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	04/24/2023

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
E 0000 Bldg. 00		E 0000		
	An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFRwith 42 CFR 494.62. Survey Dates: April 18, 19, 20, 21, and 24, 2023 Census: 84 During this Emergency Preparedness survey, Fresenius Medical Care Muncie was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62.			
V 0000 Bldg. 00		V 0000		
	This visit was for a CORE Federal recertification survey of an ESRD provider. Survey dates: April 18, 19, 20, 21, and 24, 2023 Census by Service Type: In Center Hemodialysis: 72 Home Hemodialysis: 3 Home Peritoneal dialysis: 9 Total Census: 84 Isolation Room: 1 QR: 5/8/23, Area 2			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Betsey Farrar-McIntyre	Area Team Lead	05/19/2023

Any defiencystatement ending with an asterisk (*) denotes a deficency which the institution may be excused from correcting providing it is determin other safegaurds 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 disclo 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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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 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 observations, staff interviews, and policy review, the dialysis facility failed to ensure	V 0112	**V 112 IC-CDC** On 5/18/2023, the Clinical Manager held a staff meeting and	05/23/2023

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	all staff followed policies and procedures related to infection control for 2 of 2 physicians observed (Physician #1 and Medical Director), 2 of 4 Patient Care Technicians observed (PCT #1 and 4), and 1 of 4 in-center hemodialysis registered nurses observed (RN #4). Findings include: 1. During an observation on 04/18/2023 at 9:40 a.m., Physician #1 failed to remove gown and failed to perform hand hygiene before leaving the in-center patient treatment area. 2. During observation periods on 4/18/23 from 8:40 a.m. to 9:40 a.m., on 4/19/23 from 10:31 a.m. to 12:40 p.m., and on 4/20/23 10:55 a.m. to 11:30 a.m., observed PCT #1 and PCT #5 failed to ensure their face masks covered their noses while on the treatment floor for the duration of the observations. PCT #1 was observed wearing open back shoes with holes / vents on the top and sides; PCT #1 failed to wear shoes with a solid footbox without holes or vents on the patient treatment floor for the duration of the observations. 3. During observation on 4/18/23 at 9:27 a.m., RN #4 failed to ensure their face shield was in place to shield against possible blood or fluid spatter to the eyes, nose, and mouth while in station #11, during the time PCT #4 accessed Patient's AV fistula or graft. 4. During an interview with Clinical Manager #1, conducted on 4/20/23 at 11:36 a.m., the Clinical Manager confirmed that face masks should cover the face, nose and breathing opening should have a tight seal as much as possible, face shields should be worn down over eyes, face and nose		reinforced the expectations and responsibilities of the facility staff on policy and procedure: · Hand Hygiene Policy and Procedure · Personal Protective Equipment · Employee Dress Code Emphasis was placed on: · Staff should change gloves and practice hand hygiene between each patient and/or station to prevent cross-contamination. · Hands will be: o 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* § 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	

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	during patient care, and indicated staff should wear closed shoes that are non-porous. 5. During an observation of a home hemodialysis patient's physician appointment on 04/19/23 at 09:17 a.m., the Medical Director failed to perform hand hygiene after removing their paper gown and before exiting the exam room. 6. During an interview on 04/19/2023 at 09:35 a.m., the Medical Director indicated staff should always perform hand hygiene after removing personal protective equipment such as gowns. 7. Policy: "Hand Hygiene", dated 03/17/23, indicated that hands will be decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and water when entering and leaving the treatment area. 8. Policy: "Personal Protective Equipment", dated 02/04/18 indicated that all PPE shall be removed prior to leaving the treatment area and indicated full face shield should be worn in an area at risk for blood splatter or spill. 9. Policy: "Employee Dress Code", dated 06/18/21 indicated that when in a patient care or lab area, footwear must be worn that meets the following safety requirements: has a solid footbox (no holes or vents).		§ After contact with the dialysis wall box, concentrate, drain, or water lines. § After contact with other objects within the patient station or treatment space · Staff should adhere to Personal Protective Equipment: o face masks should cover the nose and mouth. o Face shields should be worn down over eyes, face, and nose during patient care. · When in a patient care or lab area, footwear must be: • water and slip resistant, • can be easily cleaned and • has a solid foot-box (no holes or vents). Inappropriate footwear includes, but is not limited to canvas sneakers, mesh top athletic shoes, or any type of shoe or sandal that is not enclosed. Effective 5/16/2023, the Clinical Manager or designee will conduct weekly audits with focus ensuring face masks cover nose and mouth, face shield in place covering eyes, nose and mouth during possible blood or fluid spatter events. Staff are wearing shoes that completely cover their feet with no holes are vents present. Physicians, physician extenders and facility staff remove gowns, gloves and perform hand hygiene per facility policy by staff	

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			utilizing Infection Control Audit Tool 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 Tool 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	

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			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 05/23/2023	
V 0113 Bldg. 00	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. Based on observation, interview, and policy review, the dialysis facility failed to ensure all staff followed their policies and procedures related to hand hygiene for 1 of 4 Patient Care Technicians (PCT) observed (PCT #5.) Findings include: 1. During an observation on 04/19/23 at 10:52 a.m., PCT #5 removed gloves, failed to perform hand hygiene before taking Patient #19 vitals and failed to perform hand hygiene before donning new gloves. 2. During an observation on 4/19/23 at 12:03 p.m., PCT #5 was observed during discontinuation of Dialysis on Patient #16. PCT #5 touched her mask twice and adjusted her face shield once with gloves on and failed to perform hand hygiene before continuing to care for Patient. Once dialysis lines were discontinued, PCT #5 failed to perform hand hygiene after removing gloves. PCT #5 touched RN #4's face shield, then washed	V 0113	**V 113 IC-Wear Gloves/Hand Hygiene** On 5/18/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure: · Hand Hygiene Policy and Procedure Emphasis was placed on: · Staff should change gloves and practice hand hygiene between each patient and/or station to prevent cross-contamination. · Hands will be: o 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	05/23/2023

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	hands at sink for 4 seconds, then dried her hands, donned new gloves and then adjusted their hair. PCT #5 then failed to perform hand hygiene before again touching Patient #16. 3. During an interview with Clinical Manager #1 conducted on 4/20/23 at 11:36 a.m., the Clinical Manager confirmed that staff should have performed hand hygiene after they removed gloves, after contact with patients, and after touching the face, mask or hair. 4. Review of policy "Hand Hygiene", dated 03/17/23, indicated hands should have been decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and water before and after direct contact with patients, immediately after removing gloves, and after contact with other objects within the patient station or treatment space. 5. Review of policy "Hand Hygiene Procedure," dated 09/26/2018, indicated the entire duration of handwashing procedure should have been 40-60 seconds.		§ *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* § If hands are physically soiled and require soap and water the duration of the entire procedure should be 40-60 seconds. If decontaminating hands with alcohol-based hand rub the duration of the entire procedure should be 20- 30 seconds. Effective 5/16/2023, the Clinical Manager or designee will conduct weekly audits with focus ensuring hand hygiene is performed per facility policy by staff utilizing Infection Control Audit Tool for four weeks or until 100% compliance is achieved. Once compliance is	

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			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 Tool 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	

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			minutes, education and monitoring documentation are available for review at the clinic. Completion 05/23/2023.	
V 0146 Bldg. 00	494.30(c)(2) IC-CATHETERS:GENERAL (2) The "Guidelines for the Prevention of Intravascular Catheter-Related Infections" entitled "Recommendations for Placement of Intravascular Catheters in Adults and Children" parts I - IV; and "Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients," Morbidity and Mortality Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002. 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 as the CMS 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 Based on observations, interview, and record review, the facility failed to ensure all patients with a central venous catheter (CVC) received care in compliance with facility policy in 1 of 1 observation of patient care technician (PCT) #4 during provision of care of a CVC and 1 of 2 observations of a registered nurse (RN) #4 during initiation of dialysis in a patient with a CVC.	V 0146	**V 146 IC-CATHETERS** On 5/18/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure: · Initiation of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam	05/23/2023

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	Findings include: 1. During an observation on 04/18/23 at 8:50 a.m., observed RN #4 disinfect Patient #3's CVC access ports prior to cannulation. The RN failed to cleanse the red hub for at least 10 seconds, before connecting syringes. 2. On 04/19/23 at 11:24 a.m., PCT # 4 was observed as they provided CVC exit site care to a patient with a CVC. PCT #4 was observed to remove the old dressing and discarded, changed gloves and performed hand hygiene, and then cleaned the exit site for 15 seconds. 3. During an interview on 04/20/23 beginning at 11:36 a..m., the clinical manager indicated they thought the CVC exit site should be cleaned for 40-60 seconds but would need to refer to policy. 4. Policy: "Initiation of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer", dated 07/06/2021, indicated the threads and end of the luer lock (hub) must be scrubbed with 70% sterile alcohol pad (or other antiseptic such as chlorhexidine, povidone of required by the hospital) for 10-15 seconds and any time caps are removed, or bloodlines are disconnected to reduce risk of contamination. 5. The facility Clinical Service Procedure, reference # 45664, published 5/02/22 relayed that after removal of the soiled dressing and hand hygiene and glove change, the clinician is to clean the exit site for 30 seconds.		Dialyzer · Changing the Catheter Dressing Policy and Procedure Emphasis was placed on: · When cleaning the Central Venous Catheter, the threads and end of the luer lock (hub) must be scrubbed with 70% sterile alcohol pad (or other antiseptic such as chlorhexidine, povidone of required by the hospital) for 10-15 seconds and any time caps are removed, or bloodlines are disconnected to reduce risk of contamination. · Catheter exit site disinfection and dressing change is to be completed prior to cap and hub connector disinfection. · clean the catheter exit site: o 2% Chlorhexidine and 70% alcohol: Using gentle back and forth friction, clean the exit site beginning in the center and continuing outward 2 inches in a concentric circle for 30 seconds and allow to dry a minimum of 30 seconds. Effective 5/16/2023, the Clinical Manager or designee will conduct weekly audits with focus ensuring catheter dressing change and cleaning of the catheter hub is performed per facility policy by staff utilizing Central Venous Catheter Exit Site Care Audit Tool for four weeks or until 100% compliance is achieved. Once compliance is sustained, the	

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			Governing Body will decrease frequency to resume regularly scheduled audits based on the QAI calendar. 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. 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	

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			minutes, education and monitoring documentation are available for review at the clinic. Completion 05/23/2023.	
V 0184 Bldg. 00	494.40(a) ENVIRONMENT-SECURE & RESTRICTED 8 Environment: secure & restricted The water purification and storage system should be located in a secure area that is readily accessible to authorized users. The location should be chosen with a view to minimizing the length and complexity of the distribution system. Access to the purification system should be restricted to those individuals responsible for monitoring and maintenance of the system. Based on observation and interview, the facility failed to ensure the water purification and storage system room access was restricted from unauthorized personnel and failed to ensure the doors were locked in 1 of 1 facility reviewed. Findings include: 1. Observation during the facility flash tour on 04/18/23 at 8:35 AM, revealed the storage room which also contained the bicarb storage and mixer and acid storage tanks was not secured from unnecessary entrance. The storage room has 2 entrances, one was able to be secured and was secured, the 2nd was without a system to secure. The unsecured door led to a continuous hallway in which home patients and their family members / caregivers would use when on site. 2. During an interview on 04/19/2023 at 04:58 PM, the Clinical Manager agreed the area containing the bicarb storage and mixer and acid storage	V 0184	**V 184 ENVIRONMENT-SECURE & RESTRICTED** On 5/18/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure: · Physical Security and Facility Access Emphasis was placed on: · Secure all doors that allow access to the water treatment equipment. On 4/20/2023 Area Technical Operations Manager (ATOM) spoke with contractor, Andy at Handy Repair Guys regarding the scope of work needed. On Thursday, 5/11/2023, the contractor reviewed work needed and provide facility with a quote for installing lock to secure all doors	05/19/2023

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	tanks should have been secured from unauthorized entry. 3. Review of policy "Physical Security and Facility Access," published 12/18/2013, indicated all doors that allowed access to water treatment equipment should have been locked.		in water treatment storage room. Work scheduled for completion with contractor by 5/19/2023. Effective 5/16/2023, the Clinical Manager or designee will conduct weekly audits with focus on ensuring all doors are secured for any rooms that house water treatment equipment utilizing Water and Dialysate Observation 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. 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 05/19/2023	
V 0228 Bldg. 00	494.40(a) MIXING SYSTEMS-LABELING 5.4.4.1 Mixing systems: labeling Labeling strategies should permit positive identification by anyone using the contents of mixing tanks, bulk storage/dispensing tanks, and small containers intended for use with a single hemodialysis machine. Mixing tanks: Prior to batch preparation, a label should be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. This labeling should remain on the mixing tank until the tank has been emptied. Bulk storage/dispensing tanks: These tanks should be permanently labeled to identify the chemical composition or formulation of their contents.			

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	Concentrate jugs: At a minimum, concentrate jugs should be labeled with sufficient information to differentiate the contents from other concentrate formulations used at the facility. Based on observation, staff interview, and policy review, the dialysis facility failed to ensure the bicarbonate dispensing tank was properly labeled during 1 of 1 flash tour observations. Findings include: 1. During the flash tour on 04/18/2023 beginning at 8:35 a.m., observed the bicarbonate dispensing tank failed to evidence the date and time mixed. 2. During an interview on 4/18/23 at 2:40 pm, Biomed Technician #1 relayed the bicarb dispensing tank should have been labeled with the date and time mixed. 3. Policy: "Concentrate Labeling Requirements", dated 05/27/21, indicated when a mix tank contained a solution, a label identifying the solution should have been conspicuously displayed on the tank and must have remained until the mix tank was emptied and should have included the date and time of mixing.	V 0228	**V 228 MIXING SYSTEMS-LABELING** On 5/18/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure: · Concentrate Labeling Requirements Emphasis was placed on: § When a mix tank contains a solution, a label identifying the solution ***must*** be conspicuously displayed on the tank and must remain until the mix tank is emptied. § Mix tank labeling ***must*** include: o Contents identification. o Chemical composition or formulation of concentrate o Concentrate family with appropriate symbol. o Catalog number of product o *Date and time of mixing* Effective 5/16/2023, the Clinical Manager or designee will conduct weekly audits with focus on ensuring the bicarbonate dispensing tank is properly labeled per policy utilizing Water and Dialysate Observation Audit for four weeks or until 100% compliance is achieved. Once	05/23/2023

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			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. 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.	

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			The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 05/23/2023	
V 0543 Bldg. 00	494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; 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 and failed to ensure the registered nurse (RN) completed a timely pre-dialysis treatment assessment for 6 of 6 in-center hemodialysis (ICHD) clinical records reviewed (Patients #1, 3, 6, 7, 8, and 9); failed to ensure the patient care technician [PCT] failed to notify the RN of a high BP for 1 of 6 ICHD patient records reviewed (Patient #6) and failed to ensure patient's estimated dry weight (EDW) was achieved for 4 of 6 ICHD clinical records reviewed (Patient #3, 6, 8, and 9.) Findings include: 1. Patient #1's hemodialysis treatment sheets, dated 03/30/23 - 04/15/23, was reviewed and evidenced the following: On 04/04/23, the treatment began at 05:38 AM; the RN assessment was performed at 06:47 AM, 1 hour and 9 minutes after treatment began.	V 0543	**V 543 POC-Manage Volume Status** On 5/18/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: · Nursing Supervision and Delegation · Patient Assessment and Monitoring · 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.	05/23/2023

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	On 04/06/23, the BP check was at 05:52 AM with a follow-up BP check at 07:04 AM, 1 hour and 12 minutes later. The treatment began at 05:50 AM; the RN assessment was performed at 06:58 AM, 68 minutes later. On 04/08/23, the treatment began at 05:48 AM; the RN pre-treatment assessment was performed at 07:27 AM, 1 hour and 39 minutes later. On 04/11/23 the treatment began at 05:45 AM and the RN pre-treatment assessment was performed at 08:01 AM, 2 hours and 16 minutes later. On 04/13/23, the treatment began at 05:44 AM; the RN pre-treatment assessment was performed at 07:11 AM, 1 hour and 27 minutes later. On 04/15/23 the treatment began at 05:44 AM; the RN pre-treatment assessment was performed at 06:46 AM, 1 hour and 12 minutes later. 2. Patient #7 hemodialysis treatment sheets, dated 03/31/23-4/17/23, were reviewed and evidenced the following: On 03/31/23, treatment began at 01:02 PM; the RN pre-treatment assessment was performed at 02:11 PM, 1 hour and 9 minutes later. On 04/07/23, Patient's BP check was documented at 03:32 PM with a follow-up BP check at 04:19 PM, 47 minutes later. On 04/10/23, treatment began at 01:39 PM; the RN pre-treatment assessment was performed at 02:47 PM, 68 minutes later. On 04/14/23, patient's BP check was at 03:02 PM		o 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 must evaluate each patient preferably within an hour or according to state requirements. · Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulations. o 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 o Document any findings and interventions in the medical record. · Prior to discharge, the RN must review the treatment record to: · o Confirm patent is stable for discharge. o Identify any process that could have resulted in the patient experiencing a safety event or near miss. o The record must be reviewed 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*	

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	with a follow-up BP check at 04:05 PM, 63 minutes later. Treatment began at 01:11 PM; the RN pre-treatment assessment was performed at 02:25 PM, 1 hour and 14 minutes later. On 04/17/23, treatment began at 01:19 PM; the RN pre-treatment assessment was performed at 03:37 PM, 2 hours and 18 minutes later. On 04/14/23, patient's BP was checked at 03:02 PM with a follow-up BP check at 04:05 PM, 63 minutes later. Treatment began at 01:11 PM; the RN pre-treatment assessment was performed at 02:25 PM, 1 hour and 14 minutes later. On 04/17/23, treatment began at 01:19 PM; the RN pre-treatment assessment was performed at 03:37 PM, 2 hours and 18 minutes later. 3. During an interview on 04/19/23 at 3:24 PM, the Clinical Manager stated the post dialysis treatment weight should be plus or minus 1 kilogram of the EDW and goal should be reviewed often and at the end of each treatment. 4. During an interview on 04/21/23 at 11:51 AM, the Clinical Manager relayed that blood pressure checks should have been completed every 30 minutes and RNs should have noted why a pre-treatment assessment was late if over an hour after the start of treatment. 5. Review of policy "Patient Assessment and Monitoring," published 09/29/2018, indicated but not limited to staff should have performed blood pressure checks every 30 minutes or more often as needed but no more than 45 minutes between blood pressure checks and indicated staff was to ensure the post weight was consistent with the goal set.		§ 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. Effective 5/15/2023, the Clinical Manager or designee will conduct weekly treatment sheet audits on 10% of completed treatments with focus on ensuring nursing assessments are completed timely, abnormal blood pressures reported to the RN, vital signs and safety checks are recorded every 30 minutes or not to exceed 45 minutes, EDW within 1 Kg post treatment or documentation present when EDW not met according to facility policy utilizing Treatment Sheet Audit Tool 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. The Clinical Manager is	

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	6. Review of policy "Hypertension," published 09/07/2021, indicated the patient care technician should have notified the RN of any blood pressures greater than 180 systolic or 100 diastolic. 7. Review of policy reference #45265, published 11/01/2021, indicated the registered nurse should assess each patient, preferably within one hour of initiation of hemodialysis. 8. Patient #3's hemodialysis treatment sheets, dated 03/30/23 - 04/15/23 were reviewed and evidenced the following: On 04/01/23, a BP check was completed at 9:44 AM; the next BP check was at 10:33 AM, 49 minutes later. On 04/06/23 Patient's BP was checked at 9:16 AM with a follow-up BP check at 10:03 AM, 47 minutes later. On 04/06/23 Patient's BP was checked at 11:38 AM with a follow-up BP check at 12:40 PM, 62 minutes later. On 04/08/23 Patient's BP was checked at 10:03 AM with a follow-up BP check at 11:35 AM, 1 hour and 32 minutes later. On 04/04/23 Patient's hemodialysis began at 8:35 AM; the RN assessment was at 9:47 AM, 72 minutes later. On 04/08/23, dialysis began at 9:26 AM with RN assessment at 12:14 PM, 2 hours and 48 minutes later. On 04/15/23, dialysis began at 8:51 AM with RN		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 05/23/2023	

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	assessment at 10:15 AM, 1 hour and 24 minutes later. On 03/30/23, patient's Post Dialysis weight was 99.9 kg and failed to meet the EDW of 98.50 kg. 9. Patient #6's treatment sheets, dated 04/06/23 - 04/20/23 were reviewed and evidenced the following: On 04/06/23 Patient's BP was checked at 7:05 AM with a follow-up BP check at 7:59 AM, 54 minutes later. On 04/08/23 Patient's BP was checked at 9:06 AM with a follow-up BP check at 10:09 AM, 63 minutes later. On 04/13/23 Patient's BP was checked at 6:34 AM with a follow-up BP check at 7:33 AM , 59 minutes later. On 04/06/23 Patient's BP was checked at 7:05 AM and indicated a BP of 179/101. Patient Care Technician (PCT) #1 failed to notify the Registered Nurse (RN) on duty. On 04/08/23 Patient's BP was checked at 6:30 AM and indicated a pre-dialysis BP of 205/111. RN #3 failed to notify the nephrologist prior to starting treatment. On 04/13/23 Patient's BP was checked at 6:14 AM and indicated a pre-dialysis BP of 202/83. PCT #1 failed to notify RN on duty nor was the physician made aware prior to starting treatment. On 04/20/23 Patient's BP was checked at 6:03 AM and indicated a pre-dialysis BP of 208/106. BP check at 6:11 AM indicated a BP of 215/121 and a			

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	BP check at 6:34 AM indicated a BP of 198/106. RN #6 failed to notify the physician prior to starting hemodialysis treatment and failed to obtain PRN anti-hypertensive orders. On 04/11/23, dialysis started at 6:11 AM with the RN Assessment at 8:23 AM, 2 hours and 12 minutes later. On 04/13/23, dialysis started at 6:19 AM with the RN Assessment at 7:44 AM, 1 hour and 25 minutes later. On 04/20/23, dialysis started at 6:11 AM with RN Assessment at 8:43 AM, 2 hours and 32 minutes later. On 04/06/23, Patient's Post Dialysis weight was 67.9 kg and failed to meet the EDW of 66.00 kg. 10. Patient #8 treatment sheets dated 04/03/23 - 04/18/23 reviewed on 04/21/23 evidenced the following: On 04/10/23 Patient's BP was checked at 12:18 PM with a follow-up BP check at 1:03 PM, 45 minutes later. On 04/10/23 Patient's BP was checked at 2:15 PM with a follow-up BP check at 3:06 PM, 51 minutes later. On 04/03/23, dialysis started at 12:13 PM with RN Assessment at 3:46 PM, 3 hours and 33 minutes later. On 04/05/23, dialysis started at 11:42 AM with RN Assessment at 12:53 PM, 1 hour and 11 minutes later.			

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	On 04/07/23, dialysis started at 11:40 AM with RN Assessment at 2:19 PM, 2 hours and 39 minutes later. On 04/10/23, dialysis started at 12:29 PM with RN Assessment at 3:21 PM, 2 hours and 52 minutes later. On 04/12/23, dialysis started at 11:59 AM with RN Assessment at 1:34 PM, 1 hour and 35 minutes later. On 04/14/23, dialysis started at 12:16 PM with RN Assessment at 2:58 PM, 2 hours and 42 minutes later. On 04/07/23, Patient's Post Dialysis weight was 105.00 kg and failed to meet EDW of 103.00 kg. On 04/10/23, Patient's Post Dialysis weight was 106.40 kg and failed to meet EDW of 103.00 kg. On 04/12/23, Patient's Post Dialysis weight was 106.00 kg and failed to meet EDW of 103.00 kg. On 04/14/23, Patient's Post Dialysis weight was 104.10 kg and failed to meet EDW of 103.00 kg. 9. Patient #9 hemodialysis treatment sheets, dated 04/01/23 - 04/18/23, were reviewed and evidenced the following: On 04/08/23, Patient's BP was checked at 8:45 AM with a follow-up BP check at 9:33 AM, 48 minutes later. On 04/08/23, Patient's BP was checked at 10:01 AM with a follow-up BP check at 11:03 AM, 62 minutes later.			

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	On 04/08/23, Dialysis began at 8:45 AM with RN Assessment at 12:21 PM, 3 hours and 36 minutes later. On 04/11/23, Dialysis began at 8:34 AM with RN Assessment at 3:05 PM, 6 hours and 31 minutes later. On 04/15/23, Dialysis began at 8:40 AM with RN Assessment at 10:17 AM, 1 hour and 37 minutes later. On 04/18/23, Dialysis began at 8:17 AM with RN Assessment at 10:01 AM 1 hour and 44 minutes later. On 04/04/23, Patient's Post Dialysis weight was 100.00 kg and failed to meet EDW of 94.00 kg. On 04/06/23, Patient's Post Dialysis weight was 98.10 kg and failed to meet EDW of 94.00 kg. On 04/08/23, Patient's Post Dialysis weight was 100.00 kg and failed to meet EDW of 94.00 kg. On 04/11/23, Patient's Post Dialysis weight was 95.9 kg and failed to meet EDW of 94.00 kg. On 04/15/23, Patient's Post Dialysis weight was 96.4 kg and failed to meet EDW of 94.00 kg.			
V 0544 Bldg. 00	494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.	V 0544	**V 544 POC-ACHIEVE ADEQUATE**	05/23/2023

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	Based on observation, record review, and interview, the dialysis facility failed to ensure the dialysate flow rate (DFR) and blood flow rate (BFR) were set according to physician orders for 6 of 6 in-center dialysis patient records reviewed (Patient #1, 3, 6, 7, 8, and 9) and for 1 of 4 patients observed to during the flash tour (Patient #21). Findings include: 1. During the flash tour on 04/18/23 at 09:11 AM, observed Patient #21 treatment was running with a DFR of 600. The patient treatment order indicated a physician ordered DFR of 800. Registered Nurse (RN) #3 indicated a change in DFR could have been changed due to clearance and the reason should have been documented in the comments area of the treatment run sheet. Review of Patient #21's treatment run sheet for 04/18/23 failed to evidence a reason for the DFR to differ from the physician order. 2. Patient #1 record was reviewed and included a review of the Treatment Sheets dated 03/30/23 through 04/15/23. The record evidenced a physician ordered BFR of 400 during the dialysis treatments. The treatment sheets dated 04/01/23 documented Patient #1's treatment began at 05:32 AM with a BFR of 400, then ran at a BFR of 350 beginning at 06:02 AM and for the entire treatment. The treatment sheets dated 04/04/23 documented the treatment began at 05:38 AM with a BFR of 400, then at 06:26 AM, began a BFR at 315 until 07:01 AM, then ran a BFR of 300 from 07:01 AM and for the remainder of the treatment. 3. Patient #7 Treatment Sheets dated 03/31/23 -		**CLEARANCE** On 5/18/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Patient Assessment and Monitoring Emphasis was placed on: · Document machine parameters and safety checks every 30 or more often as needed but not to exceed 45 minutes or per state regulations. o Check machine settings and measurements: § Check prescribed blood flow is being achieved or reason is documented in medical record if unable to meet prescribed blood flow. § Check dialysate flow rate setting is correct, and the prescribed flow is being delivered. Effective 5/15/2023, the Clinical Manager or designee will conduct weekly treatment sheet audits on 10% of completed treatments with focus on ensuring the dialysate flow rate (DFR) and blood flow rate (BFR) are set according to physician order, or justification documented if unable to achieve for four weeks or until 100% compliance is achieved utilizing Treatment Sheet Audit Tool. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring	

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	152634	A. BUILDING 00 B. WING	04/24/2023

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

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	04/17/23 were reviewed and evidenced the following: On 04/07/2023 physician ordered DFR was 800. Patient #7's treatment began at 01:02 PM with a DFR of 800, then ran at a DFR of 500 for the remainder of the treatment. 4. During an interview on 04/21/2023 at 11:51 AM, the Clinical Manager indicated the reason the BFR or DFR did not match the physician order should have been documented on the treatment run sheet. 5. Review of policy "Patient Assessment and Monitoring," published 09/29/2018, indicated BFR and DFR should have been checked to ensure the prescribed flow rate was being achieved. 6. Patient #3 Treatment Sheets dated 03/30/23 - 04/15/23 was reviewed and evidenced the following: On 03/30/23, the physician ordered BFR was 400. Dialysis treatment was started 9:13 a.m. with BFR at 400; the BFR was changed to 350 at 10:03 a.m. for the remainder of treatment. On 04/01/23, the physician ordered BFR was 400. Dialysis was started 8:42 a.m. the BFR at 380; the BFR was changed to 300 at 9:03 a.m. for the remainder of treatment. On 04/04/23, the physician ordered BFR was 400. Dialysis was started 8:35 a.m. with a BFR at 400; the BFR was changed to 450 at 9:32 a.m. and at 12:03 p.m., the BFR was changed to 425 for the remainder of treatment. On 04/06/23, the physician ordered BFR was 400. Dialysis was started 9:17 a.m. with BFR at 400; the		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. 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 05/23/2023	

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	BFR was changed to 350 at 9:34 a.m. and at 12:40 p.m. the BFR was changed to 300 and for the remainder of treatment. On 04/08/23 the physician ordered BFR was 400. Dialysis was started 9:26 a.m. with a BFR at 400; the BFR was changed to 350 at 11:04 a.m. for the remainder of treatment. On 04/15/23 the physician ordered BFR was 400. Dialysis was started 8:51 a.m. with BFR at 350; the BFR was changed to 325 at 10:33 a.m. for the remainder of treatment. 7. Patient #6 Treatment Sheets dated 04/06/2023-04/20/2023 were reviewed and evidenced the following: On 04/06/2023 the physician ordered BFR was 400. Dialysis was started 6:36 a.m. a BFR at 350; the BFR was changed to 300 at 7:05 a.m. and ran at a BFR of 300 to 400 throughout the remainder of the treatment. On 04/13/23 the physician ordered BFR was 400. Dialysis was started 6:18 a.m. with BFR at 400; the BFR was changed to 350 at 8:04 a.m. for the remainder of treatment. On 04/20/23 the physician ordered BFR was 400. Dialysis was started 6:11 a.m. with BFR at 400; the BFR was changed to 350 at 9:02 a.m. for the remainder of treatment. 8. Patient #8 Treatment Sheets dated 04/03/23 - 04/18/23 reviewed and evidenced the following: On 04/03/23 the physician ordered DFR was 700. Dialysis was started 12:13 p.m. with a DFR at 700; the DFR was changed to 800 at 3:05 p.m.			

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	throughout the remainder of the treatment. On 04/05/23 the physician ordered BFR was 400 and DFR was 700. Dialysis was started 11:42 a.m. with a BFR at 400 and the DFR at 700. The BFR was changed to 425 at 2:02 p.m. and DFR was changed to 800 at 3:05 p.m. throughout the remainder of the treatment. On 04/10/23 the physician ordered DFR was 700. Dialysis was started 12:29 p.m. with DFR at 200. The DFR was changed to 800 at 1:03 p.m. throughout the remainder of the treatment. On 04/12/23 the physician ordered BFR was 400 and DFR was 700. Dialysis was started 11:59 a.m. with a BFR at 375. The BFR was changed to 350 at 1:33 p.m. and ran a BFR of 350 to 370 throughout the remainder of the treatment. 9. Patient #9 Treatment Sheets dated 04/03/23 - 04/18/23 was reviewed and evidenced the following: On 04/08/23 the physician ordered BFR was 400. Dialysis was started 8:42 a.m. with a BFR at 400; the BFR was changed to 350 at 9:33 a.m. and ran a BFR of 350 to 365 throughout the remainder of the treatment. On 04/11/23 the physician ordered DFR was 700. Dialysis was started 8:32 a.m. with DFR at 800 for duration of treatment. On 04/13/23 the physician ordered DFR was 700. Dialysis was started 8:36 a.m. with DFR at 700; the DFR was changed to 800 at 9:07 a.m. throughout the remainder of the treatment. On 04/15/23 the physician ordered BFR was 400			

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	and DFR was 700. Dialysis was started 8:40 a.m. with BFR at 300 and DFR at 700; the BFR was changed to 400 at 9:00 a.m. and DFR changed to 800 at 9:00 a.m. throughout the remainder of the treatment. On 04/18/23 the physician ordered BFR was 400 and DFR was 700. Dialysis was started 8:17 a.m. with a BFR at 300 and the DFR at 800. The BFR was changed to 400 at 8:34 a.m. and DFR ran at 800 throughout the remainder of the treatment.			
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 consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. Based on observation, interview and record review, the End Stage Renal Disease (ESRD) facility failed to ensure staff followed facility policies and procedures related to fistula and graft access for 1 of 2 observations of staff performed cannulation of a fistula or graft (Patient Care Technician [PCT] #5). Findings include: 1. During an observation on 04/18/23 at 9:23 am, observed PCT #5 failed to clean Patient #20's access sites for at least 30 seconds prior to cannulation.	V 0550	**V 550 POC-VASCULAR ACCESS-MONITOR/REFERRALS** On 5/18/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Patient Assessment and Monitoring · Access Assessment and Cannulation Emphasis was placed on: · All staff to ensure patient's access remains uncovered during treatment. · Cannulation sites should be	05/23/2023

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	2. During an observation on 4/18/23 at 8:44 a.m., observed Patient #9, 24, 25 and 26 with access covered and during an observation on 4/20/23 at 11:24 a.m., observed Patient #19 and 22 with access covered. 3. Policy: "Access Assessment and Cannulation", dated 07/05/22, indicated cannulation sites should have been disinfected for a minimum of 30 seconds using 70% alcohol pad, povidone iodine pad, or 2% chlorhexidine and 70% alcohol. 4. Review of policy "Patient Assessment and Monitoring," published 09/29/2018, indicated staff should have ensured access remained uncovered throughout treatment. 5. During an interview conducted on 4/20/23 at 11:36 a.m., the Clinical Manager #1 confirmed staff should have scrubbed access sites for 30 seconds before cannulation and indicated that access sites should not have been covered during treatment.		disinfected for a minimum of 30 seconds using 70% alcohol pad, povidone iodine pad, or 2% chlorhexidine and 70% alcohol. Effective 5/16/2023, the Clinical Manager or designee will conduct daily audits with focus on ensuring the patient access is uncovered during the treatment for one week and then weekly for three weeks. Effective 6/6/2023, the Clinical Manager or designee will conduct weekly audits with focus on ensuring all patients access are disinfected per policy for four weeks or until 100% compliance is achieved utilizing the Clinical Practice Checklist 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. 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	

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			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 05/23/2023	
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, interviews, and record review, the dialysis facility failed to follow their own policies and failed to ensure water hardness test strips were labeled with the opened date and failed to ensure medication was secure when not in use and labeled with date of opening for 1 of 1	V 0715	**V 715 MD RESP-ENSURE ALL ADHERE TO P&P** On 5/18/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:	05/23/2023

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	dialysis facility. Findings include: 1. On 04/18/23 at 08:40 AM, observed an open, unattended heparin bottle without an open date, set on the counter nearest to Station #24; a patient was present in station #24. 2. On 04/20/23 during an observation that began at 04:00 AM, observed water hardness test strips without the open date or initials of individual that opened the bottle. PCT #1 confirmed the bottle of test strips was not dated. 3. During an interview on 04/20/23 at 11:36 AM, the Clinical Manager indicated heparin should not have been left in the station, should have been stored in cabinet at a medication station when not in use, indicated open heparin vials should have the time, date, and initialed by the individual that opened at the time of opening, and indicated the test strips should have been dated, when opened. 4. Review of policy reference #47488 dated 02/06/23 indicated medication vials should have been dated, timed, and initialed when opened and should have been placed in a cabinet when not in use. 5. Review of policy reference #47424 dated 10/24/2022 indicated the water hardness test strips bottle should have been labeled with the date when opened.		· Total Hardness Testing with SteriChek Sensitive Low-Range Water Hardness Test Strip Procedure · Medication Preparation and Administration Procedure Emphasis was placed on: · When bottle of water hardness test strips is opened, staff must label with open date, initials of staff who opened the bottle. · 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. · Label any open multi-dose vial that is not used immediately and store the vial accordingly. Effective 5/16/2023, the Clinical Manager or designee will conduct weekly audits with focus on ensuring all open medication vials as well as bottles containing test strips have date opened, staff initials who opened the vial, and time for four weeks or until 100% compliance is achieved utilizing Clinical Practice Checklist 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.	

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			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 take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible 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 05/23/2023	

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V 0727 Bldg. 00	494.170(a) MR-PROTECT PT RECORDS FM LOSS/CONFIDENTIAL The dialysis facility must- (1)Safeguard patient records against loss, destruction, or unauthorized use; and (2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following: (i) The transfer of the patient to another facility. (ii) Certain exceptions provided for in the law. (iii) Provisions allowed under third party payment contracts. (iv) Approval by the patient. (v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program. Based on observation, interview, and record review, the dialysis facility failed to ensure that patient records were kept in a secure, locked location for 1 of 1 agency. Findings include: 1. On 4/18/23 at 4:30 p.m., observed a stack of papers with patients' personal health information (PHI) placed face up on a small table in the unlocked conference room; surveyors were directed to work in this space. 2. Review of facility policy "HIPAA Privacy Policies and Procedures," revised 04/29/2021, indicated paper copies of PHI were to be secured in locked offices, file rooms, cabinets, or desk drawers. When paper copies of PHI were outside of storage for use, they were to be placed in folders, under a cover sheet, face down on a working surface, or handled in a similar manner to prevent unintended access to the PHI.	V 0727	**V 727 MR-PROTECT PT RECORDS FM LOSS/CONFIDENTIAL** On 5/18/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Medical Record Guidelines · HIPAA Security Standard Emphasis was placed on: · Paper copies of personal health information (PHI) must be secured in locked offices, file rooms, cabinets, or desk drawers. When paper copies of PHI are outside of storage for use, they are to be placed in folders, under a cover sheet, face down on a working surface, or managed in an equivalent manner to prevent unintended access to the PHI.	05/23/2023

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	3. During an interview on 04/19/2023 at 04:58 PM, the Clinical Manager indicated the conference room in which the papers were observed was last used approximately one week prior, indicated the conference room was not usually locked, that the cleaning company had access to the room, and the room was normally used for staff education and patient conferences were held in the room.		Effective 5/16/2023, the Clinical Manager or designee will conduct weekly audits with focus on ensuring no PHI is left unsecured within the facility for four weeks or until 100% compliance is achieved utilizing the Medical Record 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. 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	

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			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 05/23/2023	