STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152634	A. BUILDING 00 B. WING	02/12/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNCIE	4021 W KILGORE AVE MUNCIE, IN 47304

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIE (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	This visit was for a complaint survey of an ESRD provider. Survey dates: February 8, 9, 12, 2024 Complaint # IN00424125 with related findings. Census by Service Type: In Center Hemodialysis: 67 Home Hemodialysis: 4 Home Peritoneal dialysis: 9 Total Census: 80 Isolation Room: 1 QR completed on 02/16/2024 by A4.	V 0000		
V 0112 Bldg. 00	494.30(a) IC-CDC MMWR 2001 The facility must demonstrate that it follows standard infection control precautions by implementing- (1)(i) The recommendations (with the exception of screening for hepatitis C), found in "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Brianne Thornburg, RN	Clinical Manager	02/23/2024

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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	Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. The recommendation found under section header "HBV-Infected Patients", found on pages 27 and 28 of RR05 ("Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients"), concerning isolation rooms, must be complied with by February 9, 2009. Based on observation, record review, and interview, the dialysis facility failed to ensure all staff followed policies and procedures related to infection control for 4 of 7 personnel observed on the in-center treatment floor (Physician #1, PCT 2, RN 3, and RN 4). Findings include: 1. A review of agency policy "Personal Protective Equipment" indicated personal protective equipment including a full-face shield or mask and protective eyewear with full side shield, fluid resistant gowns, and gloves must be worn to protect employees from blood or other potentially infectious materials. 2. During observation periods on 2/09/24 from 8:52 AM to 9:34 AM and 10:53 AM to 12:14 PM, PCT 2 was observed without a face mask that covered	V 0112	**V112** On 02/22/24, the Clinical Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the policy. ·Personal Protective Equipment Guidance on Dialyzing and Infection Control Practices of COVID-19 in Fresenius Kidney Care (FKC) Dialysis Clinics Emphasis was placed on: Personal protective equipment including a full-face shield or mask and protective eyewear with full side shield, fluid-resistant gowns, and gloves, must be worn to protect employees from blood or other potentially infectious materials	03/12/2024

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	their nose while on the treatment floor for the duration of the observations. 3. During an interview on 2/09/24 beginning at 2:15 PM, the Clinical Manager indicated face masks should be worn above the nose, tucked below the chin and around the ears. 4. During an observation on 2/09/24 beginning at 9:28 AM, Physician #1 was observed wearing a disposable gown loosely on their lower arms while in Station #19, moving from Station #19 to Station #23 to Station #15 to Station #13 and then to Station #9. Physician #1 failed to secure the gown properly while rounding on the in-center patient treatment floor and failed to wear eye protection while on the treatment floor. 5. During an interview on 2/09/24 beginning at 2:15 PM, the Clinical Manager indicated the gown should be worn with arms completely in the sleeves and tied in the back and indicated face masks should be worn above the nose, tucked below the chin and around the ears. 6. During an interview on 2/09/24 beginning at 5:03 PM, the Clinical Manager indicated all physicians should wear a mask, gown and eye protection while on the treatment floor. 7. On 02/09/24 at 10:45 AM, RN 4 was observed, with a face mask worn below the nose and goggles on top of the head, perform a blood pressure check on the patient in Station 12. On 02/09/24 at 11:15 AM, RN 3 was observed entering Patient #10's station with goggles on and a face mask worn below the nose. On 02/09/24 at 11:52 AM, PCT 2 was observed performing standing and sitting blood pressure checks on a patient while PCT 2 was wearing goggles and was wearing a face mask below the nose.		(OPIM). PPE is used to protect employees who are occupationally exposed to blood or OPIM when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). **All** FKC Staff, physicians and physician extenders are required to wear surgical face masks or wear N95 respirator while in the treatment area (e.g., during all patient facing activities, at the nursing station, medication preparation area, patient training room, etc.). Staff face masks should be positioned over nose and mouth. Effective 02/23/24, the Clinical Manager will conduct weekly audits 3 times per week, with alternating shifts with focus on ensuring staff wear PPE per policy, as required, utilizing Infection Control Audit Tool for 2 weeks and then 2 times per week 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. The Medical Director will review the results of audits each month	

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			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 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 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 03/12/24	
V 0113 Bldg. 00	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the			

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	patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station. Based on observation, record review, and interview, the dialysis facility failed to ensure all staff and patients followed the policies and procedures related to hand hygiene for 3 of 3 personnel observed assisting patients during discontinuation of AV fistula/graft dialysis (Physician #1, RN 4 and PCT 5). Findings include: 1. A review of agency policy "Personal Protective Equipment" indicated staff must remove gloves and wash hands after patient care, exposure to blood and body fluids and touching any surfaces within the patient station. 2. A review of agency policy "Hand Hygiene" indicated hand hygiene should be performed before and after direct contact with patients; after contact with the dialysis wall box, concentrate, drain or water lines and after contact with other object within the patient station or treatment space. 3. During an observation on 2/09/24, Personal Care Technician (PCT) 5 was observed handing Patient #15 a glove to don to hold pressure on their left arm. PCT 5 failed to instruct Patient #15 to perform hand hygiene prior and failed to provide hand sanitizer to the patient prior to handing the patient the glove. 4. During an interview on 2/09/24 beginning at 2:15 PM, the Clinical Manager indicated when patient's hold their access site gauze, they should	V 0113	V113 On 02/22/24, the Clinical Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the policy. ·Personal Protective Equipment Hand Hygiene Emphasis was placed on: Personal protective equipment including a full-face shield or mask and protective eyewear with full side shield, fluid-resistant gowns, and gloves, must be worn to protect employees from blood or other potentially infectious materials (OPIM). PPE is used to protect employees who are occupationally exposed to blood or OPIM when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Hands will be decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and water: Before and after direct contact with patients Entering and leaving the treatment area	03/12/2024

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	do it with a gloved hand. The Clinical Manager also indicated the patient should perform hand hygiene before putting on a glove and the facility staff is responsible to provide hand sanitizer to the patient. 5. During an observation on 2/09/24, Physician #1 was observed in Station #19, then moving from Station #19 to Station #23 to Station #15 to Station #13 and then to Station #9. The physician touched the machine monitor in each station, had a brief discussion with each patient and then moved to the next station without performing hand hygiene or wearing gloves. 6. During an interview on 2/09/24 beginning at 2:15 PM, the Clinical Manager indicated the monitor screen is a dirty surface and hand hygiene should have been performed when leaving each station. 7. RN 4 was observed performing the discontinuation of dialysis and post dialysis access care on 02/09/24. RN 4 placed a glove on Patient #8's hand to hold gauze on his/her access site. RN 4 failed to instruct Patient #8 to perform hand hygiene and failed to provide hand sanitizer to the patient prior to placing the glove on Patient #8's hand.		Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medications Immediately after removing gloves. After contact with body fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly soiled. After contact with inanimate objects near the patient When moving from a contaminated body site to a clean body site of the same patient After contact with the dialysis wall box, concentrate, drain, or water lines. After contact with other objects within the patient station or treatment space Patients should perform hand hygiene if able, 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 regarding their vascular access and hands to all patients. Gloves must be provided to patients when performing procedures which risk exposure to blood or body fluids, such as when self-cannulating or holding access sites post treatment to achieve	

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			hemostasis. Washing Hands with Soap and Water - Duration of the entire procedure: 40-60 seconds Decontaminating Hands with Alcohol Based Hand rubs - Duration of the entire procedure: 20-30 seconds. Apply alcohol-based hand rub to the palm of one hand using the amount recommended by the product manufacturer. An adequate amount of product must be used for maximum effectiveness. *Rub hands together covering all surfaces of the hands and fingers, until hands are dry.* Allowing alcohol to dry completely allows adequate contact time to kill germs, allows alcohol to evaporate and prevents risk of igniting flames due to alcohol's flammable properties. Effective 02/23/24, the Clinical Manager will conduct weekly audits 3 times per week, with alternating shifts with focus on ensuring staff wear PPE per policy and offer patients hand hygiene pre and post treatment, as required, utilizing Infection Control Audit Tool for 2 weeks and then 2 times per week 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	

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			the Clinic Audit Checklist per QAI calendar. 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 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 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.	

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V 0115 Bldg. 00	494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. Based on observation, policy review, and interview, the dialysis center failed to ensure staff wore the required personal protective equipment (PPE) when spurting or spattering of blood might occur for 3 of 6 Personnel observed. (PCT 2, PCT 3, RN 4.) Findings include: 1. The Personal Protective Equipment policy, revised 11/06/23, indicated PPE including a full-face shield or a mask and protective goggles must be worn when performing procedures during which spurting or spattering of blood might occur. 2. The Initiation and Termination of Treatment Using a Central Venous Catheter (CVC) policy, revised 07/05/22, indicated staff must wear a mask that covers the nose and mouth for all procedures that require accessing the catheter. 3. Registered Nurse (RN) 4 was observed performing the discontinuation of dialysis and post dialysis access care of fistula or graft for	V 0115	V115 On 02/22/24, the Clinical Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the policy. ·Personal Protective Equipment Termination of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer Emphasis was placed on: Personal protective equipment including a full-face shield or mask and protective eyewear with full side shield, fluid-resistant gowns, and gloves, must be worn to protect employees from blood or other potentially infectious materials (OPIM). PPE is used to protect employees who are occupationally	03/12/2024

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	Patient #8 on 02/09/24. RN 4 returned to Patient #8's station after dialysis discontinuation to check for homeostasis of the access site with RN 4's face mask below their nose and their goggles on top of their head. RN 4 failed to wear their face mask covering the nose and failed to wear protective goggles over the eyes when performing a procedure during which spurting or spattering of blood might occur. 4.RN 4 was observed providing care to the access of a fistula or graft for the initiation of dialysis for Patient #7 on 02/09/24 at 11:01 AM. RN 4 performed cannulation with goggles on and with a face mask worn below the nose. RN 4 failed to wear their face mask covering the nose when performing a procedure during which spurting or spattering of blood might occur. 5. Patient Care Technician (PCT) 3 was observed accessing a fistula or graft site for the Patient in Station 15. PCT 3 was wearing goggles and was wearing a face mask below the nose. PCT 3 failed to wear a full-face shield or goggles and a mask covering the nose when performing a procedure during which spurting or spattering of blood might occur. 6. PCT 2 was observed performing Central Venous Catheter (CVC) exit site care for Patient #6 on 02/09/24. PCT 2 wore a face mask below the nose and goggles during the exit site care. PCT 2 failed to wear a full-face shield or goggles and a mask covering the nose when performing a procedure during which spurting or spattering of blood might occur. 7. PCT 2 was observed performing the initiation of dialysis with a CVC for Patient #6 on 02/09/24 PM. PCT 2 wore a face mask below their nose and		exposed to blood or OPIM when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). **All** FKC Staff, physicians and physician extenders are required to wear surgical face masks or wear N95 respirator while in the treatment area (e.g., during all patient facing activities, at the nursing station, medication preparation area, patient training room, etc.). Staff face masks should be positioned over the nose and cover the mouth. Effective 02/23/24, the Clinical Manager will conduct weekly audits 3 times per week, with alternating shifts with focus on ensuring staff wear PPE per policy and position face masks above nose and cover mouth, as required, utilizing Infection Control Audit Tool for 2 weeks and then 2 times per week 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. The Medical Director will review	

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	goggles during the entire initiation of dialysis. PCT 2 failed to wear a full-face shield or goggles and a mask covering the nose when performing a procedure during which spurting or spattering of blood might occur.8. During an observation on 2/09/24, PCT 2 was observed performing discontinuation of dialysis on Patient #14's CVC. PCT 2 failed to ensure their face mask covered their nose for the duration of the CVC discontinuation. 9. During an interview on 2/09/24 beginning at 2:15 PM, the Clinical Manager indicated face masks should be worn above the nose, tucked below the chin and around the ears.		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 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 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 03/12/24	
V 0543	494.90(a)(1) POC-MANAGE VOLUME STATUS			

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Bldg. 00	The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; Based on record review and interview, the dialysis facility failed to follow their policy when they failed to ensure the patient's blood pressure (BP) was checked every 30 minutes during in-center hemodialysis (ICHD) for 2 of 3 active patient clinical records reviewed (Patient #2 and #3); failed to ensure the Registered Nurse (RN) completed an assessment within one hour of the start of hemodialysis treatment for 2 of 3 active patient clinical records reviewed (Patient #1 and #3); failed to ensure the RN was notified of high blood pressures for 1 of 2 active patient clinical records reviewed with high blood pressures recorded during ICHD treatments (Patient #1); and failed to ensure the RN performed interventions and/or reported high blood pressures to the physician for 1 of 2 active patient clinical records reviewed with high blood pressures recorded during ICHD treatments (Patient #3). Findings include: 1. Policy Patient Assessment and Monitoring, revised 05/01/23, indicated blood pressure should be monitored every 30 minutes or more often as needed but not to exceed 45 minutes during ICHD treatments. The policy indicated diastolic blood pressures greater than 100 are to be reported to the nurse. 2. Policy Nursing Supervision and Delegation, revised 11/06/23, indicated RN's may not delegate assessment of the patient within one hour of	V 0543	V543 On 02/22/24, the Clinical Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the policies. ·Patient Assessment and Monitoring ·Nursing Supervision and Delegation ·Hypertension Emphasis was placed on: Direct patient care staff may collect data such as weight, BP, pulse, respirations, temperature, general observations, access, and complaints reported by the patient. If the PCT/LPN note any changes or abnormal findings in the patient's condition or vascular access are observed or reported by the patient, or the patient was hospitalized, the registered nurse must assess the patient. *Report to the nurse:* *Systolic blood pressures greater than 180 mm/Hg* *Diastolic blood pressure greater than 100 mm/Hg* *Blood Pressure less than or equal to 100 mm/hg systolic* Any complaints by the patient	03/12/2024

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	ICHD treatment start time. 3. Policy Hypertension, dated 09/07/21, indicated staff will recognize, report, and immediately address diastolic BP's greater than 100. The policy indicated the nurse should be notified if the diastolic BP is greater than 100. The RN should then assess the patient and decrease estimated dry weight if the hypertension is related to hypervolemia (fluid overload.) If the hypertension is not related to hypervolemia, the RN should notify the physician for additional orders or treatments, and these steps should be documented in the patient's treatment record. 4. Patient #2's ICHD treatment sheets dated 01/25/24 to 02/28/24, were reviewed and evidenced the following: On 01/25/24, ICHD treatment began at 6:20 AM. A BP check was conducted at 9:04 AM with a follow-up BP check at 10:30 AM, 1 hour and 26 minutes later. At 9:04 AM, Patient #2's BP of 178/108 was obtained by an RN. The clinical record failed to evidence the RN notified the physician and/or performed interventions to address the diastolic blood pressure over 100. On 01/27/24, ICHD treatment began at 6:30 AM. A BP check was conducted at 7:32 AM with a follow-up BP check at 8:36 AM, 1 hour and 4 minutes later. A licensed practical nurse (LPN) obtained Patient #2's BP of 169/104 at 7:03 AM and 154/103 at 7:32 AM. The clinical record failed to evidence the RN was notified of the diastolic BP's greater than 100. At 9:02 AM, an RN obtained Patient #2's BP of 129/109. The clinical record failed to evidence the RN notified the physician and/or performed interventions to address the diastolic blood pressure over 100.		before, during, or after treatment (i.e., nausea, vomiting, cramping) Fluid balance is an integral component of the HD treatment to prevent patient hyper- or hypovolemia both of which have been demonstrated to influence mortality and cardiovascular complications in ESRD patients on HD. Registered nurse should complete a fluid assessment on all ESRD patients receiving HD treatments. Assessment should evaluate patients for hypo- and hypervolemia. At a minimum, fluid assessment will include review of the following clinical indicators: EDW Pre/Post Weight Post Weight comparison to EDW Pre/Post Blood Pressure Lowest Intradialytic Blood Pressure Signs/symptoms of fluid overload Physical examination including lung assessment, cardiovascular (i.e., heart sounds) and peripheral vascular assessment (edema) If any of the following patient clinical conditions occur refer to the volume algorithm if applicable or consult with provider for appropriate fluid interventions: Pre-treatment signs or symptoms of hypervolemia Pre-treatment sitting systolic BP	

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	On 01/30/24, ICHD treatment began at 6:36 AM. A BP check was conducted at 8:35 AM with a follow-up BP check at 10:04 AM, 1 hour and 29 minutes later. On 02/01/24, ICHD treatment began at 6:15 AM. A BP check was conducted at 9:32 AM with a follow-up BP check at 10:30 AM, 58 minutes later. An RN obtained Patient #2's BP of 181/104 at 8:35 AM. The clinical record failed to evidence the RN notified the physician and/or performed interventions to address the diastolic blood pressure over 100. On 02/03/24, ICHD treatment began at 6:42 AM. A PCT obtained Patient #2's BP of 174/107 at 7:33 AM, 162/106 at 9:32 AM, 171/118 at 10:01 AM, and 170/108 at 10:20 AM. The clinical record failed to evidence the PCT notified the RN of the diastolic greater than 100. An RN obtained Patient #2's BP of 180/106 at 6:42 AM, 168/105 at 8:02 AM, and 152/102 at 8:32 AM. The clinical record failed to evidence the RN notified the physician and/or performed interventions to address the diastolic blood pressure over 100. On 02/06/24, ICHD treatment began at 6:31 AM. A BP check was conducted at 9:03 AM with a follow-up BP check at 10:03 AM, 1 hour later. An RN obtained Patient #2's BP of 168/101 at 10:03 AM. The clinical record failed to evidence the RN notified the physician and/or performed interventions to address the diastolic blood pressure over 100. On 02/08/24, ICHD treatment began at 6:30 AM. A PCT obtained Patient #2's BP of 170/108 at 10:05 AM and 172/103 at 10:12 AM. The clinical record failed to evidence the RN was notified of the diastolic BP's greater than 100.		is greater than 160 mmHg and prior treatment post dialysis sitting systolic BP is greater than 140 mmHg. Pre-treatment signs or symptoms of hypovolemia Unable to achieve EDW due to UF intolerance. New to dialysis within 13 treatments Post-hospitalization Pre-treatment weight is less than or equal to EDW. Prior treatment was shortened by more than 15 minutes. Prior missed treatment Treatment adjustments based on fluid assessment, symptoms, and blood pressure are critical to improve a patient's volume status. EDW order should be updated post treatment to reflect treatment adjustments and patient fluid status. The RN is accountable for delivering care within the framework of the nursing process. The RN uses clinical findings to formulate nursing diagnoses and prioritize problems according to patient need. *The registered nurse must evaluate each patient preferably within an hour or according to state requirements to:* Confirm identity. Review the patient's condition. Review accuracy and completeness of treatment and patient data	

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	5. During an interview on 02/09/23 beginning at 2:15 PM, the Clinical Manager indicated BP checks were missing for Patient #2 on 01/25/24, 01/27/24, 01/30/24, 02/01/24, and 02/06/24. The Clinical Manager indicated Patient #2's treatment record did not contain documentation of notifications or interventions related to Patient #2's diastolic BP's greater than 100 on the dates reviewed. 6. Patient #1's ICHD treatment sheets, dated 1/24/24 to 2/08/24, were reviewed and evidenced the following: On 1/24/24, the ICHD treatment began at 1:06 PM; the RN assessment was performed at 2:15 PM, 1 hour and 9 minutes after treatment began. The BP check at 3:33 PM indicated BP of 192/96. PCT 3 failed to notify the RN regarding high BP reading. On 1/30/24, the ICHD treatment began at 6:52 AM; the RN assessment was performed at 8:04 AM, 1 hour and 12 minutes after treatment began. On 2/05/24, the ICHD treatment began at 1:07 PM, the BP check at 2:33 PM indicated BP of 183/97. PCT 3 failed to notify the RN regarding high BP reading. 7. Patient #3's ICHD treatment sheets, dated 1/25/24 to 2/07/24, were reviewed and evidenced the following: On 1/25/24, the ICHD treatment began at 12:00 PM, the RN assessment was performed at 2:32 PM, 2 hours and 32 minutes after treatment began. and Patient #3 failed to receive the oral Vitamin D medication as prescribed during their treatment. On 1/27/24, the ICHD treatment began at 11:50		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, new injuries, information/education needs or complaints, satisfaction with care. *The RN will notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instruction.* *The Registered Nurse will assess/reassess any findings addressed pre or during treatment as needed.* Prior to discharge, the RN must confirm the patient is stable for discharge and review the treatment record for: Slow/fast/irregular heart rate Low or high blood pressures Whether patient is achieving dry weight and identifying reason for patient not achieving dry weight Heart rate <50 or >120 addressed by the registered nurse with documentation present. *Blood pressures < 100 systolic or greater than 180 systolic*	

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	AM, the BP check was performed at 3:02 PM with a follow-up BP check at 4:02 PM, 1 hour later. On 2/07/24, the ICHD treatment began at 11:31 AM, the RN assessment was performed at 1:55 PM, 2 hours and 24 minutes after treatment began. 8. During an interview on 2/08/24 beginning at 4:38 PM, the Clinical Manager indicated the above findings for Patient's #1 and #3 were accurate and indicated BP checks should have been performed every 30 minutes, with a fifteen-minute grace period and the RN assessment should be completed within the first hour of treatment start time. They also indicated the PCT should notify the RN when a patient's blood pressure is elevated.		*addressed by the registered nurse with or documentation present.* Reported fall, and if heparin was held and MD notified. Correct dialysate prescription was delivered. *Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulations.* Effective 02/23/24, the Clinical Manager will conduct 10 treatment sheets daily, 3 times per week, alternating shifts, with focus on ensuring patient's blood pressure checked every 30 minutes, Registered Nurse and/or physician notified for vital signs out of parameters, and Registered Nurse to re-assess patients with abnormal vital signs, and RN completes assessment within 1 hour of the start of hemodialysis treatment, 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 The Medical Director will review the results of audits each month	

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			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 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 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 03/12/24	
V 0544 Bldg. 00	494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Achieve and sustain the prescribed dose of			

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	dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. Based on record review and interview, the registered nurse (RN) failed to document the shortened run-time reason in the chairside charting and failed to document collaboration with the physician for 1 of 3 active records reviewed (Patient #1). Findings include: 1. A review of agency policy "Early Termination or Arriving Late for Treatment" indicated staff must document in Chairside the specific unexpected end reason that the treatment was shortened and all discussion with the physician must be documented in the patient's medical record. 2. Patient #1's hemodialysis treatment sheets, dated 1/24/24 to 2/08/24, were reviewed and evidenced a physician ordered total run time of 3 hours 45 minutes during the dialysis treatments. On 1/30/24, the treatment began at 6:52 AM and the total run time was 2 hours 43 minutes. The RN failed to document a shortened run time reason and failed notify the physician regarding the shortened run time. On 2/02/24, the treatment began at 1:01 PM and the total run time was 3 hours and 6 minutes. The RN failed to document a shortened run time reason and failed notify the physician regarding the shortened run time.	V 0544	V544 On 02/22/24, the Clinical Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the policy. ·Early Termination or Arriving Late for Treatment Emphasis was placed on: Patients requesting early termination of a treatment in an outpatient facility early will be referred to the supervising registered nurse. The registered nurse (RN) will evaluate the patient and discuss with the patient their reasons for requesting to terminate their treatment earlier than prescribed. If the patient's reasons for terminating the treatment early are due to complications of the treatment such as cramping, discomfort, or anxiety, the RN will discuss these issues with the patient and physician and implement any prescribed measure to alleviate the patient's symptoms. The RN who evaluates the patient must document the rationale for early termination and reinforce the consequences of not receiving the entire prescribed	03/12/2024

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	On 2/05/24, the treatment began at 1:07 PM and the total run time was 3 hours 10 minutes. The RN failed to document a shortened run time reason and failed notify the physician regarding the shortened run time. On 2/08/24, the treatment began at 7:02 AM and the total run time was 2 hours and 38 minutes. The RN failed notify the physician regarding the shortened run time. 3. During an interview on 2/08/24 beginning at 4:27 PM, the Clinical Manager indicated the above run times were accurate and stated they would review the clinical records for proper documentation of the shortened run times. 4. During an interview on 2/12/24 beginning at 11:10 AM, the Clinical Manager indicated the clinical record failed to include a reason the above run times were shortened and failed to include documentation that the physician was notified regarding the shortened run times for Patient #1.		treatment. The RN is responsible to notify the physician, and document on the "AMA", or ***Against Medical Advice*** form. If the patient frequently requests to end their treatment before the prescribed time, the RN should discuss the patient's reasons for frequently terminating early. Effective 02/23/24, the Clinical Manager will conduct 10 treatment sheets daily, 3 times per week, alternating shifts, with focus on any shortened hemodialysis treatments the RN will document the reason, notify the physician and obtains the AMA signed form from the patient, 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 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	

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			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 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 03/12/24	
V 0546 Bldg. 00	494.90(a)(3) POC-MANAGE MINERAL METABOLISM Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease. Based on record review and interview, the registered nurse (RN) failed to administer Vitamin	V 0546	V546 On 02/22/24, the Clinical Manager held a staff meeting, elicited	03/12/2024

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	D medication as prescribed for 1 of 3 active clinical records reviewed (Patient #3). Findings include: 1. A review of agency policy "Medication Preparation and Administration" indicated medications must be administered with an order by a physician. 2. Patient #3's hemodialysis treatment sheets, dated 1/25/24 to 2/07/24, were reviewed and evidenced a physician order for Vitamin D 0.25 mcg oral to be administered every dialysis treatment. 3. On 2/7/24, the treatment began at 11:31 AM. Patient #3 received oral Vitamin D medication that was entered into the electronic medical record (EMR) to be given during each treatment. The physican prescribed the medication to be given only on Mondays and Fridays. The patient should not have received the medication on 02/07/2024. The facility failed to ensure the patient's oral Vitamin D prescription was entered into the EMR correctly and failed to ensure Patient #3 received the medication as prescribed by the physician. 4. During an interview on 2/08/24 beginning at 4:56 PM, the Clinical Manager indicated the Vitamin D order had been entered incorrectly on 2/02/24 and the Vitamin D should have been administered on Monday and Friday during treatment.		input, and reinforced the expectations and responsibilities of the facility staff on the policy. ·Medication Preparation and Administration Emphasis was placed on: Medications must be administered with an order by a physician (or physician extender where allowed) on the medical staff of the facility. Effective 02/23/24, the Clinical Manager will conduct 10 treatment sheets daily, 3 times per week, alternating shifts, with focus on ensuring all patients receive medication as prescribed by the physician, 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 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	

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			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 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 03/12/24	
V 0550 Bldg. 00	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			

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	consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. Based on observation, policy review, and interview, the dialysis facility failed to ensure staff followed facility policies and procedures related to fistula and graft access for 1 of 1 observations. (Registered Nurse [RN] 4.) Findings include: 1. Policy Access Assessment and Cannulation, revised 07/05/22, indicated cannulation sites are not to be touched after skin disinfection. 2. On 02/09/24 at 11:01 AM, RN 4 was observed accessing Patient #7's fistula or graft. RN 4 disinfected Patient #7's cannulation site for 61 seconds and then touched the cannulation site with gloved fingers prior to inserting the first needle. 3. On 02/09/24 at 2:15 PM, the Clinical Manager relayed that when accessing a fistula or graft, the site should not be touched again after it was disinfected.	V 0550	V550 On 02/22/24, the Clinical Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the policy. ·Access Assessment and Cannulation Emphasis was placed on: Disinfect cannulation site as follows using any of the disinfectants below: 70% isopropyl alcohol pad: Using gentle friction, clean the access site beginning in the center and continuing outward 2 inches in a concentric circle for 30 seconds and allow to dry before cannulating. 2% Chlorhexidine and 70% alcohol: Work outward 2 inches in a concentric circle using gentle back and forth friction to clean for a minimum 30 seconds and allow to dry before cannulating Perform skin antisepsis on one site at a time, allow to dry and then cannulate. Do not touch cannulation sites after skin disinfection. Note: This method minimizes the risk of contaminating the second site while cannulating the first site Observe cannulation site for any reaction to antimicrobial solution.	03/12/2024

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			Effective 02/23/24, the Clinical Manager will conduct weekly audits 3 times per week, with alternating shifts with focus on ensuring staff disinfection of cannulation site per policy, utilizing Infection Control Audit Tool for 2 weeks and then 2 times per week 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. 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 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 for providing oversight, reviewing findings, and taking actions as appropriate. The root cause	

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIE (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
			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 03/12/24	
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, policy review, and interview, the dialysis facility failed to ensure their policies were followed related to medication storage for 1 of 1 treatment floor observation. Findings include: 1. Policy Medication Preparation and Administration, revised 02/06/23, indicated all medications will be kept in a locked cabinet when not in use.	V 0715	V715 On 02/22/24, the Clinical Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the policy. Medication Preparation and Administration Emphasis was placed on: All medications in syringes not being administered immediately shall be labeled	03/12/2024

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152634	A. BUILDING 00 B. WING	02/12/2024

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	2. On 02/09/24 at 11:16 AM, a multi-dose heparin (a medication used to prevent blood clotting) bottle, dated 02/09/24 but with no time, was observed unattended on the counter near Station 24 in the patient treatment area. The bottle was observed to still be unattended on the same counter on 02/09/24 at 11:35 AM and 11:46 AM. 3. During an interview on 02/09/23 beginning at 2:15 PM, the Clinical Manager indicated Heparin could be outside the medicine cabinet within 4 hours of being open but would otherwise need to be locked up. The Clinical Manager indicated pill bottles could be left on counters when the nurse was present on the treatment floor but would otherwise need to be locked up. 4. On 2/09/24 at 11:55 AM, one bottle of Azicef (a medication used to treat infection) and four bottles of Vitamin D was observed sitting on the counter nearest to Station #7 unattended; a patient was present in station #7. 5. During an interview on 2/09/24 beginning at 2:15 PM, the Clinical Manager indicated all medications should be in the locked cabinet when a nurse is not at the counter.		appropriately with the name of the medication, route, dose, name of patient, date, time and initials of the person who prepared the medication. If more than one syringe of the same medication is needed for a single patient, mark the label as “1 of 2, 2 of 2.” Reconstituted medication admixtures shall also include on the label the date and time the solution was prepared. Filled syringes do not have to be labeled if drawn up and administered immediately. These unlabeled, filled syringes must not be placed down at any time. Only one unlabeled, filled syringe can be drawn up and administered at one time. Oral medications not being administered immediately must also be labeled as indicated above. When preparing medications if the vial is not used immediately in its entirety, the nurse or PCT (if allowed by state regulations), must place the date and time the vial was opened on the medication label along with their initials. Note: To ensure all open vials are properly marked, the nurse must never walk away from an opened multi-dose vial without writing the date and time the vial was opened. Label any open multi-dose vial that is not used immediately and store vial accordingly.	

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			All medications will be kept in a locked cabinet except when in use. Effective 02/23/24, the Clinical Manager will conduct weekly audits 3 times per week, with alternating shifts with focus on ensuring staff medication stored per policy, as required, utilizing Infection Control Audit Tool for 2 weeks and then 2 times per week 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. 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 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 for providing oversight, reviewing	

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			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 03/12/24	