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	08/21/2024

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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V 0000 Bldg. 00	This visit was for a Federal/State complaint survey of an ESRD Provider. Survey Dates: August 20 and 21, 2024 Complaint: IN00441200 with related deficiencies cited. Census by Service Type: In-Center Hemodialysis: 68 Home Hemodialysis: 4 Home Peritoneal dialysis: 10 Total Active Census: 82 Isolation Room: 1 QR 9/4/24 A2	V 0000		
V 0113 Bldg. 00	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Based on observation, policy review, and interview, the ESRD facility failed to ensure staff followed their policies related to hand hygiene and personal protective equipment (PPE) for 1 of 4 Registered Nurses (RN 2) and 1 of 5 Patient Care Technicians (PCT 5) observed on the treatment floor. Findings include: 1. Review of the "Hand Hygiene" policy, revised	V 0113	**V 113** On 09/06/2024, 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 Personal Protective Equipment Emphasis was placed on: Staff should change gloves	09/19/2024

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Brianne Thornburg, RN	Clinical Manager	09/13/2024

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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	11/06/23, indicated hand hygiene must occur including but not limited to after contact with wound dressings, when entering and leaving the treatment area, after contact with inanimate objects near the patient, and immediately after removing gloves. 2. Review of the "Personal Protective Equipment" policy, revised 11/06/23, indicated hand hygiene must always be performed after glove removal. 3. During a treatment floor observation on 8/21/24, RN 2 changed gloves at 9:58 AM without performing hand hygiene after removing the gloves. At 10:12 AM, RN 2 returned from wheeling a patient to the lobby and donned gloves without first performing hand hygiene. RN 2 then went to Station 4 and touched the machine. During an interview on 8/21/24 at 10:15 AM, RN 2 relayed she should perform hand hygiene before or after gloves and before touching a patient. During an interview on 8/21/24 at 3:58 PM, the Clinical Manager relayed staff should perform hand hygiene including but not limited to before and after gloves and before and after touching the machine or the patient. 4. An observation of a central venous catheter (CVC, used to provide access to a large vein) site care for Patient #12 occurred on 8/21/2024 at 10:20 AM. Patient Care Technician (PCT) 5 removed the old bandage and discarded it. PCT 5 removed a cleaning swab and cleaned the access site. PCT 5 failed to remove gloves and complete hand hygiene after removing the soiled dressing. During an interview on 8/21/2024 at 1:45 PM, PCT 5 indicated hand hygiene and glove change occurred after cleaning the access site and prior to		and practice hand hygiene between each patient and/or station to prevent cross-contamination. 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 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	

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	the application of the new dressing. PCT 5 indicated she was unsure if she changed her gloves during the process. During an interview on 8/21/2024 at 3:50 PM, the Clinical Manager indicated hand hygiene and glove change should occur after removing the soiled dressing and cleaning the access site.		decontaminating hands with alcohol-based hand rub the duration of the entire procedure should be 20- 30 seconds. Effective 9/09/2024, the Clinical Manager will conduct daily audits with focus ensuring hand hygiene is performed per facility policy by all staff utilizing Infection Control Audit Tool for one week and then weekly for an additional three 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	

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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 09/19/2024.	
V 0147 Bldg. 00	494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE Based on observation, policy review, and interview, the dialysis facility failed to ensure staff followed infection control policies for 1 of 1 Registered Nurse (RN) observed providing central venous catheter (CVC) exit site care (RN 2). Findings include: 1. The "Termination of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer" policy, revised 2/07/22, indicated the threads and end of the luer lock, or hub, should be scrubbed with an alcohol pad for 10 to 15 seconds each time caps are removed or bloodlines are disconnected. 2. The "Central Venous Catheter (CVC) Dressing	V 0147	**V 147** On 09/06/2024, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure: Termination of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer Changing the Catheter Dressing Procedure Emphasis was placed on: Disinfection of the Catheter Connections Threads and end of the luer lock	09/19/2024

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	Change" policy, revised 5/06/24, indicated when using povidone iodine to disinfect, the site should be disinfected for 30 seconds and allowed to dry for at least two minutes. 3. During an observation of RN 2 discontinuing dialysis and performing CVC exit site care for Patient #9 on 8/21/24 beginning at 9:46 AM, RN 2 scrubbed the red hub and the blue hub for 7 seconds each with alcohol swabs after disconnecting the dialysis tubing. After discontinuation of dialysis and CVC dressing removal, RN 2 cleansed the exit site with povidone iodine for 15 seconds and applied the dressing immediately after cleansing the site. 4. During an interview on 8/21/24 at 10:15 AM, RN 2 indicated she usually cleanses the CVC exit site for 30 seconds and indicated she thought it was supposed to be 15 to 30 seconds. RN 2 further indicated she was supposed to let the povidone iodine dry before applying the dressing but that Patient #9 likes it applied while a little bit damp. RN 2 also indicated CVC hubs should be scrubbed for 15-30 seconds. 5. During an interview on 8/21/24 at 3:38 PM, the Clinical Manager relayed the CVC exit site should be cleansed for 30 seconds with povidone iodine and allowed to dry before applying the dressing and further indicated CVC hubs should be scrubbed for 15 seconds when disconnecting from dialysis.		(hub) must be scrubbed with 70% sterile alcohol pad ***for 10-15 seconds*** and any time caps are removed, or bloodlines are disconnected to reduce risk of contamination. Follow the steps below to clean the catheter exit site: Perform hand hygiene and don clean gloves. Remove swabstick from package by stick end without touching foam applicator. Handle only the stick portion. **2% Chlorhexidine and 70% alcohol:** Using gentle back and forth friction, clean the exit site beginning in the center and continuing outward the area of the size of the dressing to be applied (2 inches) in a concentric circle for 30 seconds and allow to dry a minimum of 30 seconds. If exudate or crusting is noted, an additional swabstick may be necessary to clean the exit site. • Applying CHG on the skin in a gentle back and forth motion allows the solution to penetrate the cell layers of the epidermis where 80% of microorganisms reside. • Reminder: Chlorhexidine swab contains alcohol. The alcohol must vaporize to dry. Allow the area to dry for approximately 30 seconds. Do not blot or wipe away. If a dressing is applied prior to drying, the alcohol vapors will be trapped resulting in blistering of	

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			the skin. **If using povidone pad:** Using gentle friction, disinfect the exit site beginning in the center and continuing outward 2 inches in a concentric circle for 30 seconds and allow to dry for at least 2 minutes. **If using 70% alcohol pad:** Using gentle friction, disinfect the access site beginning in the center and continuing outward 2 inches in a concentric circle for 30 seconds and allow to dry. **If using ExSept Plus**: Using gentle friction, use one saturated 4x4 to disinfect the access site beginning in the center and continuing outward 2 inches in a concentric circle for 30 seconds. Discard and repeat with second 4x4. Allow to dry at least 2 minutes. Effective 9/09/24, Clinical Manager will conduct weekly audits with focus on ensuring staff disinfect the threads and end of the leur lock of the central venous catheter for 10-15 seconds any time caps are removed, or bloodlines are disconnected; using gentle back and forth friction, clean the exit site beginning in the center and continuing outward the area of the size of the dressing to be applied (2 inches) in a concentric circle for 30 seconds and allow to dry at least 2 minutes with use of povidone, utilizing Infection Control	

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			Audit Tool for 2 weeks, 3 times per week, alternating shifts, then weekly, 2 times per week for 2 additional 2 weeks or until 90% compliance is achieved utilizing Infection Control Audit Tool. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic 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	

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			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 09/19/24.	
V 0401 Bldg. 00	494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT Based on observation, record review, and interview, the dialysis facility failed to ensure expired medical supplies were removed from labratory area during for 1 of 1 flash tour observations, which had the potential to affect all ICHD patients. Findings include: During a tour on 8/20/2024 at 8:50AM, observed expired laboratory supplies in the facility laboratory area. Two boxes of 4 bottle blood culture kits expired 7/31/2024. During an interview at 8:50 AM, registered nurse (RN) 1 indicated all staff were responsible to check expiration dates prior to using the supplies.	V 0401	**V 401** On 09/06/2024, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure: Storage of Supplies Emphasis was placed on: Supplies must be rotated First in-First Out (FIFO) to ensure products maintain quality and do not expire. Appropriately dispose of items that have reached the expiration date. Effective 9/09/24, Clinical Manager will conduct weekly audits with focus on ensuring no expired supplies in lab area, treatment	09/19/2024

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			floor or supply storage area, utilizing Infection Control Audit Tool for 2 weeks, 3 times per week, alternating shifts, then weekly, 2 times per week for 2 additional 2 weeks or until 100% compliance is achieved utilizing Infection Control Audit Tool. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic 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	

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			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 09/19/24	
V 0715 Bldg. 00	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P Based on observation, record review and interview, the medical director failed to ensure clinical staff stored and accessed medications per the facility policy for 1 of 1 oral medication administration observation and 2 of 2 heparin storage areas inspected on 8/20/2024. Findings include: 1. The Medication Preparation and Administration policy, dated 2/6/2023, indicated medications should be locked in a cabinet when not in use. The policy indicated a multidose vial required the date, time and initials of the staff person who first accessed the vial. Additionally,	V 0715	**V715** On 09/06/2024, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure: Medication Preparation and Administration Emphasis was placed on: All medications in syringes not being administered immediately shall be labeled appropriately with the name of the medication, route, dose, name of patient, date, time and initials of the person who prepared the	09/19/2024

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	the policy indicated medications in a syringe that were not administered immediately required a label with medication name, dosage, route (how the medication was to be administered), patient name, date, time, and initials of the staff who prepared the medication. 2. The first treatment floor observation occurred on 8/20/2024 at 8:50 AM. Observed on the medication preparation area were 4 medication cups with one or more capsules inside. The medication cups contained a label with the patient's name and medication for Patients #18, 19, 20, and 21. During an interview moments after the observation, Registered nurse (RN) 1 indicated they could set up medications ahead of time since they labeled the medication cups. RN 1 then left the medication area, leaving the medications unattended. During an interview on 8/21/2024 at 3:45 PM, the Clinical Manager indicated medications should not have been left unattended on the counter. 3. During an inspection of the heparin storage on 8/20/2024 at 10 AM, one supply cart contained an open and partially used vial of heparin. The vial failed to include a notation of the date and time the vial was opened. The second supply cart contained 3 syringes filled with heparin. The syringes lacked a label with patient name, medication and dosage and date/ time and initials of staff who drew up the medication. During an interview on 8/20/2024 at 10:15 AM, RN 1 indicated they could not identify the date the vial was accessed and indicated the vial should have included the date and time it was opened.		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. Medications may be pre-drawn up to 4 hours prior to administration. These pre-drawn medications shall be labeled and	

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	RN 1 indicated the medication could have been extra or not needed. RN 1 could not identify which patients should have received the medication. RN 1 indicated the syringes should have been labeled with patient name, date, and time if it was not used immediately after being prepared. During an interview on 8/21/2024 at 3:45 PM, the Clinical Manager indicated the staff person who first accessed the heparin should have dated and timed the heparin vial. The Clinical Manager further indicated there should never be filled syringes without a patient label which included the name, date, dosage, route, and person who prepared the syringe. 4. During an interview on 8/21/2024 at 4:10 PM, the Medical Director indicated the staff failed to manage the medications per policy and the Medical Director was responsible for the clinical policies and to ensure staff followed them.		must be kept under the preparer's control or in a locked designated medication storage area or refrigerated, if necessary, until delivery to the appropriate patient for administration. Effective 9/09/24, Clinical Manager will conduct weekly audits with focus on ensuring no medication left unattended, all pre-drawn syringes are labeled per policy, all open vials labeled per policy, utilizing Medication Floor Observation Audit Tool for 2 weeks, 3 times per week, alternating shifts, then weekly, 2 times per week for 2 additional 2 weeks or until 100% compliance is achieved utilizing Medication Floor Observation 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 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.	

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			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 09/19/24	