other patients, hand hygiene must be performed.</li> </ul>	

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	<p>Station 12 cannulating Patient #16's fistula. The technician evaluated the access then applied antiseptic over the cannulation sites, failing to change gloves and perform hand hygiene prior to applying the antiseptic.</p> <p>During an interview on 5/12/25 beginning at 2:19 PM, PCT 4 reported when cannulating a fistula, gloves should be changed and hand hygiene performed between evaluating the fistula and applying antiseptic.</p> <p>6. During an ICHD treatment floor observation on 5/12/25 beginning at 12:20 PM, RN 2 was at the medication preparation counter preparing an IV medication for Patient #18. The nurse took the medication syringe to Station 9, donned gloves, then injected the medication into a port on the dialysis tubing. The nurse failed to perform hand hygiene prior to donning gloves.</p> <p>During an interview on 5/12/25 beginning at 2:42 PM, RN 2 reported staff should perform hand hygiene prior to donning gloves.</p> <p>7. During an ICHD treatment floor observation on 5/12/25 beginning at 11:45 AM, PCT 4 removed Patient #17's fistula needles in Station 11 at the end of treatment. Patient donned a glove and held pressure to both cannulation sites. After the sites had stopped bleeding, Patient removed their glove. RN 3 walked with Patient from the station to the treatment doorway. PCT 4 and RN 3 failed to instruct Patient to perform hand hygiene after removing their glove.</p> <p>During an interview on 5/12/25 beginning at 2:19 PM, PCT 4 reported patients were to perform hand hygiene after holding pressure to their cannulation sites and removing their glove. The</p>		<p>Access Assessment and Cannulation</p> <ul style="list-style-type: none"> <li>• To clarify glove changes during the cannulation procedure:           <ul style="list-style-type: none"> <li>o After assessing the access, staff must perform hand hygiene and don new gloves.</li> <li>o With the new gloves, staff may perform the full cannulation procedure (both needles) including skin disinfection, lidocaine administration (if applicable) and cannulation.</li> <li>o If any of the steps in the procedure are interrupted, hand hygiene must be performed, and new gloves must be donned.</li> </ul> </li> </ul> <p>Termination of Treatment using a Central Venous Catheter</p> <ul style="list-style-type: none"> <li>• When dialysis treatment is complete, the machine will alarm, indicating that the prescribed time of treatment has been completed and fluid goal achieved. Verify and acknowledge treatment completion.</li> <li>• Ensure that a clean under pad is below the catheter limbs to protect the work area and the clothing.</li> <li>• Follow the steps listed in the policy to return blood from the arterial portion of the extracorporeal system back to the patient.</li> <li>• Follow the steps listed in policy to return blood from the venous portion of the extracorporeal system back to the patient.</li> <li>• Follow the steps below to disinfect the catheter and to</li> </ul>	

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	<p>technician was unsure if Patient was advised to perform hand hygiene after their treatment as RN 3 had walked Patient out of the treatment floor.</p> <p>During an interview on 5/12/25 beginning at 3:09 PM, RN 3 could not recall if Patient #17 was advised to perform hand hygiene after holding pressure to their cannulation sites and removing their glove.</p> <p>8. During an ICHD treatment floor observation on 5/13/25 beginning at 10:19 AM, PCT 7 removed Patient #22's fistula needles in Station 16 at the end of treatment. Patient donned a glove and held pressure to both fistula cannulation sites. After the site had stopped bleeding, Patient removed their glove, and PCT 7 walked Patient from the station to the treatment doorway. PCT 7 failed to instruct Patient to perform hand hygiene after removing their glove.</p> <p>During an interview on 5/13/25 beginning at 3:13 PM, PCT 7 reported the patient should perform hand hygiene after holding pressure to cannulation sites and removing their glove. The technician was unsure if Patient performed hand hygiene on 5/13/25 because Patient "leaves quickly" after treatment.</p> <p>9. During an ICHD treatment floor observation on 5/13/25 beginning at 10:39 AM, PCT 2 was in Station 14 discontinuing Patient #21's dialysis. Patient had a CVC. The technician reinfused the extracorporeal circuit, moved Patient's belongings, assisted Patient in standing to obtain a BP, then disconnected the blood lines and disinfected the CVC's open hubs. PCT 2 failed to change gloves and perform hand hygiene prior to disconnecting the blood lines and disinfecting the CVC open hubs.</p>		<p>disconnect the patient from the extracorporeal system:</p> <ul style="list-style-type: none"> <li>o Threads and end of the luer lock (hub) must be scrubbed with 70% sterile alcohol pad (or other appropriate antiseptic product such as chlorhexidine or povidone if required by the hospital) for 10-15 seconds any time caps are removed, or bloodlines are disconnected (i.e. End of treatment or treatment interruption) to reduce risk of contamination.</li> <li>• Obtain the patient's sitting blood pressure (with legs down) and standing blood pressure (if patient is able to stand) prior to disconnecting the patient.</li> <li>• Discard gloves and perform hand hygiene. Don clean gloves.</li> <li>• Verify that both arterial and venous bloodlines and arterial and venous catheter limbs are clamped.</li> <li>• Carefully remove Fresenius® HemaClip device from the bloodline and then from catheter limb and discard.</li> <li>• Disconnect the arterial bloodline line from the catheter limb.</li> <li>• Using a sterile alcohol pad, (or other appropriate antiseptic product such as chlorhexidine or povidone if required by the hospital) scrub the sides (threads) and end of the hub thoroughly with friction, making sure to remove any residue (e.g., blood) (see Figure (1). (This step should take</li> </ul>	

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	<p>During an interview on 5/13/25 beginning at 3:09 PM, PCT reported when discontinuing dialysis from a CVC, staff should change gloves and perform hand hygiene before disconnecting the blood lines from the CVC.</p> <p>10. During an interview on 5/13/25 beginning at 3:19 PM, Charge Nurse 1 reported staff should perform hand hygiene prior to donning gloves. Staff should remind patients to perform hand hygiene after the patient holds pressure to a fistula cannulation site. Charge Nurse 1 reported when discontinuing dialysis from a CVC, staff should change gloves and perform hand hygiene after disconnecting the blood lines and before cleaning the CVC hubs.</p>		<p>10-15 seconds)</p> <ul style="list-style-type: none"> <li>• Hold the limb while allowing the antiseptic to dry.</li> <li>• Immediately attach a prefilled saline syringe to the catheter limb.</li> <li>• Repeat steps 5 through 8 for the venous end of the catheter limb.</li> <li>• Follow the steps listed in policy to flush and prepare the catheter for patient discharge.</li> </ul> <p>Effective 6/9/25, the FA will conduct 3 days per week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring staff are wearing gloves when touching potentially contaminated surfaces and disinfecting their hands prior to applying gloves and after removing gloves. A focus will also be on ensuring patients are disinfecting their hands before and after treatments. A focus will also be on ensuring the above listed procedure will be followed for discontinuing treatment using a Central Venous Catheter. The audits will then go to weekly for an additional 2 weeks or until 100% compliance is achieved.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The FA 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 0126  Bldg. 00	494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF  Based on personnel file review and interview, the dialysis facility failed to ensure all staff susceptible to Hepatitis B were offered the vaccine series upon hire for 1 of 3 ICHD personnel files reviewed (Employee C).  Findings include:	V 0126	<p>The DO 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.</p> <p>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>Completion DATE: 6/19/2025</p>	06/19/2025

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	<p>1. The review of Employee C's personnel file evidenced a hire date of 7/22/24. The employee's duties included direct patient contact. The file indicated the employee completed an Anti-HBS blood test (evaluates for the presence of antibodies in the blood which indicate immunity or susceptibility to the hepatitis B virus) on 11/06/24. The employee's result was "&lt;10," indicating the employee was susceptible to Hepatitis B. The file failed to evidence the employee received or declined the Hepatitis B vaccine series upon hire.</p> <p>During an interview on 5/19/25 beginning at 4:06 PM, Administrator reported the facility did not have record of Employee C being offered the Hepatitis B vaccine upon hire.</p>		<p>Employee Requirements for Testing and Vaccination for Hepatitis B</p> <p>Emphasis will be placed on:</p> <ul style="list-style-type: none"> <li>• The Hepatitis B vaccine shall be offered to all employees upon hire or rehire.</li> <li>o Prior to vaccine administration, draw the hepatitis B antibody (anti-HBs) to determine susceptibility.</li> <li>• If susceptible, offer vaccine.</li> <li>o Refer to Special Consideration policies for ENGERIX-B or HEPLISAV-B for vaccine administration.</li> <li>o If the employee declines, a signed declination must be maintained in the employee file.</li> </ul> <p>Effective 6/9/25, the FA will conduct weekly audits, ensuring all staff are offered the Hepatitis B vaccine if susceptible for 2 weeks. The audits will then go to monthly for 2 months 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.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The FA is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to</p>	

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V 0142  Bldg. 00	494.30(b)(1) IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P  Based on personnel file review, policy review, and interview, the dialysis facility failed to implement infection control policies and procedures specific to ensuring all staff had been screened for tuberculosis prior to direct patient contact for 1 of 3 home dialysis personnel files reviewed	V 0142	<p>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.</p> <p>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>Completion DATE: 6/19/2025</p>	06/19/2025

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	<p>(Employee A) and 3 of 3 ICHD personnel files reviewed (Employees B, C, D).</p> <p>Findings include:</p> <p>1. A facility policy #47630 "Employee Tuberculosis [TB, a highly contagious respiratory infection] Testing," dated 5/05/25, indicated a two-step tuberculin skin test (TST, a screening test for TB, which is done by injecting an inactive form of TB under the skin on 2 separate occasions and assessing the area for a reaction) would be performed on hire. If the first-step TB test had a negative result (no evidence of reaction), the second-step TB test was to be completed within 1-3 weeks.</p> <p>2. The review of Employee A's personnel file evidenced a hire date of 2/06/23. The employee's duties included direct patient contact. The file indicated the employee received a first-step TST on 4/23/24. The file failed to evidence the employee had completed a second step TST.</p> <p>Employee A completed a "Tuberculosis Risk Assessment Employee Questionnaire" form on 3/12/25. The employee indicated he/she had experienced symptoms of TB including "Change in cough or coughing up blood ... Fever or night sweats for more than 1 week ... Recent 'cold' or upper respiratory infection lasting more than 7-10 days ...." The file failed to evidence further investigation was conducted based on the employee's answers.</p> <p>During an interview on 5/19/25 beginning at 10:16 AM, Home Therapy Manager 4 reported a two-step TST was performed on hire, unless the employee had performed a TST in the "past few years." If the employee had a previous TST, a</p>		<p>responsibilities of the facility staff on the Policies.</p> <ul style="list-style-type: none"> <li>• Employee Tuberculosis Testing Emphasis will be placed on:           <ul style="list-style-type: none"> <li>• The Healthcare Personnel TB Baseline Risk Assessment and TB Risk Assessment Review Questionnaire (TB-RAQ) are required to be completed on all new employees.</li> <li>• Employees should be educated on signs and symptoms of TB disease and immediately notify their manager if they become symptomatic. If symptomatic, complete the TB-RAQ and refer them to their PCP or other healthcare provider for further evaluation.</li> <li>• TB testing using the two-step tuberculin skin test (TST) method is required upon hire.               <ul style="list-style-type: none"> <li>o If a new employee has a documented baseline TST result within the previous 12 months, a single TST can be administered as this additional TST represents the second stage of the two-step testing.</li> </ul> </li> <li>• TST Results:               <ul style="list-style-type: none"> <li>o Read results within 48-72 hours. Employees may not read their own skin test result. This applies to both the first and second step of the two-step TB skin test. If unable to read TST results within 48-72 hours, another skin test should be administered.</li> <li>o If the first step TST result is negative then Administer second</li> </ul> </li> </ul> </li> </ul>	

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	<p>copy was to be obtained and placed in the employee's personnel file. The manager stated if an employee reported potential symptoms of TB on the questionnaire, the employee would be sent for a chest x-ray. Home Therapy Manager 4 was unsure if there had been any follow-up to Employee A's potential symptoms of TB on 3/12/25.</p> <p>During an interview on 5/19/25 beginning at 11:28 AM, Employee A reported he/she had one TST performed upon hire. The employee reported the facility did not perform any follow-up to the TB questionnaire completed on 3/12/25.</p> <p>3. The review of Employee B's personnel file evidenced a hire date of 4/29/24. The employee's duties included direct patient contact. The file failed to evidence the employee was screened for TB prior to date of survey entrance.</p> <p>4. The review of Employee C's personnel file evidenced a hire date of 7/22/24. The employee's duties included direct patient contact. The file indicated the employee received a first-step TST on 11/06/24. The file failed to evidence the employee had completed a second-step TST.</p> <p>5. The review of Employee D's personnel file evidenced a hire date of 11/11/24. The employee's duties included direct patient contact. The file indicated the employee received a first-step TST on 3/05/25. The file failed to evidence the employee had completed a second-step TST.</p> <p>6. During an interview on 5/19/25 beginning at 4:06 PM, Administrator reported all employees were to complete one TST upon hire. Administrator reported the facility did not have record of Employee B completing a TST prior to</p>		<p>TST within 1-3 weeks By 7/18/25 all staff members will have a 2 step TB test complete and in their employee file. By 6/13/25 all staff members will complete the TB risk assessment questionnaire, and any follows up needed from assessment will be completed. Effective 6/9/25, the FA will conduct weekly audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring all staff members have 2 step TB testing completed and that if a staff member has any symptoms as evidenced by the TB risk assessment questionnaire they will be referred to their PCP and the appropriate steps will be made to ensure further testing per policy. 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. The FA 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</p>	

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

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V 0407  Bldg. 00	<p>survey entrance. Employee C and Employee D's first-step TST was done late as the facility was "catching up" to performing TSTs on hire. Administrator reported he had not been performing a second step TST on hire.</p> <p>494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS</p> <p>Based on observation, record review, and interview, the dialysis facility failed to ensure all patients access sites were visible for 2 of 2 days of ICHD treatment observations and failed to ensure all staff documented access site checks according to facility policy for 4 of 6 ICHD records reviewed (Patients #1, 2, 3, 4).</p>	V 0407	<p>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.</p> <p>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>Completion DATE: 6/19/2025</p>	06/19/2025

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	<p>Findings include:</p> <p>1. The facility policy "Patient Assessment and Monitoring," dated 5/01/23, indicated safety checks were to be documented "every 30 [minutes] ... not to exceed 45 minutes." Staff were to ensure the patient's access site "remains uncovered throughout the treatment."</p> <p>2. During an ICHD flash tour on 5/12/25 beginning at 8:38 AM, the following was observed:</p> <p>a. At 8:38 AM, Patient #11 was receiving dialysis treatment in Station 21. Patient's access site was not visible.</p> <p>At 9:09 AM, Patient #11's access site was still not visible. PCT 3 was observed at a supply station near Station 21. The technician failed to instruct Patient to keep their access site visible.</p> <p>b. At 8:42 AM, Patient #1 was receiving dialysis treatment in Station 20. Patient's access site was not visible.</p> <p>c. At 8:46 AM, Patient #13 was receiving dialysis treatment in Station 17. PCT 5 was observed standing next to Station 17. The technician failed to instruct Patient to keep their access site visible.</p> <p>d. At 8:57 AM, PCT 1 and PCT 5 were observed at a supply station near Stations 17 and 20. Patient #13 and Patient #1's access sites were not visible. The technicians failed to instruct the patients to keep their access sites visible.</p> <p>e. At 9:35 AM, Patient #1 and Patient #13's access sites were not visible.</p>		<p>on the Policies.</p> <ul style="list-style-type: none"> <li>• Patient assessment and Monitoring</li> </ul> <p>Emphasis will be placed on:</p> <ul style="list-style-type: none"> <li>• Document machine parameters and safety checks every 30 or more often as needed but not to exceed 45 minutes or per state regulations.</li> <li>• Observe connections are secure and visible.</li> <li>o If an external catheter is in use, observe and document that the HemaClip device is in place.</li> <li>o Ensure access remains uncovered throughout the treatment</li> <li>o Observe and ensure: <ul style="list-style-type: none"> <li>¿ Tape is secure</li> <li>¿ Needles are intact</li> <li>¿ No bleeding or infiltration is noted</li> </ul> </li> <li>• Document any findings and interventions in the medical record.</li> </ul> <p>Effective 6/9/25, the FA will conduct 3 days per week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring all patient accesses are uncovered and visible the entire treatment, and any abnormal findings are documented and reported to the RN. 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</p>	

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	<p>3. During an ICHD observation on 5/12/25 from 2:15 PM - 3:30 PM, the following was observed:</p> <p>a. At 2:15 PM, Patient #14 was receiving dialysis treatment in Station 23. Patient's access was not visible. PCT 6 was observed at a supply station near Station 23. The technician failed to instruct Patient to keep their access site visible.</p> <p>b. At 2:57 PM, Patient #12 was observed receiving dialysis treatment in Station 20. Patient's access was not visible. PCT 5 was observed at a supply station near Station 20. The technician failed to instruct Patient to keep their access site visible.</p> <p>4. During an ICHD observation on 5/13/25 from 5:40 AM - 7:10 AM, the following was observed:</p> <p>a. At 6:22 AM, Patient #21 was receiving dialysis treatment in Station 14. Patient's access was not visible.</p> <p>At 6:29 AM, PCT 1 and PCT 2 were observed at a supply station near Station 14. Patient's access was not visible. The technicians failed to instruct Patient to keep their access visible.</p> <p>5. During an ICHD observation on 5/13/25 from 9:23 AM - 10:57 AM, the following was observed:</p> <p>a. At 9:30 AM, Patient #25 was receiving dialysis treatment in Station 19. Patient's access site was not visible.</p> <p>At 10:50 AM, Patient #25 was receiving dialysis treatment in Station 19. Patient's access site remained not visible.</p> <p>b. At 10:08 AM, Patient #28 was receiving dialysis</p>		<p>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 FA 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.</p> <p>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>treatment in Station 2. Patient's access site was not visible. PCT 3 took supplies into the station, placed them on the dialysis chair's side table, then left the station. The technician failed to instruct Patient to keep their access site visible.</p> <p>c. At 10:52 AM, Patient #29 was receiving dialysis treatment in Station 11. Patient's access site was not visible. PCT 1 walked by Station 11 but did not instruct Patient to keep their access site visible.</p> <p>6. During an interview on 5/12/25 beginning at 3:12 PM, PCT 6 reported patient access sites should remain uncovered. The technician stated staff should perform access site checks every 30 minutes.</p> <p>7. During an interview on 5/12/25 beginning at 3:21 PM, PCT 5 reported patient access sites should remain uncovered. The technician stated she was "always" watching patients to ensure their sites were visible and access checks should be documented every 30 minutes.</p> <p>8. During an interview on 5/13/25 beginning at 9:47 AM, PCT 3 reported staff were "constantly watching" patients during treatment, and should monitor for access site visibility whenever staff "walk by" or were "around" a patient.</p> <p>9. During an interview on 5/13/25 beginning at 3:16 PM, PCT 1 reported staff should perform access site checks every 30 minutes or when walking by patients to ensure access sites were visible.</p> <p>10. Patient #1's clinical record included treatment flowsheets between 4/30/25 - 5/12/25. The flowsheets evidenced on 5/09/25, Patient's</p>		Completion DATE: 6/19/2025	

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	<p>treatment began at 7:56 AM. The record failed to evidence access site checks were documented between 7:57 AM - 8:45 AM, which was 48 minutes between checks.</p> <p>During an interview on 5/16/25 beginning at 2:47 PM, PCT 3 reported access site checks should be performed and documented every 30 minutes. The technician was unsure of the reason no site checks were documented between 7:57 - 8:45 AM.</p> <p>11. Patient #2's clinical record included treatment flowsheets between 4/25/25 - 5/12/25. The flowsheets evidenced the following:</p> <p>a. On 4/25/25, Patient's treatment began at 11:30 AM. The record failed to evidence access site checks were documented between 11:33 AM - 12:31 PM, which was 58 minutes between checks.</p> <p>b. On 5/02/25, Patient's treatment began at 11:22 AM. The record failed to evidence access site checks were documented between 12:00 PM and 1:09 PM, which was 1 hour and 9 minutes between checks.</p> <p>During an interview on 5/15/25 beginning at 2:34 PM, PCT 5 reported access site checks should be performed and documented every 30 minutes. The technician stated she was likely on break on 4/25/25 and 5/02/25 when site checks were not documented.</p> <p>12. Patient #3's clinical record included a treatment flowsheet dated 5/02/25. The record failed to evidence access site checks were documented between 7:10 AM - 8:00 AM, which was 50 minutes between checks.</p> <p>During an interview on 5/16/25 beginning at 2:37</p>			

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V 0547  Bldg. 00	<p>PM, PCT 2 reported access site checks should be documented every 30 minutes and she was likely on break when site checks were not documented.</p> <p>13. Patient #5's clinical record included a treatment flowsheet dated 5/07/25. The record failed to evidence access site checks were documented between 11:00 - 11:48 AM, which was 48 minutes between checks.</p> <p>During an interview on 5/19/24 beginning at 9:41 AM, PCT 4 was unsure of the reason Patient's access site checks were not documented between 11:00 - 11:48 AM.</p> <p>494.90(a)(4) POC-MANAGE ANEMIA/H/H MEASURED Q MO Based on record review and interview, the dialysis facility failed to administer medications to treat anemia according to its anemia management protocols, which resulted in the patient failing to achieve his/her goal hemoglobin level, for 1 of 2 ICHD records reviewed of patients not meeting anemia goals (Patient #1).</p> <p>Findings include:</p> <p>1. The facility policy "CMAB Recommended Anemia Algorithm Venofer (InCenter) Version 4.0," dated 7/08/19, indicated for patients new to dialysis, an Erythropoietin Stimulating Agent (ESA, a class of medications including Mircera used to treat anemia) was not to be started until the patient received a total of 1 gram (g) of iron (Venofer) in consecutive treatment doses ("Iron Series"). For patients with a Transferrin Saturation (TSAT, a laboratory test used to assess and treat low iron and/or anemia) result less than 30% and Ferritin (a laboratory test used to assess and treat</p>	V 0547	<p>V547 POC-MANAGE ANEMIA/H/H MEASURED Q MO CFR(s): 494.90(a)(4) On 6/9/25, the FA, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policies.</p> <ul style="list-style-type: none"> <li>CMAB Recommended Anemia Algorithm Venofer (InCenter) Version 4.0</li> <li>CMAB Recommended Anemia Algorithm Mircera</li> </ul> <p>Emphasis will be placed on:</p> <ul style="list-style-type: none"> <li>If Hgb is less than 10.0 g/dL and either TSAT is less than 20% or ferritin is less than 100 ng/mL</li> <li>Do not start Erythropoietin Stimulating Agent (ESA) therapy until the patient has received a total of 1 gram of iron in consecutive treatment doses (Iron</li> </ul>	06/19/2025

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	<p>low iron levels and/or anemia) less than 800 nanogram (ng) per milliliter (mL), an Iron Series consisting of 100 milligram (mg) iron administered for 10 consecutive treatments was to be administered.</p> <p>2. The facility policy "Corporate MAB Recommended Anemia Algorithm Mircera [IV Push] Administration ...," last revised 9/07/17, indicated patients new to dialysis with a hemoglobin level (laboratory test used to assess for anemia) less than 10.0 were to be started on Mircera once the patient received an Iron Series.</p> <p>3. Patient #1's clinical record evidenced an admission date of 3/11/25. A plan of care (POC) dated 4/23/25 evidenced an "Area of Focus" of "Anemia Management," with a goal of a hemoglobin (Hgb) level of "10 - 11." The POC indicated Patient had not met his/her goal.</p> <p>On 3/11/25, Patient's Hgb was 11.4, TSAT was 14%, and Ferritin was 12 ng/mL. On 3/14/25, Corporate Employee 1 documented due to Patient's 3/11/25 lab results, Patient was to begin receiving an Iron Series consisting of 100 mg Venofer three times a week for 10 doses. Patient did not need to begin Mircera due to his/her Hgb level. The record evidenced Patient received only one dose of Venofer between 3/15/25 - 4/05/25.</p> <p>On 4/07/25, Patient's Hgb was 9.0.</p> <p>On 4/14/25, Patient's Hgb was 9.7, TSAT was 15%, and Ferritin was 22 ng/mL. On 4/16/25, Corporate Employee 1 documented due to Patient's lab results, Patient was to begin receiving an Iron Series consisting of 100 mg Venofer three times a week for 10 doses. Patient was not to begin Mircera until he/she had received the complete</p>		<p>Series)</p> <ul style="list-style-type: none"> <li>• TSAT is less than 30% and ferritin is less than 800 mg/mL or TSAT is less than 30% and ferritin is 800 -1200 ng/mL</li> <li>o Follow Venofer, <math>\downarrow</math> Dosing Chart.</li> <li><math>\downarrow</math> Iron Series: 100 mg X 10 consecutive treatments for a total of 1 gram. (maximum 3 doses per week). Followed by Maintenance Dosing: 50 mg once per week*</li> <li>• Upon completion of the 1 gram iron sequence, recheck Spectra Hgb at next scheduled facility lab draw. If Hgb is less than 10.0 g/dL, start Mircera, <math>\downarrow</math> according to Starting Dose Chart.</li> </ul> <p>Effective 6/9/25, the FA will conduct 3 days per week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring the Venofer and Mircera algorithms are followed and patients received all ordered medications. 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 FA is responsible to review, analyze and trend all data and</p>	

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V 0587  Bldg. 00	<p>Iron Series.</p> <p>During an interview on 5/15/25 beginning at 11:48 AM, Corporate Employee 1 reported she would adjust patients' Mircera and Venofer doses based on the facility's anemia algorithms. Corporate Employee 1 reported Patient was unable to begin receiving doses of Mircera on 4/14/25 as Patient had not received a full Iron Series. The employee was unsure of the reason Patient did not receive the full Iron Series ordered to be administered 3/15/25 - 4/05/25.</p> <p>During an interview on 5/16/25 beginning at 2:59 PM, Charge Nurse 1 was unsure of the reason Patient did not receive the full Iron Series ordered to be administered between 3/15/25 - 4/05/25.</p>	V 0587	<p>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.</p> <p>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>Completion DATE: 6/19/2025</p>	06/19/2025

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152526	(X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	(X3) DATE SURVEY COMPLETED 05/19/2025
NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE KOKOMO		STREET ADDRESS, CITY, STATE, ZIP COD 2350 S DIXON RD STE 450 KOKOMO, IN 46902		
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	<p>signs for 1 of 2 HHD records reviewed (Patient #10) and failed to ensure the IDT noted trends and documented re-education for patients not documenting PD catheter site appearance for 2 of 3 PD records reviewed (Patients #6, 8).</p> <p>Findings include:</p> <p>1. Patient #6's clinical record evidenced Patient's admission date was 7/20/20. Patient was to receive Continuous Cycling Peritoneal Dialysis (CCPD) through a PD catheter. Review of Patient's PD flowsheets from 3/03/25 - 5/17/25 failed to evidence Patient documented the appearance of their PD catheter site, including if signs of infection, such as redness, drainage, and/or warmth was present.</p> <p>The record evidenced Patient went to the facility for a nurse visit on 4/02/25 and 5/05/25. The record failed to evidence the IDT noted and/or discussed the need to document the appearance of Patient's PD catheter site daily.</p> <p>2. Patient #8's clinical record evidenced Patient's admission date was 7/08/24. Patient was to receive CCPD daily through a PD catheter. Review of Patient's PD flowsheets from 3/07/25 - 5/04/25 failed to evidence Patient documented the appearance of their peritoneal catheter site, including if signs of infection, such as redness, drainage, and/or warmth was present.</p> <p>The record evidenced Patient went to the facility for a nurse and/or IDT visit on 3/07/25, 3/18/25, 4/02/25, 4/22/25, 4/30/25, and 5/05/25. Patient reported symptoms of peritonitis on 4/30/25 with laboratory results confirming the infection. The record failed to evidence the IDT noted and/or discussed the need to document the appearance of Patient's peritoneal catheter site daily.</p>		<p>meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policies.</p> <ul style="list-style-type: none"> <li>• Home Therapies Patient Treatment Record Keeping</li> <li>• Routine Exit Site and Tunnel Assessment</li> </ul> <p>Emphasis will be placed on:</p> <ul style="list-style-type: none"> <li>▫ A record is required for each dialysis treatment.</li> <li>▫ Patients and/or patient care partners will be taught to complete a daily record of home dialysis treatments and dialysis related home medication administration, and educated regarding the importance of maintaining the records completely and accurately.</li> <li>▫ Patient use of electronic flowsheets in conjunction with other electronically submitted and/or portably stored cycler data is preferred for treatment data submission.</li> <li>▫ Patients who do not use electronic flowsheets shall be highly encouraged to use other available connected health technologies, when applicable, to capture cycler data.</li> <li>▫ Patients who do not use electronic flowsheets or other connected health technologies will record treatment data on paper treatment flowsheets.</li> <li>▫ Electronically transmitted data will be reviewed by the home therapies nurse or appropriate staff</li> </ul>	

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	<p>3. During an interview on 5/19/25 beginning at 1:45 PM, Home Therapy Nurse 7 reported patients should be documenting the appearance of their PD catheter site daily. The nurse reported Patient #6 and Patient #8's flowsheets failed to evidence the patients were documenting the appearance of their PD catheter site daily.</p> <p>4. Patient #10's clinical record evidenced Patient transferred from an outside hemodialysis facility to Fresenius Medical Care Kokomo on 1/23/25. Patient performed his/her hemodialysis at home and did not have a caregiver assisting with the treatment. Review of Patient's HHD flowsheets from 3/31/25 - 4/17/25 failed to evidence Patient documented vital sign and access checks every 30 minutes.</p> <p>During an observation of a HHD clinic visit on 5/12/25 beginning at 12:22 PM, the facility's IDT, including Medical Director, Home Therapy Manager 4, LPN 4, Social Worker 1, Dietitian 1, and PCT 8 met with Patient. Medical Director and LPN 4 reviewed Patient's HHD flowsheet summary. During the clinic visit, the IDT failed to note and/or discuss the need to document vital signs and access checks every 30 minutes with Patient.</p> <p>During an interview on 5/19/25 beginning at 3:20 PM, Home Therapy Manager 4 reported HHD patients were to document vital signs every 30 minutes during treatment.</p>		<p>member on an ongoing basis. Patients shall bring portable cycler data devices (USB, data cards) and all paper flowsheets to each monthly clinic visit.</p> <p>Home treatment records will be reviewed by the home therapy registered nurse during patient monthly clinic visits to identify trends, errors or omissions, and other issues or concerns to be addressed with the patient and/or care partner.</p> <p>Treatment data downloaded from cycler USB/data cards will be printed and placed in the medical record if it is not otherwise available in the electronic record. Non-RN staff may assist with collection (e.g., USB, paper) and printing of treatment records.</p> <p>Home treatment flowsheets will be maintained in the patient medical record.</p> <p>Policy Exit site and tunnel will be assessed:</p> <ul style="list-style-type: none"> <li>Post-operatively at each dressing change until the exit site is classified as good or perfect.</li> <li>At a minimum, during each clinic visit.</li> <li>When indicated by patient complaint of symptoms of inflammation, trauma, or infection.</li> <li>Any time a patient presents with peritonitis.</li> </ul> <p>Patient and/or care partner will be trained to evaluate the tunnel and exit site. All training will be documented in the patient's</p>	

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			<p>medical record and will include:</p> <ul style="list-style-type: none"> <li>• Evaluation of the exit site and tunnel.</li> <li>• Signs and symptoms of infection.</li> <li>• When and how to notify the home therapies nurse of identified problems.</li> <li>• Document assessment and findings in the patient electronic medical record.</li> <li>• Patient and/or care partner are to document findings on the treatment flowsheet.</li> </ul> <p>Effective 6/9/25, the Home Therapy Program Manager will conduct 3 days per week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring PD patients are documenting in their flowsheet the appearance of their exit site and the nurse is following up on any abnormal findings and or documenting any findings and or interventions in the medical record. A focus will also be ensuring that HHD patients are documenting vital signs in their flow sheets and the nurse is following up on any missed documentation and providing education to the patient. 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</p>	

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			<p>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 FA 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> <p>Completion DATE: 6/19/2025</p>	

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V 0628  Bldg. 00	<p>494.110(a)(2) QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS</p> <p>Based on QAPI minute review, policy review, and interview, the dialysis facility failed to review and evaluate all ICHD patient deaths to identify potential trends, which had the potential to affect 76 active ICHD patients.</p> <p>Findings include:</p> <p>1. The facility policy "Quality Assessment and Performance Improvement Program," dated 11/04/24, indicated the dialysis facility's QAPI committee would "monitor data/information ... determine potential root causes ...." Data to be reviewed included but was not limited to "patient care outcomes ... medical records ...." The QAPI committee was also to identify "commonalities, circumstances, conditions, or barriers that are impacting quality improvement and facility indicators."</p> <p>2. The review of the agency's QAPI meeting minutes analyzing October 2024 - February 2025 data evidenced the following:</p> <p>a. The QAPI meeting held 11/27/24, analyzing October 2024 data, evidenced three ICHD patients had died. The QAPI minutes failed to evidence all patient deaths were evaluated to identify potential trends in causes and/or contributing factors.</p> <p>b. The QAPI meeting held 12/17/24, analyzing November 2024 data, evidenced one ICHD patient had died. The QAPI minutes failed to evidence all patient deaths were evaluated to identify potential trends in causes and/or contributing factors.</p> <p>c. The QAPI meeting held 1/22/25, analyzing</p>	V 0628	<p>V628 QAPI-MEASURE/ANALYZE/TRA CK QUAL INDICATORS CFR(s): 494.110(a)(2)</p> <p>On 6/9/25, the FA, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policies.</p> <ul style="list-style-type: none"> <li>• Quality Assessment and Performance Improvement Program</li> </ul> <p>Emphasis will be placed on:</p> <ul style="list-style-type: none"> <li>• The QAPI Committee will monitor data/information; prioritize areas for improvement; determine potential root causes; develop, implement, evaluate, and revise action plans that result in sustainable improvements in patient care.</li> <li>• Performing a Root Cause Analysis on the identified opportunities to include:</li> </ul> <p>o Identification of commonalities, circumstances, conditions or barriers that are impacting quality improvement and facility indicators</p> <p>Effective 6/9/25, the FA will conduct monthly audits, utilizing the facility specific audit tool for 2 months, with a focus on ensuring the QAPI Committee monitors all data, complete root cause analysis on any identified opportunities and follow up on the root causes if trends are noted</p>	06/19/2025

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	<p>December 2024 data, evidenced one ICHD patient had died. The QAPI minutes failed to evidence all patient deaths were evaluated to identify potential trends in causes and/or contributing factors.</p> <p>d. The QAPI meeting held 2/19/25, analyzing January 2025 data, evidenced one ICHD had died. The QAPI minutes failed to evidence all patient deaths were evaluated to identify potential trends in causes and/or contributing factors.</p> <p>e. The QAPI meeting held 3/26/25, analyzing February 2025 data, evidenced three ICHD had died. The QAPI minutes failed to evidence all patient deaths were evaluated to identify potential trends in causes and/or contributing factors.</p> <p>During an interview on 5/19/25 at 5:15 PM, Administrator reported the QAPI committee tracked and analyzed only the number of patient deaths. The QAPI committee did not review the cause of death nor contributing factors.</p>		<p>including but not limited to patient deaths. The audits will then go to weekly for an additional 2 months 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 FA 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</p>	

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V 0637  Bldg. 00	<p>494.110(a)(2)(ix) QAPI-INDICATOR-INF CONT-TREND/PLAN/ACT</p> <p>Based on QAPI documentation, policy review, and interview, the dialysis facility failed to ensure its QAPI program identified low vaccination rates among its ICHD patients and developed action plans to promote immunization, which had the potential to affect 76 active ICHD patients.</p> <p>Findings include:</p> <p>1. The facility policy "Quality Assessment and Performance Improvement Program," dated 11/04/24, indicated the dialysis facility's QAPI committee would "monitor data/information ... develop, implement, evaluate, and revise action plans that result in sustainable improvements in patient care ...." Data to be reviewed included but was not limited to "patient care outcomes. Infection surveillance ... medical records ...." The QAPI committee was also to prioritize identified opportunities for improvement and develop action plans for identified problems.</p> <p>2. The review of the agency's QAPI meeting minutes analyzing October 2024 - March 2025 data evidenced the following:</p> <p>a. The QAPI meeting held 11/27/24, analyzing</p>	V 0637	<p>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>Completion DATE: 6/19/2025</p> <p>V637 QAPI-INDICATOR-INF CONT-TREND/PLAN/ACT CFR(s): 494.110(a)(2)(ix)</p> <p>On 6/9/25, the FA, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policies.</p> <ul style="list-style-type: none"> <li>• Quality Assessment and Performance Improvement Program</li> </ul> <p>Emphasis will be placed on:</p> <ul style="list-style-type: none"> <li>• Following a Root Cause Analysis, action plans will be determined and prioritized by the QAPI Committee, considering the prevalence and severity of identified problems and by ranking those which have potential to affect patient health and safety as a higher priority than those that do not have such potential. The facility must take immediate and appropriate actions to address any serious threats and ensure patient safety.</li> <li>• A developed appropriate action</li> </ul>	06/19/2025

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	<p>October 2024 data, evidenced:</p> <p>i. The facility had received the flu vaccine and "started to discuss and administer the flu shot."</p> <p>ii. 38.5% of ICHD patients had received a pneumonia vaccine. 20 patients needed to be offered the vaccine.</p> <p>b. The QAPI meeting held 12/17/24, analyzing November 2024 data, evidenced:</p> <p>i. 41% of ICHD patients had received a flu vaccine and 37 patients needed to be offered the vaccine.</p> <p>ii. 39.2% of ICHD patients had received a pneumonia vaccine. 17 patients needed to be offered the vaccine.</p> <p>c. The QAPI meeting held 1/22/25, analyzing December 2024 data, evidenced:</p> <p>i. 44% of ICHD patients had received a flu vaccine. 34 patients needed to be offered the vaccine.</p> <p>ii. 43.8% of ICHD patients had received a pneumonia vaccine. 15 patients needed to be offered the vaccine.</p> <p>d. The QAPI meeting held 2/19/25, analyzing January 2025 data, evidenced:</p> <p>i. 42% of ICHD patients had received a flu vaccine. 34 patients needed to be offered the vaccine.</p> <p>ii. 43.1% of ICHD patients had received a pneumonia vaccine. 15 patients needed to be</p>		<p>plan will include:</p> <ul style="list-style-type: none"> <li>o Implementing the action plan with a specific goal</li> <li>o Identifying staff member(s) responsible for action plan</li> <li>o Monitoring progress and effectiveness of the action plan</li> <li>o Review and document monthly updates in eQUIP until a resolution is achieved</li> <li>o Reassessment of plan if portions are unsuccessful</li> <li>o Sustaining the plan if successful</li> </ul> <p>The QAPI Committee should communicate on a monthly basis with facility staff regarding improvement activities and projects.</p> <p>Effective 6/9/25, the FA will conduct monthly audits, utilizing the facility specific audit tool for 2 months, with a focus on ensuring the QAPI Committee monitors all data, complete root cause analysis on any identified opportunities and follow up on the root causes if trends are noted including but not limited to patient vaccinations. The QAPI Committee will develop and maintain action plans when opportunities are identified through the QAPI process. The audits will then go to weekly for an additional 2 months 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</p>	

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	<p>offered the vaccine.</p> <p>e. The QAPI meeting held 3/26/25, analyzing February 2025 data, evidenced:</p> <ul style="list-style-type: none"> <li>i. 45% of ICHD patient had received a flu vaccine. 32 patients needed to be offered the vaccine.</li> <li>ii. 44.3% of ICHD patients had received a pneumonia vaccine. 15 patients needed to be offered the vaccine.</li> </ul> <p>f. The QAPI meeting held 4/23/25, analyzing March 2025 data, evidenced:</p> <ul style="list-style-type: none"> <li>i. 43% of ICHD patients had received a flu vaccine. 36 patients needed to be offered the vaccine.</li> <li>ii. 40.8% of ICHD patients had received a pneumonia vaccine. 19 patients needed to be offered the vaccine.</li> </ul> <p>During an interview on 5/19/25 at 5:15 PM, Administrator reported the facility had been tracking its ICHD patient vaccination rates, but had not created any formal action plans to address the low flu and pneumonia vaccination rates.</p>		<p>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 FA 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> <p>Completion DATE: 6/19/2025</p>	

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V 0715  Bldg. 00	<p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&amp;P</p> <p>Based on observation, record review, and interview, the medical director failed to ensure policies were followed specific to medication labeling and storage for 2 of 2 days of ICHD treatment floor observations, fistula access site disinfection for 1 of 2 observations of ICHD fistula cannulation (Patient #16), patient monitoring and reporting of abnormal vital signs and/or weights for 6 of 6 ICHD records reviewed (Patients #1, 2, 3, 4, 5, 10).</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. The facility policy "Medication Preparation and Administration", dated 2/06/23, indicated all medications were to be kept in a locked cabinet except when in use. Any open multi-dose vial not used immediately must be labeled with the date the vial was opened.</li> <li>2. The facility policy "Access Assessment and Cannulation," dated 5/05/25, indicated after evaluating a fistula, staff should apply antiseptic to disinfect the cannulation sites. Staff were not to touch the cannulation sites after disinfection.</li> <li>3. The facility policy "Nursing Supervision and Delegation", dated 11/06/23, indicated the RN must evaluate each patient within an hour of treatment initiation to "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." PCTs were to report the following to the nurse for further assessment:</li> </ol>	V 0715	<p>V715 MD RESP-ENSURE ALL ADHERE TO P&amp;P CFR(s): 494.150(c)(2)(i)</p> <p>On 6/9/25, the FA, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policies.</p> <ul style="list-style-type: none"> <li>• Medication Preparation and Administration</li> <li>• Access Assessment and Cannulation</li> <li>• Nursing Supervision and Delegation</li> <li>• Patient assessment and Monitoring</li> <li>• Guidelines for Recognizing and Treating Orthostatic Hypotension</li> <li>Emphasis will be placed on: Medication Preparation and Administration</li> <li>• All medications will be kept in a locked cabinet except when in use.</li> <li>• One key to the medication cabinet will be kept by the charge nurse/team leader. The Clinical Manager will retain a spare key, kept in a secure location.</li> <li>• When preparing medications if the vial is not used immediately in its entirety, the nurse or PCT (if allowed by state regulations), must place the date and time the vial was opened on the medication label along with their initials.</li> <li>• Label any open multi-dose vial</li> </ul>	06/19/2025

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	<p>a. Any post treatment weight more than 1.0 kilogram (kg) above the Estimated Dry Weight (EDW, the weight a patient is ordered to be at after dialysis had removed excess fluid from the body)</p> <p>b. A systolic (SBP, top number in a BP reading) reading greater than 180 millimeters of mercury (mmHg) at any time before, during, or after treatment</p> <p>c. A diastolic (DBP, bottom number in a BP reading) reading greater than 100 mmHg at any time before, during, or after treatment</p> <p>d. A drop in SBP of 20 mmHg between sitting and standing</p> <p>4. The facility policy "Patient Assessment and Monitoring," dated 5/01/23, indicated pre-treatment, staff were to verify SBP greater than 180 mmHg and DBP greater than 100 mmHg. During treatment, staff were to report the following to the nurse:</p> <p>a. SBP greater than 180 mmHg or less than 100 mmHg</p> <p>b. DBP greater than 100 mmHg</p> <p>c. Heart rates (HR) less than 60 or greater than 100.</p> <p>The policy also indicated a patient's BP and HR were to be obtained "every 30 minutes or more as needed but not to exceed 45 minutes."</p> <p>5. The facility policy "Guidelines for Recognizing and Treating Orthostatic (Postural) Hypotension," dated 2/07/22, defined orthostatic hypotension as</p>		<p>that is not used immediately and store vial accordingly.</p> <p>Access Assessment and Cannulation</p> <ul style="list-style-type: none"> <li>• After assessing the access, staff must perform hand hygiene and don new gloves. With the new gloves, staff may perform the full cannulation procedure (both needles) including skin disinfection, lidocaine administration (if applicable) and cannulation. If any of the steps in the procedure are interrupted, hand hygiene must be performed, and new gloves must be donned.</li> <li>• Perform skin antisepsis on one site at a time, allow to dry and then cannulate. Do not touch cannulation sites after skin disinfection.</li> </ul> <p>Nursing Supervision and Delegation</p> <ul style="list-style-type: none"> <li>• The registered nurse must evaluate each patient preferably within an hour or according to state requirements to: <ul style="list-style-type: none"> <li>o Confirm identify</li> <li>o Review the patient's condition.</li> <li>o Review accuracy and completeness of treatment and patient data</li> <li>o Review patient treatment prescription and equipment parameters to verify correct settings, and if dialysis prescription is being followed.</li> <li>o Confirm that the correct vascular access is being used, and that the access is visible. Observe</li> </ul> </li> </ul>	

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	<p>"a drop in blood pressure from sitting to standing that is equal to or greater than 20 mmHg systolic or 10 mmHg diastolic." If a patient exhibited signs or symptoms of orthostatic hypotension, staff were to place the patient in modified Trendelenburg position (on the back with the legs elevated), recheck the patient's vital signs, and administer normal saline in bolus doses of 100 - 200 milliliters (ml). Patients were to be re-assessed after 10-15 minutes, and the physician was to be notified if signs and symptoms of orthostatic hypotension continued.</p> <p>6. During an ICHD flash tour observation on 5/12/25 beginning at 8:38 AM, four vials of Heparin (a medication used to thin the blood) were observed unsecured on a counter. One bottle of Calcitrol (medication used to treat low calcium levels), one bottle of Cinacalcet (medication used to treat an elevated parathyroid level), one vial of Heparin (a blood thinner), and one bottle of Midodrine (a medication used to treat low blood pressure) were observed open without a label indicating the date the bottles/vial were opened.</p> <p>During an interview on 5/12/25 beginning at 9:30 AM, Charge Nurse reported multi-use medication bottles and vials should be labeled with the date the bottle/vial was opened.</p> <p>7. During an ICHD floor observation on 5/13/25 from 5:40 AM - 7:10 AM, four vials of Heparin were observed unsecured on a counter.</p> <p>During an interview on 5/13/25 beginning at 3:19 PM, Charge Nurse 1 was unsure how the Heparin vials were kept secured when stored on the counter.</p>		<p>patient's response to treatment</p> <ul style="list-style-type: none"> <li>o Verify machine safety checks have been completed.</li> <li>o 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> <li>• The following criteria can be used as a guideline to identify when a PCT/LPN/LVN or RN shall refer a patient to the Team Leader/Charge Nurse for further assessment pre, during or post treatment. The Team Leader/Charge Nurse will use their clinical judgment based on individual patient needs to determine if any clinical interventions are necessary:</li> <li>o Fluid Status Any weight gains greater than 4 kg pre-treatment. Any swelling in the facial area, and lower extremity edema. Any post treatment weight with a variance from the estimated dry weight of 1.0 kg. Any weight loss or no change in weight from a patient's last treatment post weight.</li> <li>o Blood Pressure A Systolic blood pressure greater than 180 mm/Hg and / or diastolic blood pressure greater than 100 mm/Hg at any time before, during or after the treatment. If B/P less than or equal to 100 mm/hg systolic during treatment. A systolic blood pressure less than 100 mm/Hg</li> </ul>	

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	<p>8. During an ICHD treatment floor observation on 5/12/25 beginning at 11:19 AM, PCT 4 was in Station 12 cannulating Patient #16's fistula. After applying antiseptic to the second cannulation site, PCT 4 re-evaluated the access site by palpating with her fingers. The technician then cannulated the second fistula site, failing to re-apply antiseptic prior to cannulation.</p> <p>During an interview on 5/12/25 beginning at 2:19 PM, PCT 4 reported when cannulating a fistula, antiseptic should be re-applied if the site needed to be re-evaluated after it was disinfected.</p> <p>9. Patient #1's clinical record evidenced the Dialysate Flow Rate (DFR) was ordered to be 800 milliliters per minute (ml/min). Treatment flowsheets reviewed between 4/30/25 - 5/12/25 evidenced the following:</p> <p>a. On 4/30/25, Patient's post-treatment sitting BP was 163/85 and standing BP was 139/76, a decrease by 24 mmHg. The record failed to evidence the nurse was notified nor did the facility enact any interventions to address orthostatic hypotension according to its policy.</p> <p>b. On 5/02/25, Patient's post-treatment sitting BP was 146/84 and standing BP was 119/67, a decrease by 27 mmHg. The record failed to evidence the nurse was notified nor did the facility enact any interventions to address orthostatic hypotension according to its policy.</p> <p>c. On 5/05/25, Patient's treatment began at 7:55 AM. At 11:53 AM, Patient's heart rate was 103. Patient's treatment ended at 11:54 AM. Patient's post-treatment heart rate was 107, sitting BP was 139/68, and standing BP was 115/65. Patient's BP dropped by 24 mmHg. The record failed to</p>		<p>post treatment when standing. A drop in systolic BP of 20 mmHg between sitting and standing. Patient Assessment and Monitoring</p> <ul style="list-style-type: none"> <li>• Follow the steps below for obtaining pre-treatment assessment data:           <ul style="list-style-type: none"> <li>o The direct patient care staff may obtain the following data:</li> <li>o Record blood pressure. Verify: Systolic blood pressures greater than 180 mm/Hg and / or diastolic blood pressures greater than 100 mm/Hg</li> <li>o Systolic blood pressures less than or equal to 100 mm/hg systolic during treatment.</li> </ul> </li> <li>• 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.</li> <li>• Report to the nurse:           <ul style="list-style-type: none"> <li>o Systolic blood pressures greater than 180 mm/Hg</li> <li>o Diastolic blood pressure greater than 100 mm/Hg</li> <li>o Blood Pressure less than or equal to 100 mm/hg systolic</li> </ul> </li> <li>• Report to the nurse patients whose heart rates have dropped below 60, risen above 100 or become irregular.</li> </ul> <p>Guidelines for Recognizing and Treating Orthostatic Hypotension</p> <ul style="list-style-type: none"> <li>• Orthostatic Hypotension: A drop in blood pressure from sitting to standing that is equal to or greater than 20 mm Hg systolic or 10 mm</li> </ul>	

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	<p>evidence the nurse was notified of Patient's elevated HR or drop in BP, and failed to evidence the facility enacted interventions to address Patient's orthostatic hypotension according to its policy.</p> <p>During an interview on 5/15/25 beginning at 2:24 PM, PCT 4 reported she would not report a drop in SBP at the end of treatment. The technician stated she would only report if the SBP was less than 100 mmHg. PCT 4 reported a HR above 100 or below 60 should be reported to the nurse. The PCT was unsure if Patient's post-treatment elevated HR was reported to the nurse.</p> <p>d. On 5/07/25, Patient's pre-treatment sitting BP was 128/84 and standing BP was 103/71, a drop by 25 mmHg. Patient's treatment began at 7:52 AM. At 11:01 AM, Patient's DFR was noted to be 500 milliliters per minute (ml/min). The DFR remained at 500 ml/min until Patient's treatment ended at 11:52 AM. The record failed to evidence the nurse was notified of Patient's drop in BP and failed to evidence the reason Patient's DFR was not followed according to physician order.</p> <p>During an interview on 5/15/25 beginning at 3:08 PM, PCT 7 was unsure Patient's DFR was not run according to physician orders.</p> <p>e. On 5/09/25, Patient's treatment began at 7:56 AM. The record failed to evidence vital signs were documented between 7:57 AM - 8:45 AM, which was 48 minutes between vital sign checks. Patient's nurse assessment was documented at 9:55 AM, which was 1 hour and 59 minutes after Patient's treatment began. Patient's post-treatment sitting BP was 146/72 and standing BP was 124/66, a drop in 22 mmHg.</p> <p>During an interview on 5/15/25 beginning at 2:57</p>		<p>Hg diastolic.</p> <ul style="list-style-type: none"> <li>• Staff, patients and care partners will recognize, report, and treat orthostatic hypotension occurring post hemodialysis treatment.</li> <li>• If the patient exhibits signs or symptoms of orthostatic hypotension follow the steps below: <ul style="list-style-type: none"> <li>o Instruct the standing patient to sit back down in the dialysis chair and place the patient into modified Trendelenburg position.</li> <li>o Obtain vital signs. As necessary to reverse hypotension, administer normal saline (NS) in bolus doses of 100-200mL or unless otherwise prescribed by the patient's attending physician. Evaluate patient's condition, take B/P and pulse and document after each NS administration. If a total of 200mL NS does not resolve the patient's signs and symptoms, notify the Registered Nurse (RN). Additional bolus doses may be administered up to 500mls.</li> <li>o If a total of 500mL of NS does not resolve the patient's signs and symptoms, the physician shall be notified for additional direction/orders.</li> </ul> </li> </ul> <p>Effective 6/9/25, the FA will conduct 3x a week audits for 2 weeks using the facility specific audit tool with a focus on ensuring all medications are stored secured and locked in a cabinet. A focus will be on ensuring all multi use vial that are not used in its entirety</p>	

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	<p>PM, RN 2 reported she tried to assess all patients within one hour of treatment start. The nurse was unsure of the reason Patient's nurse assessment was documented 1 hour and 59 minutes into treatment, but stated she was likely the only nurse on the treatment floor at the time. RN 2 reported PCTs should report a decrease by 30 mmHg from sitting to standing SBP.</p> <p>During an interview on 5/16/25 beginning at 2:47 PM, PCT 3 reported vital signs should be performed and documented every 30 minutes. The technician was unsure of the reason vital signs were not documented between 7:57 - 8:45 AM.</p> <p>During an interview on 5/15/25 beginning at 2:34 PM, PCT 5 stated she would report a decrease by 30 mmHg from sitting to standing SBP. The technician referenced an undated document taped to a medication cabinet titled "Reporting to the RN," which indicated PCTs should report a decrease by 30 mmHg from sitting to standing SBP.</p> <p>During an interview on 5/15/25 beginning at 4:30 PM, Administrator reported the "Reporting to the RN" document was outdated, and staff should follow the facility policies for reporting a drop in SBP from sitting to standing.</p> <p>10. Patient #2's clinical record evidenced a physician-ordered Blood Flow Rate (BFR) of 400 ml/min, Estimated Dry Weight (EDW) of 98.0 kilograms (kg), and special attention order of "ok to run [Patient] with low BP readings if patient asymptomatic." Treatment flowsheets reviewed between 4/25/25 - 5/12/25 evidenced the following:</p> <p>a. On 4/25/25, Patient's record failed to evidence a pre-treatment standing BP was obtained. A nurse</p>		<p>they will be labeled with the date and time it was accessed and the initials of the person accessing it. A focus will be on ensuring the patients access will be disinfected after being assessed and will not be touched after disinfecting and prior to cannulation. A focus will be on ensuring if a patient exhibits orthostatic hypotension the above listed procedure will be followed per Fresenius policy. A focus will be on ensuring the patient care staff will report all abnormal vitals as listed above and in the Fresenius policy to the registered nurse, the nurse will follow up on abnormal vitals and report to MD any needed interventions and will document in the medical record. A focus will be on ensuring that vitals will be taken and documented on every 30 minutes but not to exceed 45 minutes. A focus will be on ensuring the Nurse completes and documents the nursing assessment within one hour of the start of the treatment and ensure the above listed items are included in the assessment. A focus will be on ensuring the physician is notified if the patient is above EDW more than 1kg. A focus will be on ensuring if a patient is ambulatory that a standing BP will be checked pre and post treatment. A focus will be on ensuring the nurse will address hypertension and give any ordered PRN</p>	

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	<p>assessment indicated Patient was ambulatory. Patient's treatment began at 11:30 AM. The record failed to evidence vital signs were documented between 11:33 AM - 12:31 PM, which was 58 minutes between checks. Patient's BPs during treatment included:</p> <ul style="list-style-type: none"> <li>i. At 11:33 AM, BP was 93/75</li> <li>ii. At 1:02 PM, BP was 89/46</li> <li>iii. At 1:33 PM, BP was 90/29</li> <li>iv. At 2:41 PM, BP was 82/47.</li> </ul> <p>The record failed to evidence Patient was evaluated for symptoms of low blood pressure.</p> <p>Patient's post-treatment weight was 100 kg, which was 2.0 kg above Patient's EDW. The record failed to evidence Patient's physician was notified of the post-treatment weight more than 1 kg above the EDW.</p> <p>b. On 4/28/25, Patient's record failed to evidence a pre-treatment standing BP was obtained. A nurse assessment indicated Patient was ambulatory. Patient's BP during treatment included:</p> <ul style="list-style-type: none"> <li>i. At 11:34 AM, BP was 92/79</li> <li>ii. At 12:02 PM, BP was 83/45</li> <li>iii. At 1:12 PM, BP was 140/113</li> <li>iv. At 2:06 PM, BP was 147/104 and 147/114</li> </ul> <p>The record failed to evidence Patient was evaluated for symptoms of low BP and failed to evidence the nurse was notified of a diastolic BP above 100.</p> <p>During an interview on 5/15/25 beginning at 3:08 PM, PCT 7 reported a DBP greater than 100 should be reported to the nurse. He was unsure if Patient's elevated DBP was reported. PCT also reported all ambulatory patients should have a standing BP documented prior to start of</p>	<p>medication as needed. 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 FA 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.</p> <p>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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CENTERS FOR MEDICARE & MEDICAID SERVICES

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	<p>treatment.</p> <p>c. On 5/02/25, Patient's record failed to evidence a pre-treatment standing BP was obtained. A nurse assessment indicated Patient was ambulatory. The record failed to evidence vital signs were documented between 12:00 PM and 1:09 PM, which was 1 hour and 9 minutes between checks. Patient's BP during treatment included:</p> <ul style="list-style-type: none"> <li>i. At 11:23 AM, BP was 97/85</li> <li>ii. At 12:00 PM, BP was 92/45 and 82/57</li> <li>iii. At 1:31 PM, BP was 89/53</li> <li>iv. At 2:03 PM, BP was 87/78</li> </ul> <p>The record failed to evidence Patient was evaluated for symptoms of low BP.</p> <p>d. On 5/05/25, Patient's record evidenced the following vital signs:</p> <ul style="list-style-type: none"> <li>i. At 12:04 PM, BP was 165/102 and HR was 47</li> <li>ii. At 12:32 PM, HR was 49</li> <li>iii. At 1:35 PM, HR was 52</li> <li>iv. At 2:32 PM, HR was 48</li> </ul> <p>The record failed to evidence the nurse was notified of the low heart rate and elevated diastolic BP.</p> <p>During an interview on 5/15/25 beginning at 2:24 PM, PCT 4 reported a heart rate less than 60 and a DBP above 100 should be reported to the nurse. The technician thought Patient had a standing order for his/her HR to run lower than 60, and reported the nurse notification of Patient's elevated DBP was not documented.</p> <p>e. On 5/09/25, Patient's record failed to evidence a pre-treatment standing BP was obtained. A nurse assessment indicated Patient was ambulatory,</p>		<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>Completion DATE: 6/19/2025</p>	

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	<p>patient lung sounds were clear, and no shortness of breath was documented. Patient's vital signs during treatment included:</p> <p>i. At 11:21 AM, BP was 131/107. The record failed to evidence the nurse was notified of the elevated diastolic BP.</p> <p>During an interview on 5/15/25 beginning at 2:57 PM, RN 2 stated the reporting of a post-treatment weight to the MD was patient-specific and depended on the patient's trends, but generally would report a post-treatment weight which was "4-5 kg" above the EDW. RN 2 stated she would not have reported Patient's post-treatment weight of 2.0 kg above the EDW on 4/25/25. The nurse reported a PCT should report a SBP "trending up" above 180 mmHg, "trending down" below 90 mmHg, DBP above 100 or below 50 mmHg. RN 2 stated Patient's standing order to dialyze with low SBPs was not specific. The nurse stated staff should be documenting that Patient was asymptomatic when his/her SBP was low.</p> <p>During an interview on 5/19/25 beginning at 9:05 AM, PCT 3 reported standing BPs were to be performed prior to treatment initiation. The technician stated many patients were short of breath at the beginning of treatment and would not get up to obtain a standing BP. The technician reported this should be documented as "patient refused."</p> <p>During an interview on 5/15/25 beginning at 2:34 PM, PCT 5 reported vital signs should be obtained and documented every 30 minutes. The technician stated she was likely on break on 4/25/25 and 5/02/25 when vital signs were not documented. PCT 5 reported patients will often "plop down" in the chair at the beginning of</p>			

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	<p>treatment, and staff do not always ask the patient to stand to obtain a standing BP. The technician also stated Patient's SBP typically ran low during treatment, and was "generally ok" if the SBP was "70s - 80s." PCT 5 stated she didn't always document if Patient was asymptomatic.</p> <p>11. Patient #3's clinical record evidenced orders to administer Clonidine (a medication used to treat elevated BP) as needed for a SBP greater than 180 and administer 100 mL saline flush every 30 minutes during treatment in order to prevent clotting as Patient was allergic to Heparin. Treatment flowsheets reviewed between 4/30/25 - 5/12/25 evidenced the following:</p> <p>a. On 4/30/25, Patient's pre-treatment BP was 215/98 sitting and 233/98 standing. Patient's treatment started at 6:50 AM. Patient's BP during treatment included:</p> <ul style="list-style-type: none"> <li>i. At 6:51 AM, BP was 232/94</li> <li>ii. At 7:31 AM, BP was 232/94</li> <li>iii. At 8:01 AM, BP was 208/89</li> <li>iv. At 8:35 AM, BP was 222/95</li> <li>v. At 9:01 AM, BP was 197/82</li> <li>vi. At 9:33 AM, BP was 208/91</li> <li>vii. At 10:14 AM, BP was 194/89</li> </ul> <p>Patient's post-treatment BP was 207/81 sitting and 193/89 standing. The record failed to evidence the nurse was notified of Patient's elevated BPs before, during, and after treatment, failed to evidence Clonidine was administered per order, and failed to evidence saline flushes were administered per order.</p> <p>During an interview on 5/19/24 beginning at 9:41 AM, PCT 4 reported whether an elevated SBP was reported to the nurse was patient-specific. She would generally report an elevated SBP to the</p>			

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	<p>nurse if the number was "in red" on the EMR. The technician reported Patient's BP "runs high" and the nurse notification should be documented in the record. PCT 4 was not aware Patient had an order to administer saline flushes every 30 minutes.</p> <p>b. On 5/02/25, Patient's treatment began at 7:09 AM. The record failed to evidence vital signs were documented between 7:10 AM - 8:00 AM, which was 50 minutes between checks.</p> <p>A nurse assessment was documented at 8:14 AM, which was one hour and five minutes after Patient's treatment began.</p> <p>The record failed to evidence saline flushes were administered per order.</p> <p>During an interview on 5/16/25 beginning at 2:37 PM, PCT 2 reported a SBP above 180 mmHg should be reported to the nurse. The technician stated vital signs should be documented every 30 minutes and she was likely on break during the time no vital sign checks were documented. PCT 2 reported saline flushes were only administered for Patient on an as-needed basis.</p> <p>During an interview on 5/19/25 beginning at 3:02 PM, Charge Nurse 1 reported the nurse assessment should be documented within one hour of the start of treatment. The nurse was unsure of the reason Patient's nurse assessment was documented late.</p> <p>c. On 5/05/25, Patient's pre-treatment sitting BP was 194/80 and standing BP was 101/72, a drop of 93 mmHG. The record failed to evidence the nurse was notified of the drop in SBP nor did the facility enact any interventions to address orthostatic</p>			

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	<p>hypotension according to its policy, and failed to evidence saline flushes were administered per order.</p> <p>During an interview on 5/16/25 beginning at 2:37 PM, PCT reported a drop in SBP by 20 mmHg should be reported to the nurse. The PCT stated the nurse notification was not documented on 5/05/25.</p> <p>d. On 5/07/25, Patient had a pre-treatment standing BP documented. A nurse assessment indicated Patient was ambulatory. The record failed to evidence a post-treatment standing BP was performed and failed to evidence saline flushes were administered per order.</p> <p>During an interview on 5/19/25 beginning at 9:24 AM, PCT 2 reported standing BPs were to be obtained after a patient completed treatment. The technician reported Patient would intermittently leave the facility by wheelchair. PCT 2 stated this was not documented in the treatment flowsheet.</p> <p>e. On 5/09/25, Patient's BPs during treatment included:</p> <ul style="list-style-type: none"> <li>i. At 7:14 AM, BP was 188/81</li> <li>ii. At 9:06 AM, BP was 136/109</li> <li>iii. At 10:02 AM, BP was 192/85</li> <li>iv. At 10:31 AM, BP was 202/86</li> <li>v. At 11:05 AM, BP was 192/85</li> <li>vi. At 11:12 AM, BP was 188/78</li> </ul> <p>Patient's post-treatment BP was 188/78 sitting and 197/83 standing. The record failed to evidence the nurse was notified of Patient's elevated BPs during and after treatment, failed to evidence Clonidine was administered per order, and failed to evidence saline flushes were administered per order.</p>			

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	<p>During an interview on 5/16/25 beginning at 2:17 PM, PCT 7 reported a SBP above 180 should be reported to the nurse. The PCT was unsure of the reason Patient's elevated SBP was not documented as reported. PCT 7 was unaware Patient had orders for saline flushes to be administered every 30 minutes.</p> <p>f. On 5/12/25, the record failed to evidence saline flushes were administered per order.</p> <p>During an interview on 5/16/25 beginning at 3:11 PM, Charge Nurse 1 reported Patient had no "special attention" orders indicating it was ok for Patient's BP to be elevated, therefore PCTs should notify the nurse of a SBP above 180 mmHg. Charge Nurse 1 reported the nurse should administer Clonidine for Patient's SBP above 180 mmHg. The nurse was unsure of the reason Patient did not receive Clonidine on 4/30/25 or 5/09/25. Charge Nurse 1 reported staff should be administering saline flushes every 30 minutes per standing order.</p> <p>12. Patient #4's clinical record included orders for a DFR of 800 ml/min. Treatment flowsheets between 4/30/25 - 5/12/25 were reviewed and evidenced:</p> <p>a. On 5/05/25, Patient's DFR throughout treatment was 500 ml/min. Patient's HR during treatment included:</p> <ul style="list-style-type: none"> <li>i. At 1:03 PM, HR was 50</li> <li>ii. At 2:07 PM, HR was 53</li> <li>iii. At 2:16 PM, HR was 49</li> <li>iv. At 2:03 PM, HR was 56</li> <li>v. At 3:09 PM, HR was 56</li> <li>vi. At 3:31 PM, HR was 53</li> </ul>			

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	<p>The record failed to evidence the nurse was notified of Patient's low HR.</p> <p>During an interview on 5/19/25 beginning at 9:24 AM, PCT 2 stated she would report a HR less than 60 to a nurse. The technician thought Patient had a special attention order indicating it was ok for Patient's heart rate to be less than 60. The technician was unsure of the reason Patient's DFR was not run according to the prescribed rate, but stated it could have been a conductivity or machine issue.</p> <p>During an interview on 5/19/25 beginning at 9:41 AM, PCT 4 stated she would report a HR less than 50 to a nurse. The technician was unsure of the reason Patient's DFR was not run according to the prescribed rate, but stated it could have been an issue with the bicarbonate bag attached to the machine.</p> <p>b. On 5/09/25, Patient's HR prior to treatment was 56. Patient's HR during treatment included:</p> <ul style="list-style-type: none"> <li>i. At 11:55 AM, HR was 51</li> <li>ii. At 12:31 PM, HR was 55</li> <li>iii. At 1:12 PM, HR was 53</li> <li>iv. At 2:01 PM, HR was 53</li> <li>v. At 2:31 PM, HR was 53</li> <li>vi. At 3:02 PM, HR was 57</li> </ul> <p>The record failed to evidence the nurse was notified of Patient's low HR.</p> <p>During an interview on 5/19/25 beginning at 9:19 AM, PCT 5 reported she would have reported Patient's low HR to the nurse. The technician reported she may have forgotten or gotten busy and did not document reporting the low HR.</p> <p>13. Patient #5's clinical record included flowsheets</p>			

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	<p>between 4/30/25 - 5/12/25 which evidenced:</p> <p>a. On 4/30/25, Patient's vital signs during treatment included:</p> <ul style="list-style-type: none"> <li>i. At 1:03 PM, BP was 180/83 and HR was 106</li> <li>ii. At 1:31 PM, HR was 105</li> <li>iii. At 2:01 PM, HR was 116</li> </ul> <p>The record failed to evidence the nurse was notified of the elevated BP and HR.</p> <p>b. On 5/05/25, Patient's treatment began at 10:55 AM. A nurse assessment was documented at 12:14 PM, which was one hour and 19 minutes after start of treatment. Patient's HR during treatment included:</p> <ul style="list-style-type: none"> <li>i. At 1:02 PM, HR was 105</li> <li>ii. At 1:33 PM, HR was 103</li> </ul> <p>During an interview on 5/19/25 beginning at 9:15 AM, RN 2 reported the nurse assessment may be documented late due to only having one nurse on the treatment floor at the time.</p> <p>c. On 5/07/25, Patient's treatment began at 10:36 AM. The record failed to evidence vital signs were documented between 11:00 - 11:48 AM, which was 48 minutes between checks. At 12:32 PM, Patient's HR was 113. The record failed to evidence the nurse was notified of the elevated HR.</p> <p>During an interview on 5/19/24 beginning at 9:41 AM, PCT 4 reported whether an elevated SBP or HR was reported to the nurse was patient-specific. She would generally report an elevated SBP or HR to the nurse if the number was "in red" on the EMR. PCT 4 she would document in the EMR when the nurse was notified. The technician was unsure of the reason Patient's vital signs were not</p>			

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	<p>done between 11:00 - 11:48 AM.</p> <p>14. Patient #10's clinical record evidenced Patient transferred from an outside hemodialysis facility to Fresenius Medical Care Kokomo on 1/23/25. Patient received respite ICHD from 4/22/25 - 5/03/25. Patient's ordered EDW was 88.0 kg. The ICHD flowsheets evidenced:</p> <p>a. On 4/22/25, Patient's nursing assessment evidenced Patient was dyspneic, had decreased breath sounds and wheezing, and pitting edema (swelling which causes an indentation when pressed, graded on a scale of 1+ to 4+, with 1+ edema evidencing a small indentation which disappears quickly and 4+ evidencing a very deep pit which takes more than one minute to disappear) of 2+ in the left ankle and 1+ in the left lower leg. Patient's post-treatment weight was 90.0 kg. The record failed to evidence the physician was notified Patient's post-treatment weight was 2.0 kg above EDW with signs of fluid overload.</p> <p>b. On 4/24/25, Patient's nursing assessment evidenced Patient was dyspneic and pitting edema of 2+ in both ankles and lower legs. Patient's post-treatment weight was 89.6 kg. The record failed to evidence the physician was notified Patient's post-treatment weight was 1.6 kg above EDW with signs of fluid overload.</p> <p>c. On 4/26/25, Patient's nursing assessment evidenced Patient had pitting edema of 1+ in both ankles and lower legs. Patient's post-treatment weight was 91.5 kg. The record failed to evidence the physician was notified Patient's post-treatment weight was 3.5 kg above EDW with signs of fluid overload.</p> <p>d. On 4/29/25, Patient's nursing assessment</p>			

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	<p>evidenced Patient had pitting edema of 1+ in both ankles and lower legs. Patient's post-treatment weight was 91.5 kg. The record failed to evidence the physician was notified Patient's post-treatment weight was 3.1 kg above EDW with signs of fluid overload.</p> <p>e. On 5/01/25, Patient's nursing assessment evidenced Patient had pitting edema of 3+ to both ankles and 2+ to both lower legs. Patient's post-treatment weight was 90.0 kg. The record failed to evidence the physician was notified Patient's post-treatment weight was 2.0 kg above EDW with signs of fluid overload.</p> <p>f. On 5/03/25, Patient's nursing assessment evidenced Patient had pitting edema of 3+ to both ankles and lower legs. Patient's post-treatment weight was 91.1 kg. The record failed to evidence the physician was notified Patient's post-treatment weight was 3.1 kg above EDW with signs of fluid overload.</p> <p>During an interview on 5/19/25 beginning at 9:34 AM, RN 2 stated she did not recall reporting Patient's post-treatment weights above the EDW to the physician.</p> <p>During an interview on 5/19/25 beginning at 3:02 PM, Charge Nurse 1 reported he would report a post-treatment weight four kg or higher than the EDW to the MD. The nurse stated a post-treatment weight above the EDW should be reported to the physician if the patient was exhibiting signs and/or symptoms of fluid overload. Charge Nurse 1 stated he would document the MD notification if orders were received.</p> <p>15. During an interview on 5/13/25 beginning at</p>			

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	<p>3:19 PM, Charge Nurse 1 reported vital signs should be documented every 30 minutes.</p> <p>During an interview on 5/16/25 beginning at 2:59 PM, Charge Nurse 1 reported PCTs should report a SBP greater than 180 or less than 100, a DBP greater than 100, a HR greater than 100 or less than 60, and a drop in SBP of 20 or more mmHg. Charge Nurse 1 reported staff should document vital sign and access checks every 30 minutes. Standing blood pressures should be obtained for all ambulatory patients.</p> <p>16. During an interview on 5/15/25 beginning at 11:24 AM, Medical Director reported the PCT should report a drop in SBP of more than 20 mmHg from sitting to standing and the patient should be assessed for presence or absence of symptoms of orthostatic hypotension, as patients may need to receive a fluid infusion or have other interventions. The physician also stated the PCT should report a SBP less than 100 mmHg and greater than 150 - 160 mmHg to the nurse.</p>			