

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152503	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	(X3) DATE SURVEY COMPLETED 12/01/2022
NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE OHIO VALLEY		STREET ADDRESS, CITY, STATE, ZIP COD 230 BELLEMEADE AVE EVANSVILLE, IN 47713		
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E 0000  Bldg. 00	<p>An Emergency Preparedness Survey was conducted by the Indiana State Department of Health in accordance with 42 CFR 494.62.</p> <p>Survey Dates: 11/28/2022-12/1/2022</p> <p>Census: 44</p> <p>At this Emergency Preparedness survey, Fresenius Medical Care Ohio Valley was not found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62.</p> <p>QR Completed on 12/15/2022 A4</p>	E 0000		
E 0028  Bldg. 00	<p>494.62(b)(9) Dialysis Emergency Equipment §494.62(b)(9) Condition for Coverage: [(b) Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:]</p> <p>(9) A process by which the staff can confirm that emergency equipment, including, but not limited to, oxygen, airways, suction,</p>			

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

TITLE

(X6) DATE

Christopher Dobbs

Director of Operations

12/27/2022

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>defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, are on the premises at all times and immediately available.</p> <p>Based on observation, record review, and interview, the facility failed to maintain supplies according to manufacturer instructions for 2 of 2 code carts and emergency preparedness kits observed.</p> <p>Findings include:</p> <p>1. A revised 8/25/2020 checklist titled, "Emergency Code Care, Medications and Machine Hand Crank Checklist" was copied from the code cart on 11/28/2022 at 10:45 p.m. The checklist included the statement, It is the responsibility of the Medical Director in conjunction with the Governing Body to determine the size and amounts of equipment that are to be kept in the emergency cart, a place to write in the year, columns with each month listed and boxes below each with all the mandatory supplies and medications stored in the code cart, emergency drugs stored within the emergency kit, additional supplies required by state or local regulations and oxygen cylinders.</p> <p>2. During the flash tour on 11/28/2022 beginning at 9:39 a.m., the code cart and emergency kit were observed in their entirety. The following items were found to be expired:</p> <p>Code cart- 2 sets of AED (automated external defibrillator) pads expired on 8/28/2022</p> <p>Emergency kit - 2 100mL bags of saline expired May/2021</p> <p>2 1000mL bags of saline expired 2/2022 and 3/2022</p> <p>3. A review of the checklist was completed on</p>	E 0028	<p>On 12/1/2022, the Area Team Leader met with the Clinical Manager and facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policies and/or Procedures: Emergency Medications, Equipment and Supplies Emphasis will be placed on: An itemized log of the Emergency Cart must be kept indicating the contents and expiration dates of contents. Items approaching expiration must be reordered and replaced prior to the actual expiration date The Emergency Cart will be checked monthly or after use, for contents, expiration dates, cleanliness, and proper functioning of all equipment</p> <p>On 12/1/2022, the Area Team Leader removed, discarded and replaced the following expired items from the Emergency Cart:</p> <p>(2) sets of automated external defibrillator (AED) pads expired on 8/28/2022 (2) 100ml bags of saline expired May 2021 (2) 1000ml bags of saline expired 2/2022 and 3/2022 In addition, on 12/1/2022, the Clinical Manager reviewed and ensured that the 100ml and 1000ml normal saline is listed on the mandatory itemized Emergency Cart log to be</p>	01/13/2023

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	<p>11/28/2022 at 10:15 a.m. The review evidenced a checklist of mandatory supplies that included AED, AED pads (2 sets), Expiration, Suction Machine with (Turn on and check for suction, Canister, Tubing, 10 F Catheter, Expiration, 14 F Catheter, Expiration, Yankauer), Tongue Blades, Tubing, Face Mask, Nasal Cannula, Airways, Cardiac Back Board, an Ambu Bag, Sterile Normal Saline Solution, Expiration, Sterile Gloves, Expiration, Trach Mask Oxygen Adapter, Flashlight, and Cardiopulmonary Arrest Record that were all checked, had dates written in expiration boxes where required, and initials of employee who completed the check as well as a signature of who initialed. This was completed by the Clinical Manager (A1). A1 failed to dispose of AED pads with an expired date and wrote 5/28/2023 as the expiration date for months March through October. A1 failed to dispose of saline bags with an expired date, but there was no indication of this item on the checklist.</p> <p>4. During an interview on 12/1/2022 at 1:20 p.m., A1 indicated the list used to check the code cart and emergency kit did not have saline bags listed as an item to be checked. A1 did not check it. A1 indicated he/she was responsible for ensuring the checklist of items within the code cart and emergency kit were completed monthly per guidelines set by Fresenius Medical Care. A1 stated the whole cart should have been checked whether an item was on the checklist or not because there should be no expired supplies or medications in either one.</p>			checked monthly for expiration dates. To monitor staff compliance with ensuring all medications and supplies on the Emergency Cart are maintained within the manufacturers expiration dates, beginning , December 2022, the Clinical Manager will conduct the monthly Emergency Cart checks, in conjunction with another Registered Nurse monthly x 3 months. Once compliance is achieved and sustained the Governing Body will recommend resuming regularly scheduled monthly Emergency Cart checks by a Registered Nurse. It is the expectation of the Governing Body that 100% compliance is achieved and sustained. The Clinical Manager will be responsible to present a summary of the monthly Emergency Cart checks for contents, expiration dates of contents, cleanliness and proper functioning of all equipment to the QAI Committee monthly x 3 months. The Medical Director will review the results of audits each month at the QAI Committee meeting. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the

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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: 11/28/2022-12/1/2022</p> <p>Census by Service Type:</p> <p>In Center Hemodialysis: 28 Home Hemodialysis: 1 Home Peritoneal dialysis: 15 Total Census: 44</p>	V 0000	<p>resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI 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 QAI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 1/13/23</p> <p>POC listed per SOD</p>	

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V 0111  Bldg. 00	<p>Isolation Room/Waiver: No</p> <p>494.30 <b>IC-SANITARY ENVIRONMENT</b> The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.</p> <p>Based on observation, record review, and interview, the facility failed to ensure patient belongings were not stored in a designated clean area for 1 of 1 medication drawer observation (PCT3); failed to wear PPE (gloves, gown, mask) appropriately for 2 of 2 treatment floor observation days (PCT3); and failed to ensure all areas and items contained within the water room were clean, safe, and maintained appropriately for 1 of 1 water room (B1) observation.</p> <p>Findings include:</p> <p>1. A 01/04/2012 policy titled, Dialysis Precautions, was provided by the Clinical Manager (A1) on 12/1/2022 at 12:30 p.m. The policy indicated, but was not limited to, "Clean area: An area designated for clean and unused equipment, supplies, and medications."</p> <p>2. A 02/14/2018 policy titled, Personal Protective Equipment (PPE), was provided by A1 on 11/30/2022 at 1:50 p.m. The policy indicated, but was not limited to, "Employees with potential exposure to hazardous chemicals, blood, or other potentially infectious material. ... Personal protective fluid resistant gowns shall be changed whenever visibly soiled or in disrepair. ... gown may be reused by the original owner for as long as it is clean and intact. Facemasks are single-use only and must be discarded after the task for</p>	V 0111	<p>V111 IC-Sanitary environment On 12/1/2022, the Area Team Leader met with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policies and/or Procedures: Dialysis Precautions Personal Protective Equipment General Cleanliness and Infection Control Emphasis was placed on: Ensure the medication area/drawers are clearly separated and designated clean, for the preparation, handling and storage of medications and unused supplies and equipment Ensure used supplies, i.e., patient ear plugs are not stored in designated clean medication drawers Ensure fluid resistant barrier gowns are securely tied in the back. Ensure fluid resistant barrier gown ties are not removed Ensure walkways are maintained clear of supplies, equipment Ensure the water and supply areas are maintained clean and organized, clear of debris and free from clutter On 12/1/2022, the PCT 111 removed and discarded</p>	01/13/2023

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	<p>which they were needed is complete. ... Facemasks may not be maintained ... for later use."</p> <p>3. A revised 2/7/2022 policy titled "General Cleanliness and Infection Control" was provided A1 on 12/1/2022 at 12:30 p.m. The policy indicated but was not limited to, " ...maintain a clean, safe, and aesthetically pleasant environment for patients, staff and visitors ...Policy All areas must be kept clean and organized, including but not limited to the treatment area, water/supply room, and offices. Walkways must be kept clear of debris and free from clutter ..."</p> <p>4. During a flash tour on 11/28/2022 at 10:00 a.m. observed black ear plugs in an unlocked medication draw in a designated clean work area. At that time, PCT3 (Patient Care Technician) was interviewed and indicated the earplugs belonged to a patient and should not be kept in the medication drawer.</p> <p>5. During the treatment floor observation on 11/28/2022 between 10:00 a.m. and 2:00 p.m. PCT3's gown was not tied securely around his/her waste while providing direct patient care.</p> <p>6. During the treatment floor observation on 11/30/2022 at 11:25 a.m. PCT3's gown was without ties and not secured around his/her waist while providing direct patient care. PCT3 failed to wear the protective gown appropriately nor replace a disrepair gown while providing direct patient care.</p> <p>7. During an interview on 11/30/2022 at 4:00 p.m. A1 agreed that PPE should be worn appropriately, and patient personal items should not be stored in the medication drawer.</p> <p>8. During a flash tour and observation on 11/28/2022 at 9:39 a.m., the Clinical Manager (A1)</p>			<p>the patient head phones (ear plugs) from the medication drawer</p> <p>On 12/1/2022, the Bio Medical Technician: Removed the moving cart with 2 large blue barrels of liquid acid concentrate from the middle of the walkway entering the water/supply room Swept and cleaned the floor in the water area, removing the 11 used test strip and 1 deionized water bottle from the floor Discarded the (5) open containers of CitriClean without lids, labels or dates in the supply area and replaced them with appropriately dated, labeled bottles with lids Discarded the opened, unlabeled (3) bottles of standard buffer solution (7.00) (10.00)(4.00) on the cart in the supply area and replaced them with appropriately labeled bottles Discarded the (1) bottle of chlorine test strips unlabeled with date of opening and replaced it with an appropriately labeled bottle To monitor staff compliance with appropriate wearing of fluid resistant barrier gowns, maintaining clear separation and designation of clean and dirty supplies and equipment in the treatment area, and to ensure the walkways and the water and supply areas are maintained clean and free of debris and clutter, beginning 12/29/2022, the Clinical Manager or designee will conduct an observational infection control audit of the treatment floor and will</p>	

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	<p>opened the water/supply room and unlocked the gate to the water (Biotech) area. In the middle of the walkway set a moving cart with 2 large blue barrels of liquid acid concentrate, the water area evidenced 11 used test strips and 1 deionized water bottle on the floor, and in the supply area there were 5 open containers with clear liquid (Citruclean) on a cart with no lids, labels or dates, 3 bottles of standard buffer solution (7.00)(10.00) (4.00) opened and unlabeled, and opened chlorine test strips with no open date labeled. A1 failed to ensure the water/supply room and walkway was clean, organized, clear of debris and free from clutter.</p> <p>10. During a water room tour and observation on 11/28/2022 at 11:21 a.m., the BioMed technician (B1) opened the gate to the water area in the water/supply room. The water area evidenced 1 deionized water bottle and leaves on the floor throughout. B1 failed to ensure the water/supply room was clean and safe.</p> <p>11. During an interview on 11/28/2022 at 11:25 a.m., B1 indicated that the deionized bottle should not be on the floor but instead on the cart and there should not be trash or other items on the floor that doesn't maintain a clean environment.</p>			<p>conduct a walk-through of the water and supply areas daily x 2 weeks. Once compliance is achieved, the audit frequency will be decreased to weekly x 2 weeks. Once compliance is sustained, the Governing Body will recommend resuming regularly scheduled monthly audits based on the QAI calendar. It is the expectation of the Governing Body that 100% compliance is achieved and sustained, however, the Governing Body determined the facility threshold be established at 90%. If the audit findings fall below 90%, the Governing Body will reconvene and determine revision and implementation of the plan of correction. The Medical Director will review the results of audits each month at the QAI Committee meeting. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process</p>	

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V 0113  Bldg. 00	<p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.</p> <p>Based on observation, record review, and interview, the facility failed to ensure hemostasis was achieved and clean dressings were applied to AV sites prior to discharge for 2 of 3 observations of discontinuation of dialysis and post dialysis access care for an AV fistula. (Patients 9 &amp; 11); failed to remove gloves and perform hand hygiene after discontinuation of dialysis with central venous catheter for 1 of 2 observations (Patient 14); failed to prevent cross contamination with proper infection control protocols with tape boards for 2 of 2 observations days (PCT1, PCT2, PCT3, and RN2); failed to use PPE appropriately for 1 of 6 employees (PCT3); and failed to ensure staff and patient personal items were kept</p>		V 0113	<p>is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. External POC Report Page 3 of 18 Completion Date: 1/13/23</p> <p>V113 IC-Wear gloves/hand hygiene On 12/28/2022, the Clinical Manager will meet with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following Policies and/or Procedures: Personal Protective Equipment Access Assessment and Cannulation specific to tape preparation Hand Hygiene Dialysis Precautions Post Treatment Fistula Needle Removal Emphasis will be placed on: Ensure tape/tape boards are prepared and</p>	01/13/2023

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	<p>separate from Personal Protective Equipment (PPE) (gloves, gown, mask) used while in treatment area for 1 of 1 storage areas.</p> <p>Findings include:</p> <p>1. A revised 2/14/2018 policy titled Personal Protective Equipment was provided by the Clinical Manager (A1) on 11/30/2022 at 1:50 p.m. The policy indicated, but was not limited to, "The purpose of this policy is to identify the Personal Protective Equipment (PPE) and potential areas for use ... Gloves Change gloves and practice hand hygiene between each patient and/or station to prevent cross-contamination ... When touching any part of the dialysis machine or equipment at the dialysis station. Gloves must be worn appropriately ... Facemasks are single-use only and must be discarded after the task for which they were needed is complete. ..."</p> <p>2. During an observation on 11/30/2022 at 8:01 a.m., tape boards were being used by each staff member for patients in different stations. During the observation, the tape boards were not prepared, maintained, and stored in way that assured no cross contamination occurred. The boards were kept in a clean area with enough strips made to use for each patient that would receive dialysis in each station of a pod. Patient Care Technician 1 (PCT1), PCT2, and PCT4 failed to dispose of gloves, sanitize hands, and put new gloves on after leaving station and before retrieving tape strip from clean area to designate for a particular patient.</p> <p>3. During observations on 11/30/2022, tape boards were used in different ways causing opportunities for cross contamination.</p> <p>Observations were as follows: 7:20 a.m. tape strips</p>		<p>maintained in a designated, clean area, away from the patient stations to prevent the risk of cross contamination. Ensure tape prepared from a multi-use roll is torn in strips, tabbed at one end and stacked. The last piece of tape serves as a barrier, and should not be used on the patient. Ensure staff retrieve tape strips when ready to cannulate access and when ready to remove the fistula needles. Ensure gloves are removed and hands are decontaminated using alcohol based hand rub or by washing hands with antimicrobial soap and water when moving from the patient station to a designated clean area to retrieve clean supplies, i.e., tape strips. Hands will be disinfected, and clean gloves appropriately donned, not wadded, when touching any part of the dialysis machine, or equipment at the dialysis station. Patients will remove gloves and perform hand hygiene prior to leaving the patient station to obtain weight post treatment, and prior to exiting the treatment area. Staff are responsible to encourage patient hand hygiene post treatment after glove removal, i.e., offer hand sanitizer. Ensure Post needle removal, staff or patient applies pressure continuously 5-10 minutes. Staff will check for hemostasis. Once hemostasis is achieved, staff will remove the</p>	

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	<p>were observed directly on chair side table at station 13 (isolation room); 7:35 a.m. tape board lying directly onto a computer keyboard; 8:55 a.m. tape strips were attached to patient 3's treatment chair; 9:07 a.m. pre-torn tape strips attached to 2 N/S (normal saline) bags on top of the counter; 9:32 a.m. hand sanitizer bottle placed on top of a pre-torn tape board. The facility failed to prevent cross contamination of pre-torn tape for patient use.</p> <p>4. During an interview on 11/30/2022 at 12:15 p.m. the RN1 indicated that the tape boards being used were not an issue to be used for different patients in different stations because they were kept in clean areas.</p> <p>5. During an interview on 11/29/2022 at 3:20 p.m. the Medical Director (P1) indicated that it was alright to use the tape boards if they are prepared properly by staff ensuring no cross-contamination and infection control precautions were in place. P1 indicated that boards should not be stored in a way that would allow for other items or staff to come in contact with any part of it.</p> <p>6. During an interview on 11/30/2022 at 1:50 p.m., the Clinical Manager (A1) indicated gloves should be taken off, hands sanitized, and new gloves put on after discontinuing treatment and before helping a patient to pack up belongings and vacate a station. 7. During an observation on 11/28/2022 at 12:00 p.m. PCT3 was observed wading up a glove in his/her hand to touch the dialysis to turn off a sounding alarm at station 13. PCT3 failed to perform hand hygiene and apply a glove appropriately prior to touching a dialysis machine.</p> <p>8. During an observation on 11/28/2022 at 12:05</p>		<p>soiled gauze, place band-aid, adhesive dressing or clean gauze dressing secured with clean tape To monitor staff compliance with tape/tape board preparation, usage and maintenance, checking the access site for hemostasis and applying a clean dressing, and to monitor staff and patient compliance with glove usage and hand hygiene when moving from a dirty area to a clean area, beginning 12/29/2022 the Clinical Manager or designee will conduct observational infection control audits daily x 2 weeks. Once compliance is achieved, audit frequency will be decreased to weekly x 2 weeks. Once compliance is sustained, the Governing Body will recommend resuming regularly scheduled monthly infection control audits based on the QAI calendar. It is the expectation of the Governing Body that 100% staff compliance is achieved and sustained, however the Governing Body determined the facility threshold be established at 90%. If the infection control audit findings fall below 90%, the Governing Body will reconvene to determine revision and implementation of the plan of correction. The Medical Director will review the results of audits each month at the QAI Committee meeting. The Clinical Manager is responsible to review, analyze and trend all data and</p>	

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	<p>p.m. PCT3 was observed wading up a glove to press a button on the dialysis machine at station 16. PCT3 failed to perform hand hygiene and apply a glove appropriately prior to touching a dialysis machine.</p> <p>9. During an observation on 11/28/2022 at 1:30 p.m. patient 9 held pressure to his/her lower AV (arteriovenous) site with a gloved hand. PCT3 applied more tape over the taped 4x4 gauze dressing that was already in place. PCT3 failed to ensure hemostasis (stop bleeding) was achieved by lifting the 4x4 gauze dressing from the AV site and failed to replace the soiled gauze dressing with a clean dressing to the AV site prior to the patient leaving station 15. Patient 9 proceeded to remove his/her glove, walked to the weight scale, and pressed the button to obtain a weight without performing hand hygiene after glove removal. PCT3 failed to ensure patient 9 performed hand hygiene or offer hand sanitizer after glove removal before leaving the station.</p> <p>10. During an observation on 11/30/2022 at 9:20 a.m. patient 14 held pressure to his/her lower AV site with a gloved hand. PCT2 applied more tape over the taped 4x4 gauze dressing that was already in place. PCT2 failed to ensure hemostasis was achieved by lifting the 4x4 gauze dressing from the AV site and failed to replace the soiled gauze dressing with a clean dressing to the AV site prior to the patient leaving station 6.</p> <p>11. During an interview on 11/30/2022 at 4:00 p.m. A1 agreed infection control precautions should be followed, and staff should check for hemostasis and apply a new dressing to the AV sites prior to leaving the station.</p>		<p>Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI 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 QAI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 1/13/23</p>	

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V 0116  Bldg. 00	<p>494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT</p> <p>Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.</p> <p>-- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient.</p> <p>-- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.</p> <p>Based on observation, record review, and interview, the facility failed to ensure items taken into the dialysis stations were not returned to a designated clean area for 2 of 2 dialysis supply management and contamination prevention observations. (Stations 2 &amp; 6)</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. An 11/07/2022 policy, titled Cleaning and Disinfection of the Dialysis Station, was provided by A1 on 11/30/2022 at 1:50 p.m. The policy indicated, but was not limited to, "To prevent cross contamination between patients, it is important that the previous patient completely vacate the station before staff begin cleaning and disinfection of the station and set up for the next patient."</li> <li>2. A 02/14/2018 policy, titled Personal Protective Equipment (PPE), was provided by A1 on</li> </ol>	V 0116	<p>On 12/28/2022, the Clinical Manager will meet with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following Policies and/or Procedures:</p> <p>Cleaning and Disinfection of the Dialysis Station Personal Protective Equipment Emphasis will be placed on: Ensure patients completely vacate the dialysis station before the dialysis machine is externally disinfected, allowed to dry and set up for the next treatment. Ensure clean supplies for the next patient treatment are not brought into the dialysis station, until the patient receiving dialysis has completely vacated the dialysis chair/station</p>	01/13/2023

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	<p>11/30/2022 at 1:50 p.m. The policy indicated, but was not limited to, "Employees with potential exposure to hazardous chemicals, blood, or other potentially infectious material. ... Personal protective fluid resistant gowns shall be changed whenever visibly soiled or in disrepair. ... gown may be reused by the original owner for as long as it is clean and intact. Facemasks are single-use only and must be discarded after the task for which they were needed is complete. ... Facemasks may not be maintained ... for later use."</p> <p>3. During a flash tour on 11/28/2022 at 10:00 a.m. observed clean supplies (dialyzer / tubing) sitting on counter directly behind station 2's treatment chair while a patient was receiving dialysis treatment.</p> <p>4. During an observation on 11/28/2022 between 10:00 a.m. and 2:00 p.m. two face shields were hung across a plexiglass barrier marked as a designated clean area. One face shield had a name [RN2] printed on the side who was not presently in the building. The facility failed to ensure PPE was discarded or kept in a designed area for PPE.</p> <p>5. During an observation on 11/30/2022 at 2:15 p.m. observed a clean dialyzer sitting on counter directly behind station 6 while a patient was receiving dialysis. At that time, RN1 indicated the dialyzer should not be sitting on the countertop while the patient was receiving dialysis.</p> <p>6. During an interview on 11/28/2022 at 4:30 p.m. A1 indicated clean supplies should not be stored or brought to the dialysis station until the patient vacates the station. On 11/30/2022 at 4:00 p.m. A1 indicated that face shields were not to be stored on the plexiglass.</p>		<p>and the dialysis chair/station has been thoroughly cleaned and disinfected in accordance to FKC policy. Ensure clear separation and designation of clean and dirty areas. Face shields will be maintained in a designated area for Personal Protective Equipment, away from clean areas/supplies. To prevent cross contamination and to monitor staff compliance, beginning 12/29/2022, the Clinical Manager or designee will conduct observational infection control audits daily x 2 weeks. Once compliance is achieved, audit frequency will be decreased to weekly x 2 weeks. Once compliance is sustained, the Governing Body will recommend resuming regularly scheduled audits based on the QAI calendar. It is the expectation that 100% compliance is achieved and sustained, however, the Governing Body determined the facility threshold be established at 90%. If the audit findings fall below 90%, the Governing Body will reconvene to determine revision and implementation of the plan of correction. The Medical Director will review the results of audits each month at the QAI Committee meeting. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The</p>	

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V 0117 Bldg. 00	494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS  Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples		Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI 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 QAI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 1/13/23	

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	<p>are handled.</p> <p>When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.</p> <p>Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.</p> <p>Based on observation, record review, and interview, the facility failed to maintain the integrity of clean supplies and equipment in 1 of 3 clean and disinfection of dialysis station observations. (Station 3) (PCT4)</p> <p>Findings Include:</p> <ol style="list-style-type: none"> <li>1. A revised 11/7/2022 policy titled "Cleaning and disinfection of the dialysis station" was provided by Clinical Manager (A1) on 11/30/2022 at 1:50 p.m. The policy indicated but was not limited to, "Purpose The purpose of this policy is to provide guidelines to prevent the spread of infectious disease in accordance with appropriate regulations, and to maintain a clean, safe, and aesthetically pleasant environment for patients, staff and visitors ..."</li> <li>2. A revised 2/14/2018 policy titled Personal Protective Equipment was provided by the Clinical Manager (A1) on 11/30/2022 at 1:50 p.m. The policy indicated, but was not limited to, "Purpose The purpose of this policy is to identify the</li> </ol>	V 0117	<p>On 12/28/2022, the Clinical Manager will meet with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policies and/or Procedures: Cleaning and Disinfection of the Dialysis Station Hand Hygiene Emphasis will be placed on: Ensure bleach cloths that touch, or are dropped onto contaminated surfaces (dialysis chair, floor, etc.) are immediately discarded and not used Ensure staff remove gloves and perform hand hygiene with 60-90% alcohol-based hand rub or by washing hands with antimicrobial soap and water after touching the dialysis machine and prior to retrieving clean supplies from a designated clean area/cart. Ensure staff remove gloves, perform hand hygiene and don clean gloves before cleaning and</p>	01/13/2023

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	<p>Personal Protective Equipment (PPE) and potential areas for use ... Gloves Change gloves and practice hand hygiene between each patient and/or station to prevent cross-contamination ... When touching any part of the dialysis machine or equipment at the dialysis station. Gloves must be worn appropriately ... Facemasks are single-use only and must be discarded after the task for which they were needed is complete. ..."</p> <p>3. During an observation on 11/30/2022 at 9:15 a.m., Patient Care Technician (PCT4) was cleaning the dialyzer machine at station 3 with disinfectant soaked cloth with gloved hands. PCT dropped the sanitation cloth landing on the dirty patient chair. PCT4 retrieved the cloth from the patient chair, disposed of the cloth in hazard receptacle, then immediately went to the clean area, grabbed new cleaning cloths, saturated them in the bleach solution, and retrieved them from the solution. PCT4 went back to station 3 and resumed cleaning and disinfecting the dialyzer machine again. PCT4 failed to remove dirty gloves, sanitize hands, and apply new gloves prior to retrieving new cleaning cloths to finish disinfection of dialysis machine.</p> <p>4. During an interview on 11/30/2022 at 1:50 p.m. A1 indicated gloves should be doffed, hands sanitized, and new gloves donned anytime a station was left to dispose of or retrieve anything from a designated clean area.</p>			<p>disinfecting the dialysis station To monitor staff compliance with cleaning and disinfecting the dialysis station, glove usage and hand hygiene, beginning 12/29/2022, the Clinical Manager or designee will conduct observational infection control audits daily x 2 weeks. Once compliance is achieved, audit frequency will be decreased to weekly x 2 weeks. One compliance is sustained, the Governing Body will recommend resuming regularly scheduled infection control audits based on the QAI calendar. It is the expectation of the Governing Body that 100% compliance is achieved and sustained, however, the Governing Body determined the facility threshold be established at 90%. If the infection control audit findings falls to 90%, the Governing Body will reconvene to determine revision and implementation of the plan of correction. The Medical Director will review the results of audits each month at the QAI Committee meeting. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the</p>	

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V 0119  Bldg. 00	<p>494.30(a)(1)(i) IC-SUPPLY CART DISTANT/NO SUPPLIES IN POCKETS</p> <p>If a common supply cart is used to store clean supplies in the patient treatment area, this cart should remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood. Such carts should not be moved between stations to distribute supplies.</p> <p>Do not carry medication vials, syringes, alcohol swabs or supplies in pockets.</p> <p>Based on observation, record review, and interview, the facility failed to ensure items taken into the dialysis stations were not returned to a</p>	V 0119	<p>resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI 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 QAI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 1/13/23</p> <p>On 12/28/2022, the Clinical Manager will meet with facility staff to provide reeducation, elicit</p>	01/13/2023

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	<p>designated clean area for 2 of 2 dialysis supply management and contamination prevention observations. (Stations 2 &amp; 6)</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. A 01/04/2012 policy titled, Dialysis Precautions, was provided by the A1 (Administrator) on 12/1/2022 at 12:30 p.m. The policy indicated, but was not limited to, "Clean area: An area designated for clean and unused equipment, supplies, and medications."</li> <li>2. During a flash tour on 11/28/2022 at 9:50 a.m. observed black ear plugs in an unlocked medication drawer. At that time, PCT3 was interviewed and indicated it was probably a patient's personal earplugs. PCT3 indicated patient earplugs should not be kept in the medication drawer.</li> <li>3. During a flash tour on 11/28/2022 at 9:50 a.m. observed clean supplies (dialyzer / tubing) sitting on counter directly behind station 2 treatment chair while a patient was receiving dialysis treatment.</li> <li>4. During an observation on 11/30/2022 at 11:30 a.m. observed a clean dialyzer sitting on counter directly behind station 6 while a patient was receiving dialysis. At that time, RN2 indicated the dialyzer should not be sitting on the counter.</li> <li>5. During an interview on 11/28/2022 at 4: 30 p.m. the A1 indicated clean supplies should not be brought to the dialysis station until the patient vacates the station.</li> </ol>		<p>input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policies and/or Procedures: Dialysis Precautions Cleaning and Disinfection of the Dialysis Station Emphasis will be placed on: Ensure the medication area/drawers are clearly separated and designated clean. for the preparation, handling and storage of medications and unused supplies and equipment Ensure used supplies, i.e., patient ear plugs, are not placed or stored in designated clean areas/medication drawers Patients must completely vacate the dialysis station before the dialysis machine can be externally disinfected, allowed to dry and set up for the next patient treatment. Supplies for the next patient treatment will not be brought into the dialysis station until the patient has completely vacated the dialysis chair/station and the dialysis chair/station has been thoroughly cleaned and disinfected in accordance to FKC Policy. To monitor staff compliance with prevention of cross contamination, with clear separation of clean and dirty supplies, beginning 12/29/2022, the Clinical Manager or designee will conduct observational infection control audits daily x 2 weeks. Once compliance is achieved, audit frequency will be decreased to</p>	

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				weekly x 2 weeks. Once compliance is sustained, the Governing Body will recommend resuming regularly scheduled monthly infection control audits based on the QAI calendar. It is the expectation of the Governing Body that 100% compliance is achieved and sustained, however, the Governing Body determined the facility threshold be established at 90%. If the infection control audit findings falls below 90%, the Governing Body will reconvene to determine revision and implementation of the plan of correction. The Medical Director will review the results of audits each month at the QAI Committee meeting. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI 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 QAI monthly. The

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V 0122  Bldg. 00	<p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL</p> <p>[The facility must demonstrate that it follows standard infection control precautions by implementing-</p> <p>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]</p> <p>(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.</p> <p>Based on observation, record review, and interview, the facility failed to ensure standard infection control precautions were taken when cleaning and disinfecting contaminated surfaces for 3 of 3 observations of cleaning and disinfection of the dialysis station (Stations 6, 8 &amp; 14); and failed to clean and disinfect 2 of 2 countertop observations. (Station 3 &amp; 4)</p> <p>Findings include:</p> <p>1. A 11/07/2022 policy titled Cleaning and Disinfection of the Dialysis Station was provided by A1 on 11/30/2022 at 1:50 p.m. The policy indicated, but was not limited to, "Procedure ... 3.</p>	V 0122	<p>Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 1/13/23</p> <p>On 12/28/2022, the Clinical Manager will meet with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policies and/or Procedures: Cleaning and Disinfection of the Dialysis Station Emphasis will be placed on Ensure all work surfaces are thoroughly cleaned and disinfected with 1:100 Bleach solution after completion of each patient treatment. Ensure all surfaces of the dialysis chair and</p>	01/13/2023

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	<p>... Place the chair in Trendelenburg [recline] position and open side panels if chair has swing open sides so all surfaces of the chair are accessible. 4. Clean all surfaces. Make the surfaces glisteningly wet and allow to air dry ..."</p> <p>2. During a treatment floor observation on 11/28/2022 at 11:22 a.m. dust like gray matter found on countertops behind treatment chair station 3 and station 4. At that time, PCT1 was asked how often the countertops were cleaned to which he/she responded, "do not clean countertops daily".</p> <p>2. During an observation on 11/28/2022 at 12:00 p.m. observed PCT3 disinfecting a treatment chair using a zigzag wiping motion that did not visibly cover all surfaces of the treatment chair at station 14.</p> <p>3. During an observation on 11/28/2022 at 2:00 p.m. observed PCT1 disinfecting a treatment chair using a zigzag wiping motion that did not visibly cover all surfaces of the treatment chair at station 8.</p> <p>4. During an observation on 11/30/2022 at 9:32 a.m. PCT2 failed to fully recline the treatment chair at station 6 when cleaning and disinfecting the chair.</p> <p>5. During an interview on 11/30/2022 at 4:00 p.m. the A1 indicated all surfaces on the treatment chair should be disinfected.</p>		<p>equipment are made glisteningly wet and let air dry. Ensure that the dialysis wall boxes and the area/wall/countertops around the wall boxes are routinely cleaned at the end of each treatment day or immediately if splattered with blood. To monitor staff compliance with cleaning and disinfection of the dialysis station, beginning 12/29/2022, the Clinical Manager or designee will conduct observational infection control audits daily x 2 weeks. Once compliance is achieved, audit frequency will be decreased to weekly x 2 weeks. Once compliance is sustained, the Governing Body will recommend resuming regularly scheduled, monthly infection control audits based on the QAI calendar. It is the expectation of the Governing Body that 100% compliance is achieved and sustained, however the Governing Body determined the facility threshold be established at 90%. If the infection control audit findings falls below 90%, the Governing Body will reconvene to determine revision and implementation of the plan of correction. The Medical Director will review the results of audits each month at the QAI Committee meeting. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to</p>	

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V 0250  Bldg. 00	494.40(a) DIALYS PROPORT-MONITOR PH/CONDUCTIVITY 5.6 Dialysate proportioning: monitor pH/conductivity It is necessary for the operator to follow the manufacturer's instructions regarding dialysate conductivity and to measure approximate pH with an independent method before starting the treatment of the next patient.		<p>the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI 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 QAI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 1/13/23</p>	

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	<p>Based on observation, record review, and interview, the facility failed to ensure containers used for conductivity testing were labeled with appropriate name of solution for 2 of 2 RO (reverse osmosis) solution containers.</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. On 11/30/2022 at 7:52 a.m., two opened, unlabeled Rubbermaid containers of RO solution were observed in a designated clean area where conductivity testing was completed prior to dialyzing patients on the treatment floor.</li> <li>2. On 11/30/2022 at 9:30 a.m., two opened, unlabeled Rubbermaid containers of RO solution were observed in a designated clean area where conductivity testing was completed prior to dialyzing patients on the treatment floor. At 10:34 a.m., the same 2 Rubbermaid containers of RO solution were observed still opened and unlabeled while being used to do conductivity testing in the designated clean area.</li> <li>3. During an interview on 11/30/2022 at 3:55 p.m., the Clinical Manager (A1) stated the containers should be labeled as RO solution.</li> </ol>	V 0250	<p>On 12/28/2022, the Bio Medical Technician will meet with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policies and/or Procedures: Checking Conductivity and pH of Final Dialysate, specifically appropriate labeling of conductivity testing solutions Emphasis will be placed on: Ensure the Rubbermaid RO solution containers used for conductivity testing are appropriately labeled with date and contents daily To monitor staff compliance with appropriate labeling of the Rubbermaid containers of RO solution used for conductivity testing, beginning 12/29/2022, the Clinical Manager or designee will conduct an audit of the conductivity testing area/station and solution containers daily x 2 weeks. Once compliance is achieved, audit frequency will be decreased to weekly x 2 weeks. Once compliance is sustained, the the Governing Body will recommend resuming regularly scheduled monthly audits based on the QAI calendar. It is the expectation of the Governing Body that 100% compliance is achieved and sustained, however the Governing Body determined the facility threshold be established at 90%. If appropriately labeling the RO solution containers fall below 90%</p>	01/13/2023

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				<p>compliance, the Governing Body will reconvene to determine revision and implementation of the plan of correction. The Medical Director will review the results of audits each month at the QAI Committee meeting. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI 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 QAI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 1/13/23</p>	

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V 0401  Bldg. 00	<p>494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT</p> <p>The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.</p> <p>Based on observation, record review, and interview, the facility failed to provide adequate lighting to maintain a safe treatment environment during observations for 2 of 2 days.</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. A revised 12/18/2013 policy titled, "Physical Security and Facility Access" was provided by an employee on 12/1/2022 at 1:50 p.m. The policy indicated, but was not limited to, "Purpose To ensure a secure and safe environment for all staff, visitors, and patients while on FKC properties ...Physical Security Doors from the waiting area to the treatment area should remain closed and locked at all times while still allowing emergency access/exit ...All secondary external entrances (employee entrance doors, delivery doors) to the facility are to be kept closed and locked when not in use while still allowing emergency access ..."</li> <li>2. An observation of an employee only entrance door from the waiting area with access to the treatment area could be opened and allowed entrance without using the keypad on 11/28/2022 at 9:30 a.m. upon entering facility.</li> <li>3. During an interview on 11/28/2022 at 4:33 p.m., the Director of Operations (C1) indicated that the employee entrance door specified should be locked and only open with an appropriate code.</li> </ol>	V 0401	<p>On 11/29/2022, the Director of Operations met with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policies and/or Procedures: Physical Security and Facility Access Emphasis was placed on: Ensuring a secure and safe environment for all staff, visitors and patients. Doors from the waiting area to the treatment area will remain closed and locked at all times, while still allowing emergency access/exit. No persons other than the patients scheduled for treatment and authorized staff will be admitted into the treatment area while dialysis taking place On 11/29/2022, The Director of Operations immediately repaired the keypad on the employee only entrance door from the waiting area with access to the treatment area, ensuring that the door securely locks and will only open with the appropriate keypad code. To monitor staff compliance in maintaining a safe, functional and comfortable treatment</p>	01/13/2023

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			environment, beginning 11/30/2022, the Clinical Manager or designee will conduct visual observation audits of the door from the waiting room to the treatment area to ensure that it is maintained closed and locked at all times, daily x 2 weeks. Once compliance is achieved, audit frequency will be decreased to weekly x 2 weeks. Once compliance is sustained, the Governing Body will recommend resuming regularly scheduled monthly physical plant audits based on the QAI calendar. It is the expectation of the Governing Body that 100% compliance is achieved and sustained. If the audit findings fall below 100%, the Governing Body will reconvene to determine revision and implementation of the plan of correction. The Medical Director will review the results of audits each month at the QAI Committee meeting. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI	

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V 0543  Bldg. 00	<p>494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following:</p> <p>(1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status;</p> <p>Based on record review and interview, the facility failed to ensure incenter patient blood pressures (B/P) readings were monitored every 30 minutes or more during dialysis treatment for 1 of 5 record reviews (Patient 1); and failed to ensure patient's prescribed dialysis treatment matched the treatment delivered by the dialysis machine for 1 of 4 in-center patient prescription checks. (Patient 9)</p> <p>Findings include:</p>		V 0543	<p>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 QAI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 1/13/23</p> <p>On 12/28/2022, the Clinical Manager will meet with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policies and/or Procedures: Patient Assessment and Monitoring Emphasis will be placed on: Staff will ensure patient vital signs and machine safety checks are obtained every 30</p>	01/13/2023

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	<p>1. A 02/07/2022 policy titled Determination of Blood Pressure was provided by PCT 6 on 11/29/2022 at 1:52 a.m. The policy indicated, but was not limited to, "Incenter patients: Obtain blood pressure ... every 30 minutes or more during hemodialysis treatments ..."</p> <p>2. A 05/02/2022 policy titled Initiation and Termination of Treatment Using an Arteriovenous Graft or Fistula was provided by A1 on 11/30/2022 at 1:50 p.m. The policy indicated, but was not limited to, "When initiating the hemodialysis treatment, the appropriate procedure must be followed for the dialyzer and typed of machine used. ... all safety parameters must be verified."</p> <p>3. The clinical record review for patient 1 was reviewed on 11/28/2022 and indicated the following:</p> <p>On 11/28/2022 at 11:48 a.m. a blood pressure of 141/86 was recorded. At 12:33 p.m. the next recorded blood pressure was 147/91. The time between assessments was 45 minutes. The facility failed to monitor blood pressures every 30 minutes.</p> <p>On 11/23/2022 at 11:00 a.m. a blood pressure of 144/88 was recorded. At 12:09 p.m. the next recorded blood pressure was 98/74. The time between assessments was 1 hour 9 minutes. The facility failed to monitor blood pressures every 30 minutes.</p> <p>On 11/21/2022 at 2:03 p.m. a blood pressure of 141/93 was recorded. At 3:03 p.m. the next recorded blood pressure was 153/87. The time between assessments was 1 hour. The facility failed to monitor blood pressures every 30 minutes.</p>		<p>minutes or more as needed, not to exceed 45 minutes. To monitor staff compliance with patient assessment and monitoring every 30 minutes, not to exceed 45 minutes, beginning 12/29/2022, the Clinical Manager or designee will review 10% patient treatment sheets daily x 2 weeks. Once compliance is achieved, audit frequency will be decreased to weekly x 2 weeks. Once compliance is sustained, the Governing Body will recommend resuming regularly scheduled monthly medical record audits based on the QAI calendar. It is the expectation of the Governing Body that 100% compliance is achieved and sustained, however the Governing Body determined the facility threshold be established at 90%. If the treatment sheet audit falls below 90%, the Governing Body will reconvene to determine revision and implementation of the plan of correction. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions</p>	

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V 0550  Bldg. 00	<p>4. During the treatment floor observation on 11/28/2022 at 11:35 a.m. verified patient 9's prescription ordered by the physician at chairside along with A1. The dialysis prescription indicated patient 9 was to have a 180Nre Optiflux dialyzer (remove excess waste and fluid from the blood). Observed a 160NRe Optiflux dialyzer during patient 9's dialysis treatment. At that time, A1 indicated the physician ordered prescription was not followed.</p> <p>5. During an interview on 11/30/2022 at 4:00 p.m. A1 agreed that patient's blood pressures should be monitored every 30 minutes during dialysis treatment.</p> <p>494.90(a)(5) POC-VASCULAR ACCESS-MONITOR/REFERRALS The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. Based on observation, record review, and interview, the facility failed to ensure cannulation sites were not touched again after skin antisepsis</p>		V 0550	<p>taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI 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 QAI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 1/13/23</p> <p>On 12/28/2022, the Clinical Manager met with facility staff to provide reeducation, elicit input,</p>	01/13/2023

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	<p>for 1 of 3 dialysis initiation of an arteriovenous (AV) fistula. (PCT4)</p> <p>Findings include:</p> <p>A 07/05/2022 policy titled Access Assessment and Cannulation was provided by A1 on 11/30/2022 at 1:50 a.m. The policy indicated, but was not limited to, "Skin Disinfection ... 2. Perform skin antisepsis on one site at a time, allow to dry and then [sic] cannulate. Do not touch cannulation sites after skin disinfection. Note: This method minimizes the risk of contamination the second site while cannulating the first site. "</p> <p>During an observation on 11/30/2022 at 11:30 a.m. PCT4 located and palpated (examined by touch) patient 7's lower AV site. PCT4 applied an antiseptic (chemical to prevent infection) to patient 7's lower AV site. PCT4 palpated the AV site again after antiseptic was applied. PCT4 then inserted the cannulation (tube placed into vein) needle to the lower AV site. PCT4 failed to reapply the antiseptic to the AV site after the second palpation of the AV site.</p>		<p>and reinforce the expectations and responsibilities of the facility staff on the following FKC Policies and/or Procedures: Access Assessment and Cannulation Emphasis was placed on: Ensure staff do not touch cannulation sites after applying skin antisepsis and prior to cannulation of the access To monitor staff compliance with access assessment and cannulation, beginning 12/29/2022, the Clinical Manager or designee will conduct observational infection control audits of access assessment and cannulation daily x 2 weeks.. Once compliance is achieved, audit frequency will be decreased to weekly x 2 weeks. Once compliance is sustained, the Governing Body will recommend resuming regularly scheduled monthly infection control audits based on the QAI calendar. It is the expectation of the Governing Body that 100% compliance is achieved and sustained, however the Governing Body determined the facility threshold be established at 90%. If the access assessment and cannulation audit findings fall below 90%, the Governing Body will reconvene to determined revision and implementation of the plan of correction. The Medical Director will review the results of audits each month at the QAI Committee meeting . The Clinical Manager is</p>	

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V 0637  Bldg. 00	494.110(a)(2)(ix) QAPI-INDICATOR-INF CONT-TREND/PLAN/ACT The program must include, but not be limited to, the following: (ix) Infection control; with respect to this component the facility must-			responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI 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 QAI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 1/13/23

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	<p>(A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence; (B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and (C) Take actions to reduce future incidents.</p> <p>Based on record review and interview, the facility failed to ensure monthly staff audits were completed in the Quality Assessment Performance Improvement program (QAPI) for 1 of 1 facility QAPI program review.</p> <p>Findings include:</p> <p>An undated Clinical Audit Checklist Job Aid was provided by A1 on 12/1/2022 at 9:55 a.m. The job aid indicated, but was not limited to, "Purpose: Clinic Audit Checklists are tools that independently and objectively assess performance and improve the facility's operations. ... The Clinical Audit Checklist results are reported into the eQUIP system on a monthly basis with a numerical score and are to be reviewed monthly as indicated on the QAI Sample Meeting Agenda."</p> <p>Review of the Clinic Audit Checklist (General Audits) on 12/1/2022 failed to indicate the Clinical Practice Checklist, Water and Dialysate Observation, and Medication Safety audits were completed for the months of September and October of 2022.</p> <p>During an interview on 12/1/2022 at 8:05 a.m. the QAPI was reviewed along with A1 who indicated visual audits regarding patient care/ staff infection control practices that are included in the general audits should have been completed monthly.</p>	V 0637	<p>On 12/14/2022, the Clinical Quality Manager met with the Clinical Manager to provide reeducation, elicit input, and reinforce the expectations and responsibilities on the following FKC Policies and/or Procedures: Quality Assessment and Performance Improvement Clinical Audit Checklist Job Aid Emphasis will be placed on: It is the responsibility of the Clinical Manager to complete and document the Clinical Audit Checklist in accordance to FKC QAI calendar and program requirements, and to present the findings of the completed checklists to the QAI Committee monthly. To monitor Clinical Manager compliance with monthly completion and appropriate documentation of the Clinical Audit Checklist in the eQuip system, beginning December '2022, the Director of Operations will be responsible to review the completed checklists monthly x 3 months. The Clinical Manager will be responsible to print the completed Clinical Audit Checklists for the Director of Operations to review. The review</p>	01/13/2023

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				will be verified by the Director of Operations signature on the checklists. Once compliance is achieved, audit frequency will be decreased to bi-monthly x 4 months. Once compliance is sustained, the Governing Body will recommend resuming regularly scheduled monthly review of the completed monthly Clinical Audit Checklists findings in the QAI meetings. It is the expectation of the Governing Body that 100% compliance is achieved and sustained. The Medical Director will review the results of the Director of Operations review and Clinical Audit Checklist findings each month at the QAI Committee meeting. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI 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 QAI monthly. The

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V 0676  Bldg. 00	<p>494.130 LAB-CLIA LABS/MEET NEEDS OF PTS The dialysis facility must provide or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. Any laboratory services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter.</p> <p>Based on observation, record review, and interview, the agency failed to ensure laboratory supplies were maintained and disposed of according to the manufacturer's specifications for 1 of 1 facility.</p> <p>Findings include:</p> <p>1. A revised 5/2/2022 policy titled, "Medication Administration and Preparation" was provided by an employee on 12/1/2022 at 1:50 p.m. The policy indicated, but was not limited to, "...Monitoring Expired Medications Expiration dates for all stored medications are to be monitored on a monthly basis..."</p>		V 0676	<p>Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 1/13/23</p> <p>On 12/28/2022, the Bio Medical Technician will meet with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policies and/or Procedures: Expiration Dates of Sterile Supplies Emphasis will be placed on Sterile items that have reached expiration date will be appropriately discarded/disposed of Sterile items will be checked before use to ensure that they have not expired On 11/29/2022, the Area Team Leader discarded</p>	01/13/2023

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	<p>2. During an observation on 11/30/2022 at 8:20 a.m., multiple blood specimen collection tubes and [Name of Facility] Transplant Lab Box kits were found in a drawer. A review of the items evidenced 31 SST calcium tubes expired on 9/30/2022, 9 zinc tubes expired on 10/31/2022, and 5 transplant kits with a specimen tube within expired on 9/30/2021. The agency failed to ensure expired supplies were not available for use on the treatment floor and were disposed of properly.</p> <p>3. During an interview on 11/30/2022 at 8:20 a.m., Patient Care Technician (PCT1) 1 indicated that expired supplies should be disposed of and not remain on the floor.</p>		<p>the following expired items as identified in the Statement of Deficiencies: 31 SST calcium tubes expired 9/30/2022 9 zinc tubes expired 10/31/2022 5 transplant kits with a specimen tube within expired 9/30/2021 To monitor staff compliance with ensuring sterile lab supplies, available for patient use, are not expired, beginning 12/29/2022, the Clinical Manager or designee will conduct observational audits of the lab supplies weekly x 4 weeks. Once compliance is achieved, audit frequency will be decreased to bi-weekly x 4 weeks. Once compliance is sustained the Governing Body will recommend resuming regularly scheduled infection control audits based on the QAI calendar. It is the expectation of the Governing Body that 100% compliance is achieved and sustained, however, the Governing Body determined the facility threshold be established at 90%. If the lab supply audit findings fall below 90%, the Governing Body will reconvene to determine revision and implementation of the plan of correction. The Medical Director will review the results of audits each month at the QAI Committee meeting. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to</p>	

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V 0715  Bldg. 00	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; Based on observation, record review, and	V 0715	<p>the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI 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 QAI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 1/13/23</p>	01/13/2023

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	<p>interview, the Medical Director failed to ensure all policies and procedures relative to patient care and safety were adhered to by all individuals who treated patients in the facility.</p> <p>Findings include:</p> <p>A 05/02/2022 policy titled Quality Assessment and Performance Improvement was provided by A1 on 12/1/2022 at 1:10 p.m. The policy indicated, but was not limited to, "Responsibility: Medical Director, Director of Operations, Clinical Manager, Program Manager, Facility Administration .... Medical Director who is the Chairperson of the QAPI Committee and is responsible for: Effectiveness of the overall facility ... Communication with the Governing Body ... The QAPI Committee will monitor data/information; prioritize areas for improvement ... Elements to be reviewed will include: ... Infection Surveillance * Patient Safety ... Medical Records ... Staff Training and education ..."</p> <p>The Medical Director failed to ensure adherence to policies and procedures regarding the following: Emergency equipment (See tag E0028), Sanitary Environment (See tag V0111), Wearing Gloves/Hand Hygiene (See tag 0113), Cleaning/Disinfecting Dialysis Station (See tag V0116), Clean / Dirty prep areas (See tag V0117), Supplies/Dialysis Precautions (See tag V0119), Disinfection of Surfaces (See tag V0112), Safe Environment (See tag V0401), Manage Volume Status (See tag V0543), Monitoring Vascular Access (See tag V0550), QAPI (See tag V0637), Expired Supplies (See tag V0676), Complete Documentation (See tag V0726), Covid-19 Precautions (See tag V0800)</p> <p>During an interview on 11/29/2022 at 3:20 p.m. the</p>			<p>Operations met the Medical Director to review the Statement of Deficiencies, and to review the citations from the CMS Survey conducted on 12/1/2022. Emphasis was placed on: The expectations and responsibilities of the Medical Director to ensure staff adherence to all facility policies and procedures related to patient care and safety, with specific emphasis on the following: Ensure emergency equipment and supplies, available for use, are maintained within the manufacturer expiration dates (E 0028) Ensure a safe, sanitary and comfortable environment i.e., organized, free of clutter and debris for staff, visitors and patients (V 111) Ensure staff appropriately wear gloves and perform hand hygiene in accordance to FKC Policy and/or Procedure (V 113) Ensure appropriate cleaning and disinfection the dialysis station in accordance to FKC Policy and/or Procedure (V 116) Ensure clear separation, designation and maintenance of clean and dirty areas (V 117) Ensure clean patient supplies for the next treatment are not brought into the dialysis station while a patient is receiving dialysis (V 119) Ensure used patient supplies are not stored in designated clean medication drawers (V 119) Ensure doors entering the</p>	

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	Medical Director (P1) indicated the expectation was for all staff to adhere to policies and procedures at the facility.		treatment area are maintained closed and locked, secured from casual access (V 401) Ensure monitoring of patient vital signs every 30 minutes, not to exceed 45 minutes during treatment (V 543) Ensure access assessment and cannulation is performed in accordance to FKC Policy and Procedure to minimize the risk of contamination during cannulation of the access (V 550) Ensure monthly completion and documentation of Clinical Audit Checklist in accordance to FKC QAPI program requirements. (V 637) Ensure lab supplies are appropriately monitored for expiration dates and expired items are immediately discarded and not available for use (V 676) Ensure Tuberculosis (TB) Risk Assessment Patient Questionnaires are completed annually, with documented date of completion (V 726) Ensure all non-FKC visitors and vendors are appropriately screened and monitored for signs and symptoms of the COVID-19 infection upon entering the facility and before visiting any workspace (V 800) The Medical Director, as head of the QAI and Governing Body Committees of this facility, takes seriously his responsibility to ensure all policies and procedures relative to patient admissions, patient care, infection control and patient safety are adhered to by all	

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			individuals who treat patients at the facility. As such, on 12/19/2022, the Medical Director directed the Governing Body Committee to meet bi-weekly to review the progress of the plan of correction. Once 90% compliance is achieved and sustained, as determined by the Governing Body, the Medical Director will recommend resuming regularly scheduled monthly Governing Body meetings. The Governing Body will provide direct oversight to the plan of correction and will continue to follow the progress of the plan of correction through to complete resolution of the identified issues. It is the expectation of the Medical Director and the Governing Body Committee that 100% compliance is achieved and sustained, however, the Governing Body determined the facility threshold be established at 90%. If the plan of correction audit findings fall below 90%, the Governing Body will reconvene to determine revision and implementation of the plan of correction. The Medical Director will be responsible to review the results of all audits related to this plan of correction during the bi-weekly and monthly Governing Body meetings and each month at the QAI Committee meetings. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit	

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V 0726 Bldg. 00	494.170 MR-COMPLETE, ACCURATE, ACCESSIBLE The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment			results as related to this Plan of Correction prior to presenting to the Governing Body Committee bi-weekly and monthly, and the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI 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 QAI monthly. External POC Report Page 16 of 18 The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 1/13/23

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	<p>from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.</p> <p>Based on record review and interview, the facility failed to ensure patients medical records were complete and accurate for 2 of 2 records reviewed for TB risk assessments. (Patient 3 &amp; 14)</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. A 4/5/2021 policy titled Medical Record Documentation Standards was provided by the A1 on 12/1/2022 at 1:20 p.m. The policy indicated, but was not limited to, "The dialysis facility must monitor and maintain complete, accurate, and accessible records on all patients."</li> <li>2. During QAPI review on 12/1/2022 at 9:00 a.m. along with the A1, patient 14 Tuberculosis (TB) Risk Assessment Patient Questionnaire failed to indicate the date it was completed. At that time, the A1 indicated the form should have been dated.</li> <li>3. During QAPI review on 12/1/2022 at 9:10 a.m. along with A1, the facility failed to ensure a TB Risk Assessment Questionnaire was completed for patient 3 for the year 2020. At that time, A1 indicated he/she was not employed at the facility in the year 2020 and was unsure why the questionnaire was not completed.</li> </ol>	V 0726	<p>On 12/14/2022 , the Clinical Quality Manager met with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policies and/or Procedures:</p> <p>Patient Tuberculosis Testing Emphasis was placed on: On admission, patients who have no documented TB test within the last year will be tested using the Mantoux Tuberculosis Skin Test (TST) Patients who report previous positive TST and/or Interferon-Gamma Release Assay (IGRA) or previous diagnosis of TB or latent tuberculosis infection require a chest x-ray to rule out TB. Repeat TST or IGRA tests are not necessary. Chest x-ray must specify no evidence of TB For patient with a documented history of positive TST or IGRA, a Tuberculin Risk Assessment Questionnaire will be completed annually, staff are responsible to ensure the Risk Assessment Questionnaire is appropriately dated. Effective 12/19/2022, the Clinical Manager or designee will be responsible to monitor all new patient admissions to ensure appropriate tuberculosis testing and documentation in accordance to FKC policy and procedure</p>	01/13/2023

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			weekly x 4 weeks. Once compliance is achieved, audit frequency will be decreased to monthly x 3 months. Once compliance is sustained, the Governing Body will recommend resuming regularly scheduled audits based on the QAI calendar. It is the expectation of the Governing Body that 100% compliance is achieved and sustained. The Medical Director will review the results of audits each month at the QAI Committee meeting. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI 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 QAI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is	

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V 0800  Bldg. 00	<p>494.30 (b)(1)-(3)(i)-(x)</p> <p>COVID-19 Vaccination of Facility Staff</p> <p>§ 494.30 Condition: Infection control.</p> <p>(b) COVID-19 Vaccination of facility staff.</p> <p>The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.</p> <p>(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its patients:</p> <ul style="list-style-type: none"> <li>(i) Facility employees;</li> <li>(ii) Licensed practitioners;</li> <li>(iii) Students, trainees, and volunteers; and</li> <li>(iv) Individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or by other arrangement.</li> </ul> <p>(2) The policies and procedures of this section do not apply to the following facility staff:</p> <ul style="list-style-type: none"> <li>(i) Staff who exclusively provide telehealth or</li> </ul>			effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 1/13/23	

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	<p>telemedicine services outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (b)(1) of this section; and</p> <p>(ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (b)(1) of this section.</p> <p>(3) The policies and procedures must include, at a minimum, the following components:</p> <p>(i) A process for ensuring all staff specified in paragraph (b)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its patients;</p> <p>(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;</p> <p>(iv) A process for tracking and securely documenting the COVID-19 vaccination status for all staff specified in paragraph (b)(1) of this section;</p> <p>(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;</p>			

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	<p>(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;</p> <p>(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements;</p> <p>(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:</p> <p>(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and</p> <p>(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;</p> <p>(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute</p>			

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	<p>illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and</p> <p>(x) Contingency plans for staff who are not fully vaccinated for COVID-19.</p> <p>Effective 60 Days After Publication:</p> <p>(ii) A process for ensuring that all staff specified in paragraph (b)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;</p> <p>Based on observation, record review, and interview, the facility failed to ensure all visitors were screened daily for 4 of 4 survey days.</p> <p>Findings include:</p> <p>1. A revised 9/16/2022 policy titled, "COVID-19 Disease Testing and Return to Work of Non-FKC FMCNA Employees and Non-FMCNA Vendors" was provided by the Director of Operations (C1) on 12/1/2022 at 11:46 a.m. The policy indicated, but was not limited to, "Purpose To provide guidance on the Corona Virus Disease (COVID-19-virus) ...Policy ...All Non-FKC FMCNA employees and non-FMCNA vendors are required to follow daily screening practices, monitor for signs and symptoms of the COVID-19 infection before visiting any workspace..."</p> <p>2. On 11/28/2022 at 9:30 a.m., surveyors were not screened for Covid-19 upon entrance of the building or treatment floor for the following dates:</p>	V 0800	<p>On 12/1/2022, the Director of Operations met with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policies and/or Procedures: Guidance on Dialyzing and Infection Control Practices During a COVID-19 Endemic in Fresenius Kidney Care (FKC) Dialysis Clinics Emphasis will be placed on: Regardless of COVID-19 vaccination and/or booster status, all patients, visitors, staff physicians, and physician extenders entering an FKC dialysis clinic must be screened for ongoing signs and symptoms of COVID-19 disease To monitor for staff compliance in appropriate COVID-19 screening of all visitors entering the facility, beginning</p>	01/13/2023

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	<p>11/28/2022 at 9:30 a.m., 11/29/2022 at 9:00 a.m., 11/30/2022 at 7:45 a.m., and 12/1/2022 at 7:45 a.m.</p> <p>3. During an interview on 11/30/2022 at 3:55 p.m., the Director of Operations (C1) and Clinical Manager (A1) indicated that the surveyors are visitors and should have been screened daily.</p>		<p>12/2/2022, the Clinical Manager or designee will review the daily COVID-19 patient and visitor screening forms for accuracy daily x 2 weeks. Once compliance is achieved, audit frequency will be decreased to weekly x 2 weeks. Once compliance is sustained, the Governing Body will recommend resuming regularly scheduled audits based on the QAI calendar. It is the expectation of the Governing Body that 100% compliance is achieved and sustained. The Medical Director will review the results of audits each month at the QAI Committee meeting. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI 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 QAI monthly. The Governing Body is responsible to provide oversight to ensure the</p>	

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				Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 1/13/23