

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	(X3) DATE SURVEY COMPLETED 05/23/2024
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST		STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 0000 Bldg. 00	<p>This visit was for a Federal complaint survey of an ESRD Provider.</p> <p>Survey Dates: 05-20, 05-21, 05-22, and 05-23-2024.</p> <p>Facility #: 005149</p> <p>CCN#: 152502</p> <p>Complaint: IN00433879 with related and unrelated Federal deficiencies cited.</p> <p>Complaint: IN00433782 with related and unrelated Federal deficiencies cited.</p> <p>Complaint: IN00433630 with related and unrelated Federal deficiencies cited.</p> <p>Complaint: IN00433302 with related and unrelated Federal deficiencies cited.</p> <p>Census by Service Type: In Center Hemodialysis: 179 No Home Hemodialysis or Peritoneal Dialysis: 0 Total Census: 179</p> <p>Stations: 36 and 1 isolation room.</p> <p>QR completed by Area 3 on 5/04/2024.</p>	V 0000		
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 the staff</p>	V 0113	By 06/11/2024, the Clinical Manager will hold a staff meeting	06/21/2024

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

TITLE

(X6) DATE

Patrice Williams

Clinical Manager

06/14/2024

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>instructed the patients on the proper use of hand hygiene after holding their access with a gloved hand during 3 of 6 termination of treatment observations. (Patients: #24, 25, and 27)</p> <p>Findings Include:</p> <p>1. A policy dated 11-06-2023, "Hand Hygiene," indicated but was not limited to, "Purpose: The purpose of this policy is to prevent transmission of pathogenic microorganisms to patients and staff through cross-contamination. Responsibility: All staff, patients ... Policy: Hand hygiene includes either washing hands with soap and water or using a waterless alcohol-based antiseptic hand rub with 60-90% alcohol content ... Hand Hygiene: Patients: Patients should perform hand hygiene if able, prior to and after each dialysis treatment ... "</p> <p>2. On 05-23-2024 at 1:50 PM, a sign posted on the wall above the scale of the entrance to the treatment area was reviewed. The sign stated, "Please Wash Your Hands. Help Us Keep You Safe."</p> <p>3. During an interview on 05-20-2024 at 3:35 PM, when queried regarding staff offering hand hygiene after their treatment, Patient #23 confirmed the staff did not offer hand hygiene.</p> <p>4. During an observation on 05-20-2024 at 3:40 PM, PCT 6 was observed assisting Patient #24 after the patient held their left vascular access site with a right gloved hand at Station #29. Patient #24 was not instructed or offered hand hygiene prior to leaving the treatment floor.</p> <p>During an interview on 05-20-2024 at 3:45 PM, Patient #24 confirmed the staff do not offer hand</p>			<p>and reinforced the expectations and responsibilities of the facility staff on policy and procedure: Hand Hygiene Policy and Procedure Emphasis was placed on: Patients should perform hand hygiene prior to and after each dialysis treatment. As needed, direct patient care staff will demonstrate how to operate the sinks, demonstrate hand washing to patients who are able to perform hand washing, and explain the risk of contamination with regard to their vascular access and hands to all patients. By 06/11/2024, 100% of all patients will be re-educated on hand hygiene with documentation of education noted in each patient's EMR. Those patients absent on the day of education will be re-educated on their first treatment back at the facility with documentation noted in the EMR. Effective 06/12/2024, the Clinical Manager will conduct weekly audits with focus on ensuring 100% of patients are offered and/or perform hand hygiene upon entering and exiting the treatment area for 4 weeks or until 90% compliance is achieved utilizing Infection Control Audit Tool. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic</p>

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	<p>hygiene prior to them leaving the treatment floor.</p> <p>5. During an observation on 05-21-2024 at 1:16 PM, PCT 7 was observed assisting Patient #27 after the patient held their right vascular access site with a left gloved hand at Station #6. Patient #27 was not instructed or offered hand hygiene prior to leaving the treatment floor.</p> <p>6. During an observation on 05-22-2024 at 10:10 AM, RN 9 was observed assisting Patient #25 after the patient held their right vascular access site with a left gloved hand at Station #36. Patient #25 was not instructed or offered hand hygiene prior to leaving the treatment floor.</p> <p>During an interview on 05-23-2024 at 5:40 PM, PCTs 4 and 10 indicated the patients were to be offered hand hygiene after holding the access prior to leaving the treatment floor.</p>			<p>Audit Tool per QAI calendar. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>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.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body</p>	

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V 0121 Bldg. 00	<p>494.30(a)(4)(i) IC-HANDLING INFECTIOUS WASTE [The facility must demonstrate that it follows standard infection control precautions by implementing-] (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the- (i) Handling, storage and disposal of potentially infectious waste; Based on observation, record review, and interview, the facility failed to minimize the risk of occupational exposure to needlesticks with overfilled sharp containers at the treatment stations and nurses' station for 1 of 1 the stand alone in-center facilities.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. A review of a policy dated 11-06-2023, "Exposure Categories and Determination" indicated but was not limited to, " ... Direct patient care staff who are potentially exposed to injuries from contaminated sharps ... " 2. A review of a policy dated 05-02-2022, "Infection Control Overview" indicated but was not limited to, " ... FMC is committed to abiding by laws and regulations of the Occupational Safety and Health Administration (OSHA) ... Safe and efficient handling and disposal of waste and contaminants ... Engineering Controls: controls (e.g. sharps disposal containers, 	V 0121	<p>minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 06/21/24.</p> <p>By 06/11/2024, the Clinical Manager will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p> <p>General Cleanliness and Infection Control Guidelines</p> <p>Exposure and Determination Infection Control Overview</p> <p>Emphasis was placed on:</p> <p>All containers for storage or disposal of needles/sharps shall be replaced on a regularly scheduled basis or when no more than 2/3 to 3/4 full. The containers must be closed prior to being full and prior to being disposed.</p> <p>Effective 06/12/2024, the Clinical Manager will conduct weekly audits with a focus on ensuring staff replace needle/sharps containers on a regularly scheduled basis or when no more</p>	06/21/2024

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	<p>self-sheathing needles ...) isolate or remove the bloodborne pathogens hazard from the workplace ...)</p> <p>3. A review of a policy dated 04-05-2021, "General Cleanliness and Infection Control Guidelines" indicated but was not limited to, " ... All containers for storage of needles/sharps shall be replaced on a regularly scheduled basis or when no more than 2/3 to 3/4 full ... "</p> <p>4. During a flash tour on 05-20-2024 at 10:10 AM, overfilled sharps containers were observed on the treatment floor attached to the dialysis machines at Stations #25 and #26.</p> <p>5. During an observation on 05-20-2024 at 10:41 AM, observed at the Nurses' station, and Stations #10, #27, #28, and #32 overfilled sharp containers.</p> <p>During an interview on 05-20-2024 at 10:41 AM, the registered nurse (RN) confirmed the sharps container at the nurses' station was overfilled and needed replaced.</p> <p>6. During an observation on 05-21-2024 at 1:00 PM, observed at Stations #30, #31, #32, and #33 overfilled sharp containers.</p> <p>During an interview on 05-21-2024 at 1:50 PM, the Patient Care Technician (PCT) 2 indicated the sharps containers should be emptied by the PCT who works that track. PCT 2 further indicated these had not been emptied.</p>		<p>than 2/3 to 3/4 full for 4 weeks or until 100% compliance is achieved utilizing the Infection Control Audit Tool. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Tool per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The 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.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p>	

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V 0126 Bldg. 00	<p>494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF Hepatitis B Vaccination</p> <p>Vaccinate all susceptible patients and staff members against hepatitis B. Based on record review and interview, the facility failed to ensure all employees were vaccinated against Hepatitis B (Hep B) or completed a Hep B declination of refusal for 2 of 6 active personnel files reviewed. (Employees: Facility Administrator (FA) and Licensed Practical Nurse (LPN) 1)</p> <p>Findings Include:</p> <p>1. A review of a policy dated 04-05-2021, "Employee Requirements for Testing and Vaccination for Hepatitis B" indicated but was not limited to, " ... The Hepatitis B vaccine shall be offered to all employees upon hire or rehire ... Hepatitis B vaccination status shall be documented in the employee's vaccination records including: signed consent or declaration forms, dates of all the hepatitis B vaccinations,</p>	V 0126	<p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 06/21/2024.</p> <p>By 06/11/2024, the Clinical Manager will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p> <p>Employee Requirements for Testing and Vaccination for Hepatitis B Emphasis was placed on:</p> <p>The Hepatitis B vaccine shall be offered to all employees upon hire or rehire. Prior to vaccine administration, draw the hepatitis B antibody (anti-HBs) to determine susceptibility.</p>	06/21/2024

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	<p>documentation of having received the vaccination information statements ... "</p> <p>2. A review of the personnel file for FA, date of hire 01-08-2024, failed to evidence a Hep B declination of refusal, a Hep B antibody test, or dates of the Hep B vaccine series.</p> <p>During an interview on 05-23-2024 at 10:15 AM, the Regional Director of Operations/Interim Regional Vice President, Corp 2, confirmed the FA's personnel file failed to contain the required documentation of their Hep B vaccination status.</p> <p>3. A review of the personnel file for LPN 1, date of hire 12-05-2022, failed to evidence a Hep B declination of refusal, a Hep B antibody test, or dates of the Hep B vaccine series.</p> <p>During an interview on 05-23-2024 at 10:15 AM, Corp 2, confirmed LPN 1's personnel file failed to contain the required documentation of their Hep B vaccination status.</p>		<p>There is no requirement for testing Hepatitis B surface antigen (HBsAg) and hepatitis B total core antibody (anti-HBc) unless specified by state regulations.</p> <p>A protective antibody response is 10 or more milli-international units (mIU) per milliliter (anti-HBs³ 10mIU/mL).</p> <p>If susceptible, offer vaccine.</p> <p>Refer to Special Consideration policies for ENGERIX-B or HEPLISAV-B for vaccine administration.</p> <ul style="list-style-type: none"> o If the employee declines, a signed declination must be maintained in the employee file. If immune, vaccination is not needed. If the employee can provide a copy of their vaccination record (from primary care physician or previous employer), a signed declination is not required. If the employee is unable to provide proof of vaccination, a signed declination is required. <p>By 06/12/2024, the Clinical Manager will review 100% of all clinical staff currently working at the facility to ensure Hepatitis B surface antigen blood results are present or a signed declination by the employee. Employee records available upon request at the facility for review.</p> <p>Effective 06/12/2024, the Clinical Manager will conduct monthly audit with focus on ensuring new</p>	

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			<p>hire, rehire or transfer staff are offered Hepatitis B surface antigen vaccine with blood results present or a signed declination by the employee, as required, utilizing Personnel Tracker Audit Tool for 3 months and then an additional 3 months. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The 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.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to</p>	

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V 0142 Bldg. 00	<p>494.30(b)(1) IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P</p> <p>The facility must-</p> <p>(1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit;</p> <p>Based on record review and interview, the facility failed to ensure all employees were tested for tuberculosis (TB) in 4 of 6 personnel records reviewed. (Employees: Facility Administrator (FA), Patient Care Technician (PCT) 1 and 2, and Licensed Practical Nurse (LPN) 1)</p> <p>Findings Include:</p> <p>1. A review of a policy dated 02-05-2024, "Employee Tuberculosis Testing" indicated but was not limited to, " ... TB testing using the</p>	V 0142	<p>develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 06/21/2024.</p> <p>By 06/11/2024, the Clinical Manager will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p> <ul style="list-style-type: none"> Employee Tuberculosis Testing <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> TB testing using the two-step tuberculin skin test (TST) 	06/21/2024

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	<p>two-step tuberculin skin test (TST) method is required upon hire ... If a new employee has a documented baseline TST result within the previous 12 months, a single TST can be administered ... If an employee provides Interferon-Gamma Release Assay (IGRA) results ... results must be within the last 12 months ... A recent chest x-ray with the previous 6 months can be used as evidence ... "</p> <p>2. A review of the personnel file for the FA, date of hire 01-08-2024, failed to evidence a chest x-ray, 2-step TST, or IGRA results.</p> <p>3. A review of the personnel file for PCT 1, date of hire 11-28-2016, failed to evidence a chest x-ray, 2-step TST, or IGRA results.</p> <p>4. A review of the personnel file for PCT 2, date of hire 07-25-2022, failed to evidence a chest x-ray, 2-step TST, or IGRA results.</p> <p>5. A review of the personnel file for LPN 1, date of hire 12-05-2022, failed to evidence a chest x-ray, 2-step TST, or IGRA results.</p> <p>During an interview on 05-23-2024 at 10:15 AM, the Regional Director of Operations/Interim Regional Vice President, Corp 2, confirmed during the personnel record review the personnel records were missing TB testing documentation.</p>		<p>method is required upon hire. The Healthcare Personnel TB Baseline Risk Assessment and TB Risk Assessment Review Questionnaire (TB-RAQ) are required to be completed on all new employees.</p> <p>Effective 06/12/2024, Clinical Manager will conduct weekly audits with focus on ensuring all direct patient care staff complete 2-step tuberculosis test upon hire. Also, the Healthcare Personnel TB Baseline Risk Assessment and TB Risk Assessment Review Questionnaire (TB-RAQ) for all new employees utilizing Employee Personnel Audit Tool for 2 weeks and then weekly for an additional 4 weeks. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The 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.</p>	

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V 0143 Bldg. 00	494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS [The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and			<p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 06/21/2024.</p>

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST		STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
	<p>ampules; and</p> <p>Based on observation, record review, and interview, the facility failed to ensure the staff monitored and discarded the liquid nutrition within 3 months of opening at 1 of 1 medication stations.</p> <p>Findings Include:</p> <ol style="list-style-type: none"> 1. A review of a policy dated 02-06-2023, "Medication Preparation and Administration" indicated but was not limited to, " ...Expiration dates for all stored medications are to be monitored on a monthly basis ... Patient specific bulk containers of oral liquids ... expiration date/ maximum time period for use per manufacturer's expiration date ... " 2. A review of the Liquacel (a liquid protein supplement) container's label for directions indicated to use the product within 3 months of opening. <p>During a flash tour observation on 05-20-2024 at 10:10 AM, observed on the top of the medication station were 5 open 32-ounce containers of Liquacel (a liquid protein supplement). Grape Liquacel with date opened 11-15-2023, Ginger Ale with date opened 10-05-2023, the and the Peach Mango Liquacel with date opened 10-19-2023.</p> <p>During an interview on 05-20-2024 at 10:41 AM, Registered Nurse (RN) 2 indicated they were to use the Liquacel within 1 month of it being opened. RN 2 reviewed the container of Liquacel and confirmed that the containers must be used within 3 months of opening.</p>	V 0143	<p>By 06/11/2024, the Clinical Manager will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p> <p>Medication Preparation and Administration</p> <p>Emphasis was placed on:</p> <p>When preparing medications/ or Oral Nutritional Supplements (ONSP), if the vial is not used immediately in its entirety, the nurse or PCT (if allowed by state regulations), must place the date and time the vial was opened on the medication label along with their initials.</p> <p>Expiration dates for all stored medications are to be monitored on a monthly basis.</p> <p>Expired medications are to be discarded via Fresenius Kidney Care off-site return program or in accordance with local and/or state law.</p> <p>Any open multi dose vials must be discarded 28 days after opening or per manufacturer's expiration date.</p> <p>Floorstock containers of oral solids and oral liquids in bulk bottles per Manufacturer's expiration date.</p> <p>Effective 06/12/2024, the Clinical Manager will conduct weekly audits with focus on ensuring medications/ or Oral Nutritional Supplements (ONSP), are monitored for expiration dates for 4</p>	06/21/2024

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			<p>weeks or until 100% compliance is achieved utilizing Plan of Correction Audit Tool. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Tool per QAI calendar. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>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.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible</p>	

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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 ensure a safe and comfortable environment in 4 of 4 observations at the facility's entrance.</p> <p>Findings include:</p> <p>1. A review of a policy dated 04-05-2021, "General Cleanliness and Infection Control Guidelines" indicated but was not limited to, "The purpose of this policy is to provide guidance for FKC staff on the spread of infectious disease and maintaining a clean, safe, and aesthetically pleasant environment for patients, staff, and visitors.</p> <p>2. On 05-20-2024 at 9:44 AM, observed upon entering the front doors piles of cigarette butts, used paper towels, and used 3 dirty blue surgical</p>	V 0401	<p>for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 06/21/2024.</p> <p>By 06/11/2024, the Clinical Manager will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p> <p>General Cleanliness and Infection Control Guidelines Emphasis was placed on:</p> <p>To provide guidance for FKC staff on preventing the spread of infectious disease and maintaining a clean, safe, aesthetically pleasant environment for patients, staff, and visitors.</p> <p>Trash outside at the main entrance and around the building Cigarettes, mask, and other</p>	06/21/2024

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	<p>masks on the left side of the entry door.</p> <p>3. On 05-21-2024 at 8:30 AM, observed upon entering the front doors piles of cigarette butts, used paper towels, and used 3 dirty blue surgical masks on the left side of the entry door.</p> <p>4. On 05-22-2024 at 9:25 AM, observed upon entering the front doors piles of cigarette butts, used paper towels, and used 3 dirty blue surgical masks on the left side of the entry door.</p> <p>During an interview on 05-22-2024 at 11:11 AM, Patient #4 confirmed the facility had trash outside the front entrance door.</p> <p>5. On 05-23-2024 at 7:55 AM, observed upon entering the front doors piles of cigarette butts, used paper towels, and used 3 dirty blue surgical masks on the left side of the entry door.</p> <p>During an interview on 05-23-2024 at 2:00 PM, the Facility Administrator (FA) was not sure who should clean the facility grounds, the housekeeping staff or the lawn care company. The management team will verify and follow up.</p>			<p>debris on floors throughout the facility</p> <p>Effective 06/12/2024, the Clinical Manager will conduct weekly audits with focus on ensuring the facility is clean and well maintained with no trash on floor or outside at main entrance and around building utilizing Building Interior/ Exterior Physical Environment Inspection Audit for four weeks or until 100% compliance is achieved. Once compliance is sustained, the Governing Body will decrease frequency to resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Checklist Tool per QAI calendar. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>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.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting</p>	

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V 0465 Bldg. 00	<p>494.70(a)(14) PR-INFORMED OF INTERNAL GRIEVANCE PROCESS</p> <p>The patient has the right to-</p> <p>(14) Be informed of the facility's internal grievance process;</p> <p>Based on record review and interview, the facility failed to ensure patients were made aware of the grievance process, promptly acknowledged and reported all patient grievances, investigated and addressed the patient's grievance, and reported back to the patient with a resolution for 1 of 1</p>		V 0465	<p>through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 06/21/2024.</p>	06/21/2024

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	<p>stand alone in-center facilities.</p> <p>Findings include:</p> <p>1. A review of a policy dated 04-04-2014, "Patient Grievance Procedure" indicated but was not limited to, " ... To comply with federal and state regulations ... To inform patients, or patient representative of the FMCNA Grievance Process ... Educating patient on ... Promptly acknowledge the patient/family members concern ... Assisting and assessing and resolving patient grievances ... Completing the Patient Grievance status report ...provide periodic updates to the patient ... "</p> <p>2. A review of the Patient Grievance Report dated 12-27-2023 through 05-20-2024 revealed patient grievances related to staff care, attitude, chair location, treatment denial due to the patient's unstable condition, and missing phone. Requested the staff and patient grievances regarding staffing.</p> <p>During an interview on 05-20-2024 at 3:00 PM, when asked about staff and patient complaints about staffing and shortened treatments, the Facility Administrator (FA) and Director of Operations (DO), indicated they did not have those.</p> <p>3. During an interview on 05-21-2024 at 9:30 AM, Patient #3 confirmed they had filed a grievance regarding care and staffing. Patient #3 indicated they had no further problems with care and stated, "They do their best, but they need help."</p> <p>4. During an interview on 05-22-2024 at 5:15 PM, Patient #5 confirmed their treatments were shorted to 3 hours a couple of weeks ago. When asked if</p>		<p>Emphasis was placed on: Social Worker (MSW) provides "What to Do if You Have a Concern" and "Important Numbers" handouts to the patient or patient representative. Note: MSW emphasizes the following key points during review of these documents: · Patient's right to file a grievance written or verbally, anonymously or through a representative without being afraid that he/she will be treated differently or denied services. · FKC's internal grievance process and the steps to follow for filing an internal grievance. · Patient's right to seek external help to resolve grievances that cannot be resolved internally or if patient is not comfortable using the internal process, and how to contact the ESRD Network and the State survey agency to file a grievance. After review of the grievance process, MSW asks the patient to sign the Acknowledgement of Patient Grievance Procedure and file in the patient's medical record.</p> <p>All facility staff Promptly acknowledging the patient/family members concern and reporting any patient grievances to the Nurse in Charge or the Team Leader. Assisting in assessing and resolving patient grievances as appropriate.</p> <p>Nurse in Charge or Team Leader Meeting with the</p>	

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

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	<p>they complained to the management staff, Patient #5 indicated the manager was not available for calls, returned calls, or did not know who the manager was to file a complaint.</p> <p>5. During the Daily Conference on 05-20-2024 at 4:15 PM, the FA confirmed they had received complaints from staff and patients and did not complete grievance reports.</p>			<p>patient/representative within 72 hours of being notified of a grievance. · Assisting in assessing and resolving patient grievances as appropriate. · Completing as many fields as possible on the Patient Grievance Status Report.</p> <p>Clinical Manager (CM) Reviewing the Patient Grievance Status Report daily. · Meeting with the patient/representative within 5 days to discuss the grievance, resolve it as quickly as possible, and provide periodic updates to the patient. · Documenting actions taken on the Patient Grievance Status Report and reporting this information to the Quality Assessment and Performance Improvement (QAI) Committee. · Escalating unresolved grievances to the attention of the Director of Operations /Area Manager. · Ensuring the facility is adhering to the Patient Grievance Policy.</p> <p>Director of Operations (DO)/Area Manager (AM) Meeting with the patient/representative within 5 days to discuss the grievance, resolve it as quickly as possible, and provide periodic updates to the patient. · Escalating unresolved grievances to the attention of the Regional Vice President. · Ensuring the facility has posted all of the required information outlined in this policy and updating these postings as applicable. · Ensuring</p>

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

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			<p>that all patient grievances are reported to the QAI Committee and to the Governing Body. · Ensuring the facility is adhering to the Patient Grievance Policy.</p> <p>Regional Vice President (RVP) Contacting the patient/representative within 10 days to discuss the grievance and resolve as quickly as possible as possible. · Reporting escalated patient Grievances to the Governing Body and documenting any issues identified and resolution in the minutes. · Ensuring that there is a culture of caring conducive to collaborative problem solving. · Assuming responsibility for DO/AM vacancies in regard to the grievance process.</p> <p>(QAI) Committee Reviewing and trending patient grievance investigations as a means to identify opportunities to improve care.</p> <p>Governing Body Establishing an internal grievance process. · Ensuring the facility's grievance process is implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services and addressing any issues identified.</p> <p>By 06/12/2024, 100% of all patients will be re-educated by the MSW on the Patient Grievance Procedure with documentation of education noted in each patient's</p>	

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			<p>EMR. Those patients absent on the day of education will be re-educated on their first treatment back at the facility with documentation noted in the EMR.</p> <p>Effective 06/14/2024, the Clinical Manager will review/audit the grievance log daily, 3 times per week, with focus on ensuring all staff document any concern or complaint raised by the patient or the patient's representative, utilizing grievance log Tool for 2 weeks and then will complete 2 times weekly for an additional 4 weeks. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The 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.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting</p>	

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V 0503 Bldg. 00	<p>494.80(a)(2) PA-APPROPRIATENESS OF DIALYSIS RX The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>(2) Evaluation of the appropriateness of the dialysis prescription, Based on record review and interview, the facility failed to ensure the patient's targeted estimated dry weight (EDW) was met post-treatment and failed to ensure the Registered Nurse (RN) had notified the physician in 6 of 6 records reviewed. (Patients: #2, 3, 4, 5, 6, and 7)</p> <p>Findings Include:</p>	V 0503	<p>through to the sustained resolution of all identified issues. The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 06/21/2024.</p> <p>By 06/11/2024, the Clinical Manager will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p> <ul style="list-style-type: none"> ·Volume Management in ESRD Patients on Hemodialysis ·Job description titled "Staff 	06/21/2024

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	<p>1. A review of a policy dated 09-07-2021, "Volume Management in ESRD (End Stage Renal Disease) Patients on Hemodialysis" indicated but was not limited to, " ... EDW is used to calculate the target weight removal ... If any the following patient clinical conditions occur ... consult with provider for appropriate fluid interventions: ... Unable to achieve EDW ... "</p> <p>2. A review of a Fresenius Medical Care Job description titled "Staff Registered Nurse" indicated but was not limited to "Provides safe and effective delivery of care to patients with ESRD ... Identifies and communicates patient related issues to Team Leader or physician ... "</p> <p>3. The clinical record for Patient #2 was reviewed on 05-21-2024 and evidenced a document titled "Current Orders Report," which indicated orders dated 12-28-2023 for In-center Hemodialysis treatments every Tuesday, Thursday, and Saturday for 4 hours with an EDW of 122 kilograms (kg).</p> <p>A review of the treatment sheets for Patient #2 evidenced the following with no documentation that the nurse notified the physician of target EDW not met within 1 kg:</p> <p>05-09-2024 Target Weight=122 kg Post-weight=128.70 kg</p> <p>05-16-2024 Target Weight=122 kg Post-weight=127.00 kg</p> <p>4. The clinical record for Patient #3 was reviewed on 05-22-2024 and evidenced a document titled "Current Orders Report" which indicated orders dated 12-28-2023 for In-center Hemodialysis treatments every Tuesday, Thursday, and</p>		<p>Registered Nurse" Emphasis was placed on:</p> <p>Direct patient care staff may collect data such as weight, BP, pulse, respirations, temperature, general observations, access, and complaints reported by the patient.</p> <p>If the PCT/LPN note any changes or abnormal findings in the patient's condition or vascular access are observed or reported by the patient, or the patient was hospitalized, the registered nurse must assess the patient.</p> <p>Report to the nurse:</p> <p>Systolic blood pressures greater than 180 mm/Hg</p> <p>Diastolic blood pressure greater than 100 mm/Hg</p> <p>Blood Pressure less than or equal to 100 mm/hg systolic</p> <p>Any complaints by the patient before, during, or after treatment (i.e., nausea, vomiting, cramping)</p> <p>Fluid balance is an integral component of the HD treatment to prevent patient hyper- or hypovolemia both of which have been demonstrated to influence mortality and cardiovascular complications in ESRD patients on HD. Registered nurse should complete a fluid assessment on all ESRD patients receiving HD treatments. Assessment should evaluate patients for hypo- and</p>	

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	<p>Saturday, for 4 hours with an EDW of 99.5 kilograms (kg).</p> <p>A review of the treatment sheets for Patient #3 evidenced the following with no documentation that the nurse notified the physician of target EDW not met within 1 kg:</p> <p>05-02-2024 Target Weight=99.5 kg Post-weight=100.10 kg</p> <p>05-16-2024 Target Weight=99.5 kg Post-weight=100.50 kg</p> <p>05-18-2024 Target Weight=99.5 kg Post-weight=100.20 kg</p> <p>5. The clinical record for Patient #4 was reviewed on 05-23-2024 and evidenced a document titled "Current Orders Report," which indicated orders dated 02-28-2024 for In-center Hemodialysis treatments every Monday, Tuesday, and Friday, for 5 hours and 45 minutes with EDW of 196 kilograms (kg).</p> <p>A review of the treatment sheets for Patient #4 evidenced the following with no documentation that the nurse notified the physician of target EDW not met within 1 kg:</p> <p>04-24-2024 Target Weight=196 kg Post-weight=197.90 kg</p> <p>04-26-2024 Target Weight=196 kg Post-weight=197.10 kg</p> <p>04-29-2024 Target Weight=196 kg Post-weight=199.50 kg</p> <p>05-01-2024 Target Weight=196 kg Post-weight=198.50 kg</p> <p>05-03-2024 Target Weight=196 kg Post-weight=198.10 kg</p> <p>05-06-2024 Target Weight=196 kg Post-weight=202.50 kg</p>		<p>hypervolemia.</p> <p>At a minimum, fluid assessment will include review of the following clinical indicators:</p> <p>EDW</p> <p>Pre/Post Weight</p> <p><u>Post Weight comparison to EDW</u></p> <p>Pre/Post Blood Pressure</p> <p>Lowest Intradialytic Blood Pressure</p> <p>Signs/symptoms of fluid overload</p> <p>Physical examination including lung assessment, cardiovascular (i.e., heart sounds) and peripheral vascular assessment (edema)</p> <p>If any of the following patient clinical conditions occur refer to the volume algorithm if applicable or consult with provider for appropriate fluid interventions:</p> <p>Pre-treatment signs or symptoms of hypervolemia</p> <p>Pre-treatment sitting systolic BP is greater than 160 mmHg and prior treatment post dialysis sitting systolic BP is greater than 140 mmHg.</p> <p>Pre-treatment signs or symptoms of hypovolemia</p> <p><u>Unable to achieve EDW due to UF intolerance.</u></p> <p>New to dialysis within 13 treatments</p> <p>Post-hospitalization</p> <p><u>Pre-treatment weight is less than or equal to EDW.</u></p> <p>Prior treatment was shortened by</p>	

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	<p>05-08-2024 Target Weight=196 kg Post-weight=202.70 kg</p> <p>05-10-2024 Target Weight=196 kg Post-weight=200.60 kg</p> <p>05-15-2024 Target Weight=196 kg Post-weight=204.50 kg</p> <p>05-16-2024 Target Weight=196 kg Post-weight=201.40 kg</p> <p>05-17-2024 Target Weight=196 kg Post-weight=203.70 kg</p> <p>6. The clinical record for Patient #5 was reviewed on 05-22-2024 and evidenced a document titled "Current Orders Report" which evidenced orders dated 03-04-2024 for In-center Hemodialysis treatments every Monday, Wednesday, and Friday, for 4 hours with an EDW of 83.5 kg.</p> <p>A review of the treatment sheets for Patient #5 evidenced the following with no documentation that the nurse notified the physician of target EDW not met within 1 kg:</p> <p>05-06-2024 Target Weight=83.5 kg Post-weight=84.5 kg</p> <p>7. The clinical record for Patient #6 was reviewed on 05-23-2024 and evidenced a document titled "Current Orders Report" which evidenced orders dated 04-19-2024 for In-center Hemodialysis treatments every Monday, Wednesday, and Friday, for 3 hours and 45 minutes with an EDW of 50 kg.</p> <p>A review of the treatment sheets for Patient #6 evidenced the following with no documentation that the nurse notified the physician of target EDW not met within 1 kg:</p> <p>05-15-2024 Target Weight=50 kg</p>		<p>more than 15 minutes.</p> <p>Prior missed treatment</p> <p>Treatment adjustments based on fluid assessment, symptoms, and blood pressure are critical to improve a patient's volume status. EDW order should be updated post treatment to reflect treatment adjustments and patient fluid status.</p> <p>The RN is accountable for delivering care within the framework of the nursing process. The RN uses clinical findings to formulate nursing diagnoses and prioritize problems according to patient need.</p> <p>The registered nurse must evaluate each patient preferably within an hour or according to state requirements to:</p> <ul style="list-style-type: none"> Confirm identity. Review the patient's condition. Review accuracy and completeness of treatment and patient data Review patient treatment prescription and equipment parameters to verify correct settings, and if dialysis prescription is being followed. Confirm that the correct vascular access is being used, and that the access is visible. Observe patient's response to treatment. Verify machine safety checks have been completed. Talk to the patient to elicit information such as changes in condition, response to treatment, 	

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

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	<p>Post-weight=54.10 kg 05-17-2024 Target Weight=50 kg Post-weight=51.20 kg</p> <p>8. The clinical record for Patient #7 was reviewed on 05-23-2024 and evidenced a document titled "Current Orders Report" which evidenced orders dated 04-24-2024 for In-center Hemodialysis treatments every Monday, Wednesday, and Friday, for 4 hours and 15 minutes with an EDW of 118 kilograms (kg).</p> <p>A review of the treatment sheets for Patient #7 evidenced the following with no documentation that the nurse notified the physician of target EDW not met within 1 kg:</p> <p>04-26-2024 Target Weight=118.50 kg Post-weight=122.30 kg 05-03-2024 Target Weight=118.50 kg Post-weight=121.20 kg 05-08-2024 Target Weight=118.50 kg Post-weight=122.10 kg 05-15-2024 Target Weight=118.50 kg Post-weight=124.60 kg</p> <p>During an interview on 05-23-2024 at 1:45 PM, when queried when they notified the patient's physician about EDW not being met after dialysis treatment, RN 1 indicated the nurses notified the patient's physician of 1 kg or more.</p>		<p>new injuries, information/education needs or complaints, satisfaction with care.</p> <p>The RN will notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instruction.</p> <p>The Registered Nurse will assess/reassess any findings addressed pre or during treatment as needed.</p> <p>Prior to discharge, the RN must confirm the patient is stable for discharge and review the treatment record for:</p> <p>Slow/fast/irregular heart rate Low or high blood pressures <u>Whether patient is achieving dry weight and identifying reason for patient not achieving dry weight</u> Heart rate <50 or >120 addressed by the registered nurse with documentation present. Blood pressures < 100 systolic or greater than 180 systolic addressed by the registered nurse with or documentation present. Reported fall, and if heparin was held and MD notified. Correct dialysate prescription was delivered.</p> <p>Effective 06/14/2024, the Clinical Manager will conduct 10 treatment sheets daily, 3 times per week, alternating shifts, with focus on ensuring patient's EDW is met or if greater than 1 Kg variance the Registered Nurse will notify the</p>	

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			<p>patient's physician, and Registered Nurse to re-assess patients with abnormal assessment identified (i.e. EDW not met), utilizing Treatment Sheet Audit Tool for 2 weeks and then will complete weekly treatment audits on 10% of completed treatments for an additional 4 weeks. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The 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.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing</p>	

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

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V 0543 Bldg. 00	<p>494.90(a)(1) POC-MANAGE VOLUME STATUS</p> <p>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 direct patient care staff monitored the patients during their dialysis treatment per the facility policy in 6 of 6 records reviewed. (Patients: #2, 3, 4, 5, 6, and 7)</p> <p>Findings include:</p>		V 0543	<p>findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 06/21/2024.</p>	06/21/2024

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	<p>1. A review of a policy dated 09-05-2023, "Patient Monitoring and Safety Checks During Hemodialysis Treatment" indicated but was not limited to, " ... Monitor and document every 30 minutes or more frequently as needed but not to exceed 45 minutes or per state regulations ... "</p> <p>2. The clinical record for Patient #2 was reviewed on 05-21-2024. The treatment records between 04-27-2024 and 05-18-2024 evidenced the following:</p> <p>A. A review of the treatment record dated 04-30-2024 evidenced the Patient Care Technician (PCT) 9 started Patient #2's treatment at 05:31 AM. The following patient safety check was completed by the PCT, who obtained Patient #2's blood pressure, pulse, and machine safety check at 06:39 AM.</p> <p>3. The clinical record for Patient #3 was reviewed on 05-22-2024. The treatment records between 04-27-2024 and 05-18-2024 evidenced the following:</p> <p>A. A review of the treatment record dated 05-11-2024 evidenced PCT 10 completed Patient #3's blood pressure, pulse, and machine safety check at 09:30 AM. PCT 10 then completed the following patient safety check: obtained Patient #3's blood pressure, pulse, and machine safety check at 10:20 AM.</p> <p>B. A review of the treatment record dated 05-14-2024 evidenced PCT 1 started Patient #3's treatment at 06:30 AM. The PCT then completed the following patient safety check: obtained Patient #3's blood pressure, pulse, and machine safety check at 07:35 AM.</p>			<p>Emphasis was placed on: Obtain respirations, blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulations.</p> <p>Monitor and document Safety Checks every 30 minutes or more frequently as needed but not to exceed 45 minutes in the FKC Treatment Record.</p> <p>Effective 06/17/2024, the Clinical Manager will conduct 10 treatment sheets daily, 3 times per week, alternating shifts, with focus on ensuring patient's vital signs and safety checks are documented every 30 minutes or more frequently as needed but not to exceed 45 minutes, utilizing Treatment Sheet Audit Tool for 2 weeks and then will complete weekly treatment audits on 10% of completed treatments for an additional 4 weeks. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p>	

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	<p>4. The clinical record for Patient #4 was reviewed on 05-23-2024. The treatment records between 04-24-2024 and 05-17-2024 evidenced the following:</p> <p>A. A review of the treatment record dated 04-29-2024 evidenced that Registered Nurse (RN) 1 completed Patient #4's blood pressure, pulse, and machine safety check at 10:07 AM. RN 1 then obtained Patient #4's blood pressure, pulse, and machine safety check at 11:02 AM.</p> <p>B. A review of the treatment record dated 05-11-2024 evidenced PCT 12 completed Patient #4's blood pressure, pulse, and machine safety check at 07:35 AM. PCT 9 then completed the following patient safety check: obtained Patient #4's blood pressure, pulse, and machine safety check at 08:37 AM.</p> <p>C. A review of the treatment record dated 05-13-2024 evidenced PCT 9 completed Patient #4's blood pressure, pulse, and machine safety check at 06:02 AM. PCT 13 then completed the following patient safety check: obtained Patient #4's blood pressure, pulse, and machine safety check at 07:36 AM.</p> <p>D. A review of the treatment record dated 05-15-2024 evidenced RN 7 completed Patient #4's blood pressure, pulse, and machine safety check at 10:02 AM. RN 7 then completed the following patient safety check: obtained Patient #4's blood pressure, pulse, and machine safety check at 11:02 AM.</p> <p>5. The clinical record for Patient #5 was reviewed on 05-22-2024. The treatment records between 04-26-2024 and 05-17-2024 evidenced the following:</p>			<p>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.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 06/21/2024.</p>	

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

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	<p>A. A review of the treatment record dated 04-26-2024 evidenced PCT 2 completed Patient #5's blood pressure, pulse, and machine safety check at 17:34 PM. PCT 2 then completed the following patient safety check: obtained Patient #5's blood pressure, pulse, and machine safety check at 18:32 PM.</p> <p>B. A review of the treatment record dated 05-01-2024 evidenced RN 3 completed Patient #5's blood pressure, pulse, and machine safety check at 18:08 PM. RN 3 then completed the following patient safety check: obtained Patient #5's blood pressure, pulse, and machine safety check at 20:04 PM.</p> <p>C. A review of the treatment record dated 05-13-2024 evidenced PCT 15 completed Patient #5's blood pressure, pulse, and machine safety check at 17:39 PM. PCT 15 then completed the following patient safety check: obtained Patient #5's blood pressure, pulse, and machine safety check at 18:33 PM. PCT 15 then completed the following patient safety check: obtained Patient #5's blood pressure, pulse, and machine safety check at 19:00 PM, then again at 20:45 PM.</p> <p>D. A review of the treatment record dated 05-15-2024 evidenced PCT 14 completed Patient #5's blood pressure, pulse, and machine safety check at 20:02 PM. PCT 14 then completed the following patient safety check: obtained Patient #5's blood pressure, pulse, and machine safety check at 21:15 PM.</p> <p>E. A review of the treatment record dated 05-17-2024 evidenced PCT 10 completed Patient #5's blood pressure, pulse, and machine safety check at 17:44 PM. PCT 10 then completed the</p>			

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	<p>following patient safety check: obtained Patient #3's blood pressure, pulse, and machine safety check at 18:36 PM.</p> <p>6. The clinical record for Patient #6 was reviewed on 05-23-2024. The treatment records between 04-26-2024 and 05-17-2024 evidenced the following:</p> <p>A. A review of the treatment record dated 05-17-2024 evidenced PCT 16 completed Patient #6's blood pressure, pulse, and machine safety check at 17:02 PM. PCT 10 then completed the following patient safety check: obtained Patient #6's blood pressure, pulse, and machine safety check at 17:53 PM.</p> <p>7. The clinical record for Patient #7 was reviewed on 05-23-2024. The treatment records between 04-26-2024 and 05-17-2024 evidenced the following:</p> <p>A. A review of the treatment record dated 05-08-2024 evidenced PCT 18 completed Patient #7's blood pressure, pulse, and machine safety check at 06:47 AM. PCT 18 then completed the following patient safety check: obtained Patient #7's blood pressure, pulse, and machine safety check at 07:34 AM.</p> <p>B. A review of the treatment record dated 05-15-2024 evidenced PCT 7 completed Patient #7's blood pressure, pulse, and machine safety check at 08:11 AM. PCT 17 then completed the following patient safety check: obtained Patient #7's blood pressure, pulse, and machine safety check at 09:10 AM. PCT 17 then completed the following patient safety check: obtained Patient #7's blood pressure, pulse, and machine safety check at 10:01 PM.</p>			

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

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V 0757 Bldg. 00	<p>C. A review of the treatment record dated 05-15-2024 evidenced LPN 2 completed Patient #7's blood pressure, pulse, and machine safety check at 09:02 AM. RN 8 then completed the following patient safety check: obtained Patient #7's blood pressure, pulse, and machine safety check at 10:04 AM.</p> <p>During an interview on 05-21-2024 at 10:40 AM, RN 1 indicated the Patient Care Technicians (PCTs) cannot run 3 tracks (tracks contain 6 chairs) with 2 PCTs and do it all, with safety checks, taking patients off dialysis treatment, and putting patients on treatment.</p> <p>8. During an interview on 05-22-2024 at 9:30 AM, the Regional Director of Operations/Interim Regional Vice President, Admin 2, confirmed they noted on the records the patient's safety checks were being missed.</p> <p>494.180(b)(1) GOV-STAFF # & RATIO MEET PT NEEDS The governing body or designated person responsible must ensure that- (1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients; Based on observation, record review, and interview, the Facility Administrator (FA) failed to have a plan for insufficient staffing for 1 of 1 stand alone in-center facilities.</p> <p>Findings Include:</p> <p>1. During a flash tour of the Water Room on 05-20-2024 at 9:58 AM, the Patient Care</p>	V 0757	<p>By 06/11/2024, the Clinical Manager will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: Governing Body Policy</p> <p>Emphasis was placed on:</p>	06/21/2024

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	<p>Technician (PCT) 3, was observed mixing bicarb. PCT 3 indicated they were the only preceptor left, staff were leaving the facility, management was not giving yearly raises, they worked short staff, and they went home crying a lot of evenings.</p> <p>2. During a flash tour of the treatment floor on 05-20-2024 at 10:30 AM, Patient #8 indicated the facility had cut their treatment short to 3 hours a couple of weeks ago due to staffing shortages. Patient #8 stated, "They are losing help. These girls are doing their best, but they are tired."</p> <p>3. On 05-20-2024 at 9:50 AM, the Facility Administrator (FA) and Director of Operations (DO) introduced themselves. When explained that the survey was for complaints, they indicated they were not surprised due to many changes at the facility in staffing and management.</p> <p>4. During the Entrance Conference on 05-20-2024 at 10:55 AM, when queried regarding the facility shortening patient's treatments and any adverse events occurring. The Medical Director confirmed due to staffing shortages and patient safety, the facility shortened treatment times 2 days in 1 week 3, hours of treatment time for those who were treated for 4 and 4 hours for those treated for 5 hours. The Medical Director further indicated they communicated with the nurses and gave orders for shorter treatment times for only those patients without increased Potassium or other treatment needs that could not be shortened.</p> <p>5. During an interview on 05-20-2024 at 11:24 AM, the Medical Director indicated they were not surprised by the complaints and further confirmed no adverse events or negative outcomes had occurred. The Medical Director indicated due to staffing shortages, the nurses are unable to</p>		<ul style="list-style-type: none"> · The Medical Director is required to ensure adequate supervision of dialysis operations by medical and patient care staff through proper scheduling of medical personnel, direct patient care personnel, supervisory personnel, and emergency coverage. · Governing Body duties (generally in conjunction with the Medical Director) include but are not limited to: <ul style="list-style-type: none"> · Fiscal management · Medical staff appointments, coverage, and compliance with facility policies · Facility professional staff appointments · Regulatory Compliance to include: <ul style="list-style-type: none"> · Routine quarterly review of regulatory approval letters to determine if the numbers of stations and modalities of dialysis being delivered is exactly consistent with what is stated in the most recent CMS/Medicare approval letter, state certificate of need (if applicable) and state license (if applicable). · Review of each statement of deficiency resulting from an internal or external facility survey, as well as review of the development and implementation of any related plans of correction Training and educating staff 	

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	<p>document vaccines correctly, follow up on patient histories, double check weights, and have had increased patient complaints regarding staffing issues. The Medical Director indicated staff left due to the refusal of salary increases by management, and there had been less appreciation shown by management to the direct care staff. These issues they indicated they have brought up in their Quality meetings and management meetings.</p> <p>6. During an interview on 05-20-2024 at 12:38 PM, PCT 4 indicated the facility's management did not care about the staff.</p> <p>7. During an observation of the treatment floor on 05-20-2024 at 1:10 PM, 35 patients received dialysis treatment, 3 PCTs, and 2 Registered Nurses (RN).</p> <p>8. During an interview on 05-20-2024 at 1:10 PM, RN 3 indicated there were 35 patients, 3 PCTs, and 1 RN. RN 3 further indicated management is not available.</p> <p>9. During an interview on 05-20-2024 at 1:25 PM, PCT 1 and PCT 2 indicated due to staffing, they had to run 2 to 3 tracks, which included 12-18 patients who received dialysis treatments. The PCTs further confirmed management had not been out of the floor to monitor staffing issues.</p> <p>10. During an interview on 05-20-2024 at 1:45 PM, PCT 6 confirmed they started in November and indicated the staffing situation is worse now. PCT 6 indicated during the evening, and they had 30 patients who had received dialysis treatment with 3 PCTs and 1 RN.</p> <p>11. During an observation on 05-20-2024 from 1:50</p>		<ul style="list-style-type: none"> · Ensuring adequate staff coverage · Operation of Quality Assessment and Improvement Program · Directing and overseeing the facility's internal grievance process and issues · Ensuring involuntary patient discharges are carried out in compliance with regulations and facility policy and procedure · Ensuring that facility emergency coverage and facility backup plans are in place and effective · Ensuring that requisite data is submitted timely and accurately to ESRD Network and/or CMS, as required · Maintaining the facility's relationship with the ESRD Network · Maintaining compliance and adherence to federal healthcare program requirements/state regulations including staffing. <p>Effective 06/03/2024, the Facility Administrator was removed.</p> <p>Effective 06/05/2024, a Clinical Manager was in place to oversee the clinic operations and staffing schedules.</p> <p>Effective 06/12/2024, the Clinical Manager will conduct monthly audit with focus on ensuring adequate number of qualified and</p>	

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

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	<p>PM to 2:15 PM, dialysis machine alarms at Stations #7, 8, and 9 sounded. Patient #20 at Station #9 had a dialysis machine alarm regarding a high systolic blood pressure. Patient #21 at Station #8 had a low systolic blood pressure. Patient #22 at Station #7 had a low systolic blood pressure. PCT 1 answered the alarms after they had completed the initiation of dialysis treatment at Station #32 at 2:15 PM.</p> <p>During an interview on 05-20-2024 at 2:15 PM, PCT 2, entered the treatment area after they completed the water test. PCT 2 stated, "See, we need help," while they assisted PCT 1 with machine alarms.</p> <p>12. A review of the Patient Grievance Report dated 12-27-2023 through 05-20-2024 revealed patient grievances related to staff care, attitude, chair location, treatment denial due to the patient's unstable condition, and missing phone. Requested the staff and patient grievances regarding staffing.</p> <p>During an interview on 05-20-2024 at 3:00 PM, when asked about staff and patient complaints about staffing and shortened treatments, the FA and DO, indicated they did not have those.</p> <p>13. During an interview on 05-20-2024 at 3:35 PM, Patient #23 confirmed the facility shortened their treatment to 3 hours a couple of weeks ago due to a staffing shortage.</p> <p>14. During the Daily Conference on 05-20-2024 at 4:15 PM, the FA confirmed they had received complaints from staff and patients and did not complete grievance reports.</p> <p>15. During an interview on 05-21-2024 at 9:30 AM,</p>		<p>trained staff are present whenever patients are undergoing dialysis to meet the patient needs, utilizing Personnel Tracker Audit Tool for 3 months and then an additional 3 months. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The 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.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction.</p>	

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	<p>Patient #3 confirmed they had filed a grievance regarding care and staffing. Patient #3 indicated they had no further problems with care and stated, "They do their best, but they need help."</p> <p>16. During an observation on 05-21-2024 at 10:45 AM, 32 patients were connected to dialysis machines, 2 RNs, and 6 PCTs on the treatment floor. PCT 7 was observed to ask for help from RN 2, who was on the phone. PCT 7 indicated 2 PCTs cannot do 3 tracks. PCT 7 stated loudly, "I have never been at a place this bad."</p> <p>During an interview on 05-21-2024 at 10:45 AM, when questioned regarding the staffing on the treatment floor, the FA in their office stated, "What is all the noise?" Further, after the FA was led to the treatment floor to observe alarms and PCT 7, they indicated they did not know how they missed staffing a PCT.</p> <p>17. During an interview on 05-20-2024 at 10:56 AM, Patient #1 confirmed their treatments always ran late. Patient #1 indicated their start time was 10:00 AM, and they were put on for treatment at 10:27 AM.</p> <p>18. During an observation on the treatment floor on 05-20-2024 at 10:57 AM, Patient #12 at Station #29 indicated they had waited an hour before treatment and asked the surveyor if this was the surveyor's fault. RN #2 indicated Patient #1 never complained. Their scheduled time to go on was 9:50 AM, and they started treatment today at 10:23 AM. Patient #1 further indicated they had plans today, and their time matters. FA was obtained for Patient #1 to voice concerns too.</p> <p>19. A review of a facility document titled, "Meeting Minutes" dated April 20, 2024, indicated</p>		<p>The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 06/21/2024.</p>	

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

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	<p>a review of the patient experience was at 51% goal of 75% with a new schedule rolling out on 6-10-2024 to create efficiency and assist staff with patients getting on time.</p> <p>20. A review of a Fresenius Medical Care job description titled, "Facility Administrator" version date 08-11-2024, indicated but was not limited to, "... Manages and oversees the daily operations of the facility ... Manages the day to day activities and workload of the facility staff providing guidance and leadership as appropriate to ensure the effective, efficient and timely execution of duties and tasks ... Addresses the patient concerns, issues, and questions ... Creates, maintains, and communicates efficient and timely employee schedules according to staffing needs of the facility to ensure adequate staffing on a daily basis ... "</p> <p>21. During an interview on 05-21-2024 at 11:15 AM, Patient #10 was in the front lobby and stated, "This place sucks." Patient #10 indicated treatment times are always late and they had been waiting for 30 minutes.</p> <p>22. During an interview on 05-21-2024 at 11:45 AM, RN 2 indicated they were mentally drained, and the facility's staffing shortage had taken a toll on them.</p> <p>23. During an interview on 05-21-2024 at 12:30 PM, PCT 10 indicated they were becoming increasingly frustrated with taking off 12 patients, no incentives, no salary increases, and now having health concerns with chest pain.</p> <p>24. During an interview on 05-21-2024 at 3:15 PM, the Regional Director of Operations/Interim Vice President, Corp 2, confirmed the facility's</p>				

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	<p>scheduling was completed incorrectly. Corp 2 further indicated the treatment times of the patients on and off were too many at the same time for the PCT in that track.</p> <p>25. During a daily conference on 05-21-2024 at 4:20 PM, the FA indicated they entered Patient #12's complaint today and further confirmed there were staffing issues today.</p> <p>26. During an interview on 05-22-2024 at 5:15 PM, Patient #5 confirmed their treatments were shorted to 3 hours a couple of weeks ago. Patient #5 said it was horrible for the staff to take everyone off at the same time due to a staffing shortage. Patient #5 voiced their concern if other good staff left as well. When asked if they complained to the management staff, Patient #5 indicated the manager was not available for calls, return calls, or out on the treatment floor.</p> <p>27. During an interview on 05-23-2024 at 9:30 AM, the Medical Social Worker (MSW) indicated the patients had voiced concerns regarding staffing. The MSW further indicated management rotates at the dialysis center, there were communication gaps, nurses pulled to be PCTs, and the direct care staff were tired.</p> <p>28. During an interview on 05-23-2024 at 12:00 PM, Physician 1, a facility Nephrologist (a kidney doctor), confirmed they were made aware of the facility's staffing issue and agreed with the Medical director's decision to shorten treatments for safety. Physician 1 further indicated their patients had no adverse outcomes.</p>			