STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152538	A. BUILDING 00 B. WING	12/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE TRI COUNTIES	817 S 13TH ST DECATUR, IN 46733

(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	An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62. Survey Dates: December 11, 12, 13, 16, 17, 2024 Active Census: 18 At this Emergency Preparedness survey, Fresenius Medical Care Tri Counties was not found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62. Abbreviations: CM Clinical Manager EP Emergency Preparedness ESRD End Stage Renal Disease ICHD In-Center Hemodialysis MD Medical Director	E 0000		
E 0003 Bldg. 00	494.62 Establishment of the EP Program Dialysis Based on record review and interview, the dialysis facility failed to ensure the EP Plan addressed the patient population and services the facility could provide in an emergency (See Tag E0007); failed to develop a system to track the location of on-duty staff and patients, whether sheltered in place or relocated during an emergency (See Tag E0018); failed to maintain the availability of patient records in case of a facility emergency (See Tag	E 0003	The Governing Body of this facility acknowledges its responsibility to ensure the facility maintains an emergency preparedness program meeting the safety needs of our patient population. The Governing Body on, 12/26/2024, reviewed the Statement of Deficiencies and developed the following Plan of	01/15/2025

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Allison Cruea	Director of Operations	01/15/2025

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	E0023); failed to ensure the emergency cart was checked monthly for expired supplies and the facility failed to have an emergency evacuation box available for transport in an emergency (See Tag 0028); failed to ensure the EP Plan included a procedure to release patient information in the event of an emergency (See Tag E0033); failed to ensure the EP Plan included a process for communicating the facility's occupancy needs to local authorities (See Tag E0034); and failed to participate in a full-scale community-based exercise (See Tag E0039). Findings include: The cumulative effect of these systemic problems had the potential to impact all 18 active patients which resulted in the facility being found out of compliance with Condition for Coverage 42 CFR 494.62 for Emergency Preparedness.		Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. The Governing Body began meeting weekly beginning (01/02/2025) to review the results of the progress on the Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. The Governing Body will determine when the frequency of these meetings may be reduced to the regular quarterly schedule. Effective immediately: The Clinical Manager will analyze and trend all data and monitor/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAPI Committee. A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAPI (Quality Assessment and Performance Improvement) agenda. The QAPI Committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution of the issues. The Director of Operations (DO) will present a report on the Plan of Correction data and all 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 Governing Body, at its meeting of (12/26/2024), designated the Director of Operations (DO)to serve as Plan of Correction Monitor and provide additional oversight. They will participate in QAPI and Governing Body meetings. This additional oversight is to ensure the ongoing correction of deficiencies cited in the Statement of Deficiency through to resolution as well as ensure the Governance of the Facility is presented current and complete data to enhance their governance oversight role. Minutes of the Governing Body and QAPI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's direction and oversight and the QAPI Committees ongoing monitoring of facility activities. These are available for review at the facility. The responses provided for E007, E018, E023, E028, E033, E034 and E039 describe, in detail, the processes and monitoring steps taken to ensure that all deficiencies cited within this Condition are corrected to ensure ongoing compliance.	

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E 0007 Bldg. 00	403.748(a)(3), 416.54(a)(3), 418.113(a)(EP Program Patient Population Based on record review and interview, the dialysis facility failed to ensure the EP Plan addressed the patient population and services the facility could provide in an emergency for 1 of 1 facility. Findings include: 1. The review of the facility document titled" Fresenius Kidney Care 6656-Tri Counties-JV Emergency Plan," last updated 5/02/24, failed to address the patient population and the services the facility could provide in an emergency. 2. During an interview on 12/13/24 beginning at 2:58 PM, the CM relayed the EP Plan did not include a way to address the services to be provided in an emergency.	E 0007	On 12/26/2024, the Clinical Manager, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Guidelines for Emergency Preparedness Emphasis will be placed on: By 12/31/2024, the Director of Operations and Clinical Manager will update the Facility Emergency Preparedness Manual. The Clinical Manager will be responsible for updating the manual on a quarterly basis or as needed. This manual will be located at the facility and available for review upon request. Effective 12/31/2024, the Clinical Manager will conduct monthly audits utilizing specific plan of correction audit tool for 3 months ensuring updates are made and manual is current. Once compliance is sustained at 100 %, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAPI calendar. Monitoring will be done through the specific plan of correction audit tool. The Medical Director will review	01/15/2025

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			the results of audits each month at the QAPI 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 QAPI 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 QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for	

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			review at the clinic. Completion Date: 01/15/2025.	
E 0018 Bldg. 00	403.748(b)(2), 416.54(b)(1), 418.113(b)(Procedures for Tracking of Staff and Patients Based on record review and interview, the dialysis facility failed to develop a system to track the location of on-duty staff and patients, whether sheltered in place or relocated during an emergency for 1 of 1 facility. Findings include: 1. The review of the facility document titled" Fresenius Kidney Care 6656-Tri Counties-JV Emergency Plan," last updated 5/02/24, failed to include a system to track staff and patients during an emergency. 2. During an interview on 12/13/24 beginning at 2:58 PM, the CM relayed the EP Plan did not include information on how to track staff and patients during an emergency specific to the clinic.	E 0018	On 12/26/2024, the Director of Operations, and Clinical Manager, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Guidelines for Emergency Preparedness Emphasis will be placed on: The facility must develop a communication plan for all patients. This plan includes the following: Create and maintain staff, patient and facility emergency information contact lists: Quarterly, the Director of Operations/Area Manager or designee will review and update: The FKC Facility Emergency Information Directory Quarterly, the CM will review and update: The Emergency and Disaster Staff Contact Information Sheet The Emergency and Disaster Patient Contact Information Sheet	01/15/2025

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			A current copy of the emergency lists must: Be kept locked in the emergency supply boxes, or cart. Be sent to the facility's Director of Operations (DO) The DO will retain copies for each facility they manage. The patient contact lists contain PHI and must be maintained in a secure location such as on a laptop or in a locked location. On 12/31/2024, the Clinical Manager placed the Emergency and Disaster Patient & Staff Contact Information Sheets in the Emergency Preparedness binder. Effective 12/31/2024, the Director of Operations will conduct monthly audit with focus on ensuring the Emergency Preparedness binder is updated, as required, utilizing specific plan of correction Audit Tool for 3 months and then an additional 3 months or until 100% compliance is achieved. 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 QAPI Committee meeting monthly.	

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			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 QAPI 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 QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 01/15/2025.	

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E 0023 Bldg. 00	403.748(b)(5), 416.54(b)(4), 418.113(b)(Policies/Procedures for Medical Documentation Based on record review and interview, the dialysis facility failed to maintain the availability of patient records in case of a facility emergency for 1 of 1 facility. Findings include: 1. The facility policy "Emergency and Disaster Responsibility Guidelines," dated 8/02/17, indicated Clinical Manager was responsible for maintaining a current listing of patients which included their local, emergency, and evacuation contact information. 2. The review of the facility document titled" Fresenius Kidney Care 6656-Tri Counties-JV Emergency Plan," last updated 5/02/24, failed to include a patient list. 3. During an interview on 12/12/24 beginning at 2:30 PM, the CM confirmed the EP Plan did not include a patient list.	E 0023	On 12/26/2024, the Clinical Manager, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Guidelines for Emergency Preparedness Emergency and Disaster Responsibility Guidelines Emphasis will be placed on: The Clinical Manager has responsibility to maintain current listings of patients and staff including local contact, emergency contact and evacuation contact information. Quarterly, the Clinical Manager will review and update per policy. On 12/31/2024, the Clinical Manager placed the Emergency and Disaster Patient & Staff Contact Information Sheets in the Emergency Preparedness binder. Effective 12/31/2024, the Director of Operations will conduct monthly audit with focus on ensuring the Emergency Preparedness binder is updated, as required, utilizing specific plan of correction Audit Tool for 3 months and then an	01/15/2025

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			additional 3 months or until 100% compliance is achieved. 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 QAPI 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 QAPI 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 QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible	

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			to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 01/15/2025.	
E 0028 Bldg. 00	494.62(b)(9) Dialysis Emergency Equipment Based on observation record review and interview the dialysis facility failed to ensure the emergency cart was checked monthly for expired supplies and the facility failed to have an emergency evacuation box available for transport in an emergency for 1 of 1 facility reviewed. Findings include: 1. The facility policy "Emergency Medications, Equipment and Supplies," last updated 5/01/23, indicated the emergency cart must be checked monthly or after use for contents, expiration dates, cleanliness, and proper functioning of all equipment; an itemized log must be kept indicating the contents and expiration dates of the contents and cardiac arrest medications should be grouped together in the code cart. All staff must know the location of the evacuation box and who is responsible to grab it during an emergency evacuation.	E 0028	On 12/26/2024, the Director of Operations, and Clinical Manager, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+) Emphasis will be placed on: Units existing prior to 10/14/2008 which do not currently accept or treat HBsAg positive patients must have a transfer agreement with a local chronic facility which has capacity for isolation. On 01/03/2025, the Director of	01/15/2025

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	2. During an observation of the locked emergency crash cart on 12/12/24 beginning at 9:40 AM, one package of oxygen tubing was observed to be discolored and expired as of 8/22/22. The ICHD unit failed to maintain an emergency evacuation box, including cardiac arrest medications grouped together. 3. During an interview on 12/12/24 beginning at 9:48 AM, the CM stated the crash cart is checked monthly for expired supplies. 4. During an interview on 12/12/24 beginning at 2:35 PM, the CM relayed the dialysis facility does not have an emergency evacuation box. She relayed the required emergency supplies are kept in the crash cart and medications are kept in the locked medication cabinet on the ICHD treatment floor. When asked how staff would know what to take in an emergency, she relayed all the emergency medications are together on the side.		Operations secured a transfer agreement with a local chronic facility (15-2516) which has the capacity for Hepatitis B Antigen Positive isolation per policy. A copy of this agreement will be placed in the Emergency Preparedness Binder and available at the facility upon request for review. On 1/10/2025 the Director of Operations applied for isolation Waiver with CMS. Effective 12/31/2024, the Director of Operations will conduct monthly audit with focus on ensuring the Facility has in place a Hepatitis B Antigen Positive Transfer Agreement with a local chronic facility, as required, utilizing Specific Audit Tool for 3 months and then an additional 3 months or until 100% compliance is achieved. 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 QAPI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and	

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			trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI 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 QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 01/15/2025.	
E 0033	403.748(c)(4)-(6), 416.54(c)(4)-(6), 418 Methods for Sharing Information			

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Bldg. 00	Based on record review and interview, the dialysis facility failed to ensure the EP Plan included a procedure to release patient information in the event of an emergency for 1 of 1 facility. Findings Include: 1. The review of the facility document titled" Fresenius Kidney Care 6656-Tri Counties-JV Emergency Plan," last updated 5/02/24, failed to include information on how the facility planned to release patient information during an emergency. 2. During an interview on 12/13/24 beginning at 2:58 PM, the CM confirmed the EP Plan did not include information on how to release patient information during an emergency and did not include a patient list.	E 0033	On 12/26/2024, the Clinical Manager, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Guidelines for Emergency Preparedness Emphasis will be placed on: The facility must develop a communication plan for all patients. This plan includes the following: Create and maintain staff, patient and facility emergency information contact lists: Quarterly, the Director of Operations/Area Manager or designee will review and update: The FKC Facility Emergency Information Directory Quarterly, the CM will review and update: The Emergency and Disaster Staff Contact Information Sheet The Emergency and Disaster Patient Contact Information Sheet A current copy of the emergency lists must: Be kept locked in the emergency supply boxes, or cart. Be sent to the facility's Director of Operations (DO) The DO will retain copies for each facility they manage. The	01/15/2025

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			patient contact lists contain PHI and must be maintained in a secure location such as on a laptop or in a locked location. Emergency Transfer Patients may need to be moved emergently to another facility in emergency situations leading to unexpected facility closure such as severe weather, fire, water treatment failure or other unexpected problems. When this occurs, the treating clinic or “host” facility or facilities can provide services for the “home” facility according to the company wide agreement “Dialysis Unit Emergency Back Up Agreement” (established by Corporate Law Department and included with this policy). The home facility should initiate the patient transfer using the Patient Admissions and Transfers Application and select ‘declared pandemic/disaster/emergency’. The host facility will use the Patient Transfer Application to upload data into eCC. To ensure required notifications are made, notify your Senior Regulatory Manager of all facility closures leading to emergency and scheduled patient transfers. Complete the Temporary Clinic Closure Checklist. There may be occasions in an emergency when the computer	

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			system is down and paper treatment sheets must be used. Refer to the Computerized Systems Downtime policy. During a disaster situation, facilities may use the Acquisition and Disaster Standing Order form if the electronic medical record is down and for non-Fresenius patients. Medical Records for Non-FKC Transfer Print the Patient Transfer: Care Transitions Report. and provide a copy to the patient if the patient is transferred to a non-FKC facility. Provide patients with facility phone number and other emergency contact information Effective 12/31/2024, the Director of Operations will conduct monthly audit with focus on ensuring the Emergency and Disaster Patient Contact Information Sheet's and process on how to document/release patient information during an emergency, as required, utilizing Specific Audit Tool for 3 months and then an additional 3 months or until 100% compliance is achieved. 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 QAPI 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 QAPI 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 QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.	

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			Completion Date: 01/15/2025.	
E 0034 Bldg. 00	403.748(c)(7), 416.54(c)(7), 418.113(c)(Information on Occupancy/Needs Based on record review and interview, the dialysis facility failed to ensure the EP Plan included a process for communicating the facility's occupancy needs to local authorities for 1 of 1 facility. Findings include: 1. The review of the facility document titled" Fresenius Kidney Care 6656-Tri Counties-JV Emergency Plan," last updated 5/02/24, failed to include information on how the facility planned to communicate occupancy needs to local authorities during an emergency. 2. During an interview on 12/13/24 beginning at 2:58 PM, the CM confirmed the EP Plan did not include information on how to communicate with local authorities during an emergency.	E 0034	On 12/26/2024, Clinical Manager, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Guidelines for Emergency Preparedness Annual Notification Requirement Letter Emphasis will be placed on: The DO must contact their local Emergency Operations Center (EOC) or similar agency to: Understand the agency's capabilities and capacities Share our capabilities and capacities Discuss participating in a community-based drill they are running Annually per procedure, the facility will contact their local disaster management agency to ensure that the agency is aware of the dialysis facility's presence in the community in the event of an emergency. On 12/27/2024, the Director of Operations completed the annual	01/15/2025

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			notification requirement letter to the local Emergency Operations Center (EOC) per policy. A copy of this letter is placed in the Emergency Preparedness Binder and available at the facility upon request for review. Effective 12/31/2024, the Director of Operations will conduct monthly audit with focus on ensuring the Emergency Operations Center (EOC) or local authorities or aware of the facility occupancy needs, as required, utilizing Specific Audit Tool for 3 months and then an additional 3 months or until 100% compliance is achieved. 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 QAPI 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 QAPI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all	

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			other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 01/15/2025.	
E 0039 Bldg. 00	403.748(d)(2), 416.54(d)(2), 418.113(d)(EP Testing Requirements Based on record review and interview, the dialysis facility failed to participate in a full-scale community-based exercise in the past 2 years for 1 of 1 facility. Findings Include:	E 0039	On 12/26/2024, the Clinical Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Guidelines for Emergency	01/15/2025

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	1. The review of the facility document titled" Fresenius Kidney Care 6656-Tri Counties-JV Emergency Plan," last updated 5/02/24, failed to include documentation of a full-scale community-based exercise completed in the past 2 years. 2. During an interview on 12/13/24 beginning at 2:58 PM, the CM relayed she attended a solar eclipse preparation training on 3/15/24 and she thought this was a community-based exercise. 3. During an interview on 12/17/24 beginning at 8:33 AM, the CM confirmed the facility had not participated in a community-based exercise in the past 2 years.		Preparedness Emphasis will be placed on: Annually, each facility must participate in a community-based disaster drill. If unable to participate, document who you contacted in the community and why the clinic was unable to participate on the Facility Specific Disaster Safety Plan form. If the EOC or similar agency has not performed a community-based drill, or it was missed for a particular year, the DO should coordinate a dialysis facility area-based drill. The Governing Body will: Review and approve the Facility Specific Disaster Safety plan initially and annually. Review the FKC Facility Emergency Information Directory is complete and current. By 01/06/2025, Director of Operations will conduct a facility Table-Top Drill on “Blizzard”, with an after-action review for all staff. Table-Top materials with signature page will be located at facility and available for review upon request. Effective 12/31/2024, the Clinical Manager or Charge Nurse will conduct monthly audits utilizing specific plan of correction audit tool for 3 months, and then an additional 3 months or until 100%	

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			compliance is achieved. Once compliance is sustained at 100%, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAPI calendar. Monitoring will be done through the specific plan of correction audit tool. The Medical Director will review the results of audits each month at the QAPI 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 QAPI 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 QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible	

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			to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 01/15/2025.	
V 0000 Bldg. 00	This visit was for a CORE Federal recertification survey of an ESRD provider. Survey Dates: December 11, 12, 13, 16, 17, 2024 Census by Service Type-In Center Hemodialysis: 18 Total Active Census: 18 Isolation Room/Waiver: No. Waiver denied by CMS on 3/16/22 Fresenius Medical Care Tri Counties was found to be out of compliance with the Conditions of Coverage 42 CFR 494.62. Emergency Preparedness. See additional standard level deficiencies below. Abbreviations: CM Clinical Manager	V 0000		

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	ESRD End Stage Renal Disease ICHD In-Center Hemodialysis MD Medical Director RN Registered Nurse PCT Patient Care Technician POC Plan of Care QR 12/20/24 A2			
V 0111 Bldg. 00	494.30 IC-SANITARY ENVIRONMENT Based on observation, policy review and interview, the dialysis facility failed to maintain a sanitary environment within the ICHD treatment area during 2 of 2 days of ICHD treatment area observations, which had the potential to affect 18 active ICHD patients. Findings include: 1. The policy "Cleaning and Disinfecting the Dialysis Station," last updated 9/05/23, indicated bleach solution will be stored in labeled, covered opaque containers to prevent disintegration of the chemical (sodium hypochlorite) when exposed to sunlight and air. 2. During the flash tour observation on 12/11/24 beginning at 8:53 AM, 2 bleach containers sitting on a counter within the ICHD treatment floor did not have the lids secured. 3. 3. During the treatment floor observations on 12/13/2024 between 8:50 AM - 11:10 AM and 3:00 PM - 3:40 PM, bleach solution containers were observed uncovered on 4 occasions when not in use.	V 0111	On 12/26/2024, the Clinical Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Cleaning and Disinfecting the Dialysis Station Emphasis will be placed on: Bleach solution will be stored in labeled, covered opaque containers to prevent disintegration of the chemical (sodium hypochlorite) when exposed to sunlight and air Effective 12/31/2024, Clinical Manager or Charge Nurse will conduct 3 days per week audits with focus on ensuring staff maintain a sanitary environment and store bleach per policy, as required, utilizing Infection Control Audit Tool for 2 weeks and then weekly for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will	01/15/2025

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	4. During an interview on 12/13/24 beginning at 2:58 PM, the CM relayed the bleach containers should have the lid closed when not in use. 5. During an interview on 12/13/2024 at 3:40 PM, PCTs 1 and 2 indicated all staff were responsible for to keep the lids on the bleach. PCT 2 indicated keeping the lid on the bleach kept it from breaking down.		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 QAPI 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 QAPI 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 QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide 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 QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 01/15/2025	
V 0113 Bldg. 00	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Based on observation, policy review, and interview, the agency failed to ensure employees followed standards of practice for hand hygiene to reduce the spread of infections for 2 of 2 PCTs observed (PCT 1, 2). Findings include: 1. The agency policy on hand hygiene, dated 11/6/2023, imdicated hand hygiene should be performed nefore and after patient contact, immediately after removing gloves, and after contact with body fluid or potentially contaminated objects. 2. During a treatment floor observation on 12/11/2024 at 10:21 AM in Station 4, PCT 2 was observed decannuating Patient #2's fistula. The PCT had a glove on the left hand and no glove on the right hand. PCT 2 retrieved gauze pads from the supply drawer with the ungloved right hand. PCT 2 took the gauze pads to Station 4, placed a glove on her right hand, and removed Patient's dialysis needle. PCT 2 failed to complete hand hygiene immediately after removing the right -	V 0113	On 12/26/2024, the Clinical Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Hand Hygiene Personal Protective Equipment Emphasis will be placed on: Hands will be decontaminated using alcohol-based hand rub (without waving hands to dry, due to potential air borne contaminants) 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	01/15/2025

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	hand glove. During an interview on 12/13/2024 at 3:15 PM, PCT 2 indicated they removed soiled gauze from Patient #2's station with a gloved right hand, pulled the right glove off in a way to keep the soiled gauze within the glove. PCT 2 indicated they retrieved clean gauze and took it to Patient #2's station. PCT 2 indicated they put a glove on the right hand. When asked, PCT 2 indicated they did not complete hand hygiene prior to donning a new right - hand glove. PCT 2 indicated they should have removed both gloves and used hand sanitizer prior to putting on 2 new gloves. 3. During a treatment floor observation on 12/13/2024 at 8:31 AM, PCT 1 used hand sanitizer, grabbed two gloves, touched their ear, then donned the gloves. At 8:45 AM, PCT 1 used hand sanitizer, donned a glove on left hand, touched her face with ungloved right hand, then donned a glove on the right hand. During an interview on 12/13/2024 at 3:05 PM, PCT 1 indicated they had a bad habit of touching their face. PCT 1 indicated they should have used the hand sanitizer on both hands and donned 2 new gloves after touching their face.		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 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	

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			evaporate and prevents risk of igniting flames due to alcohol's flammable properties. Importance of donning gloves on both hands when touching any part of the dialysis machine or equipment at the dialysis machine, to include but not limited to answering alarms or entering data into the dialysis machine computer screen. Never wear only one glove or wrap a finger with a glove to perform any dialysis task. Effective 12/31/2024, Clinical Manager or Charge Nurse will conduct 3 days per week audits with focus on ensuring staff perform hand hygiene per policy, as required, utilizing Infection Control Audit Tool for 2 weeks and then weekly for an additional 2 weeks or until 100% compliance is achieved. 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 QAPI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and	

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			trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI 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 QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 01/15/2025.	

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V 0128 Bldg. 00	494.30(a)(1)(i) IC-HBV-ISOLATION (EXISTING FACILITY) Based on record review and interview, the dialysis facility failed to ensure an approved isolation agreement or waiver was in place for 1 of 1 ESRD facility. Findings include: The policy "Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+)," last updated 11/06/23, indicated facilities existing prior to 10/14/2008 which do not currently accept or treat HBsAg positive patients must have a transfer agreement with a local chronic facility which has capacity for isolation. If there is no local facility available to accept such transfers, the existing facility must establish an isolation room or area for use with HBsAg positive patients. 1. During the entrance conference on 12/11/24 beginning at 11:13 AM, the CM stated the dialysis facility had an isolation waiver. 2. The review of the document "Transfer Agreement-Hepatitis B Antigen Positive Patients" created 8/18/14 included a letter from Centers for Medicare & Medicaid Services (CMS) dated 3/16/22 indicated the dialysis facility was denied a waiver request. 3. During the entrance conference on 12/11/24 beginning at 11:13 AM, the CM stated the dialysis facility had an isolation waiver to send all HBsAg+ patients to another dialysis facility. 4. During an interview on 12/17/24 beginning at 11:12 AM, the Administrator indicated the dialysis	V 0128	On 12/26/2024, the Director of Operations, and Clinical Manager, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+) Emphasis will be placed on: Units existing prior to 10/14/2008 which do not currently accept or treat HBsAg positive patients must have a transfer agreement with a local chronic facility which has capacity for isolation. On 01/03/2025, the Director of Operations secured a transfer agreement with a local chronic facility (15-2516) which has the capacity for Hepatitis B Antigen Positive isolation per policy. A copy of this agreement will be placed in the Emergency Preparedness Binder and available at the facility upon request for review. On 1/10/2025 the Director of Operations applied for isolation Waiver with CMS.	01/15/2025

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	facility had not reapplied for the isolation room waiver. They would send the patient to another clinic with an isolation room in place.		Effective 12/31/2024, the Director of Operations will conduct monthly audit with focus on ensuring the Facility has in place a Hepatitis B Antigen Positive Transfer Agreement with a local chronic facility, as required, utilizing Specific Audit Tool for 3 months and then an additional 3 months or until 100% compliance is achieved. 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 QAPI 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 QAPI 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.	

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			The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 01/15/2025.	
V 0543 Bldg. 00	494.90(a)(1) POC-MANAGE VOLUME STATUS Based on record review and interview, the dialysis facility failed to ensure the Registered Nurse (RN) was notified of blood pressures (BP) and heartrate (HR) outside of parameters and failed to ensure the physician was notified of not meeting estimated dry weight (EDW) orders during ICHD treatment for 2 of 5 ICHD clinical records reviewed (Patient #8 and 9). Findings include:	V 0543	On 12/26/2024, the Clinical Manager, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Hypertension Patient Assessment and Monitoring Emphasis will be placed on:	01/15/2025

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	1. The facility policy "Hypertension," last updated 9/07/21, indicated staff will recognize, report and immediately address systolic blood pressures (top number of BP) greater than 180 mm/Hg and/or diastolic blood pressures (bottom number) greater than 100 mm/Hg. 2. The facility policy "Patient Assessment and Monitoring," last updated 5/01/23, indicated the pulse should be reported to the nurse when heart rates have dropped below 60, risen above 100 or become irregular. 3. Patient #8's ICHD treatment sheets, dated 11/27/24 to 12/11/24, were reviewed and evidenced the following: a. On 11/27/24, Patient's pre-treatment blood pressure was 168/91 and the ICHD treatment began at 10:41 AM. The BP check at 12:09 PM indicated BP of 188/92. The clinical record failed to evidence the PCT notified the RN of the high BP. The BP check at 2:42 PM indicated BP of 194/104. The clinical record failed to evidence the PCT notified the RN of the high BP. b. On 12/04/24, Patient #8's post dialysis weight was 65.2 kg (1.3 kg below ordered EDW). The clinical record failed to evidence the RN notified the physician and/or performed interventions to address EDW. c. On 12/06/24, Patient's pre-treatment blood pressure was 146/86 and the ICHD treatment began at 10:38 AM. The BP check at 2:41 PM indicated BP of 86/45. Patient #8's post dialysis weight was 65.1 kg (1.4 kg below ordered EDW). The clinical record failed to evidence the PCT notified the RN of the low BP and failed to evidence the RN notified the physician and/or		Staff will recognize, report, and immediately address systolic blood pressures greater than 180 mm/Hg and/or diastolic blood pressures greater than 100 mm/Hg. 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. 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/re-assess any findings addressed pre or during treatment as needed. The direct patient care staff may obtain the following data. Record pre-weight. Compare pre-weight to estimated dry weight. Record blood pressure. Verify: Systolic blood pressures greater than 180 mm/Hg and / or diastolic blood pressures greater than 100 mm/Hg Systolic blood pressures less than or equal to100	

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	performed interventions to address EDW at the end of treatment. d. On 12/09/24, Patient's pre-treatment blood pressure was 156/90 and the ICHD treatment began at 10:44 AM. The BP check at 12:03 PM indicated BP of 182/98. The clinical record failed to evidence the PCT notified the RN of the high BP. The BP check at 1:05 PM indicated BP of 187/95. The clinical record failed to evidence the PCT notified the RN of the high BP. During an interview on 12/16/24 beginning at 1:07 PM, RN 2 verified the above findings for Patient #8 and relayed the PCT should have notified the RN when the BP and EDW were out of range. 4. Patient #9's ICHD treatment sheets, dated 11/27/24 to 12/13/24, were reviewed and evidenced the following: a. On 11/29/24, Patient #9's post dialysis weight was 70.9 kg (1.9 kg above ordered EDW). The clinical record failed to evidence the RN notified the physician and/or performed interventions to address EDW. b. On 12/02/24, Patient's pre-treatment heart rate was 60 and the ICHD treatment began at 12:20 PM. The HR check at 12:31 PM indicated HR of 46. The clinical record failed to evidence the PCT notified the RN of the low HR. The HR check at 1:00 PM indicated HR of 41. Patient #9's post dialysis weight was 71.6 kg (2.6 kg above ordered EDW). The clinical record failed to evidence the RN notified the physician and/or performed interventions to address low HR and EDW at the end of treatment. c. On 12/04/24, Patient #9's post dialysis weight		mm/hg systolic during treatment. Record pulse. Verify pulses manually if automated readings display below 60 or greater than 100 beats per minute. Document irregular rhythms. The direct patient care staff may obtain the following post treatment: Obtain the patient's post weight. Ensure the post weight is consistent with the goal set of the machine. Ensure vital signs and overall condition are stable for discharge. Ask the patient if he or she has anything more to report or any additional observations prior to discharge. The registered nurse will assess/re-assess post treatment as indicated. Document findings in the patient's record. Effective 12/31/2024, Clinical Manager or Charge Nurse will conduct 3 days per week on 10 Treatment Sheet Audits with focus on ensuring staff notifies RN if Blood Pressure or Heart Rate is outside of parameters and failed to notify the physician if EDW is not met per policy, as required, utilizing Treatment Sheet Audit Tool for 2 weeks and then weekly on 10% of completed treatments for an additional 2 weeks or until 100% compliance is achieved. The	

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	was 71.1 kg (2.1 kg above ordered EDW). The clinical record failed to evidence the RN notified the physician and/or performed interventions to address EDW. d. On 12/09/24, Patient #9's post dialysis weight was 73.7 kg (4.7 kg above ordered EDW). The clinical record failed to evidence the RN notified the physician and/or performed interventions to address EDW. e. On 12/11/24, Patient #9's post dialysis weight was 74.1 kg (5.1 kg above ordered EDW). The clinical record failed to evidence the RN notified the physician and/or performed interventions to address EDW. f. On 12/13/24, Patient's pre-treatment blood pressure was 140/78 and the ICHD treatment began at 11:43 AM. The BP check at 3:23 PM indicated BP of 183/80. The clinical record failed to evidence the PCT notified the RN of the high BP The post-treatment BP was 198/84. Patient #9's post dialysis weight was 71.5 kg (2.5 kg above ordered EDW). The clinical record failed to evidence the RN notified the physician and/or performed interventions to address high BP and EDW at the end of treatment. During an interview on 12/16/24 beginning at 1:17 PM, RN 2 verified the above findings for Patient #9 and relayed the PCT should have notified the RN when the HR, BP and EDW were out of range. 5. During an interview on 12/13/24 beginning at 2:58 PM, the CM relayed the PCT should notify the RN when the BP is out of parameters when the systolic is below 100 millimeters of mercury (mmHg) or greater than 180 mmHg.		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 QAPI 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 QAPI 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 QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to	

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	6. During an interview on 12/16/24 beginning at 2:04 PM, the CM relayed the PCT should notify the RN when the HR is low unless the patient has special parameters ordered and the RN should have collaborated with the physician regarding the EDW not being met.		address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 01/15/2025.	
V 0544 Bldg. 00	494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Based on record review and interview, the dialysis facility failed to ensure the MD was notified and aware of shortened run times when patient requested to leave Against Medical Advice (AMA) for 1 of 1 ICHD patient records reviewed with shortened run times (Patient #9). Findings include: 1. The facility policy "Early Termination or Arriving Late for Treatment," last updated 11/07/22, indicated the RN is responsible to notify the physician, and document on the "AMA" form and 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. 2. Patient #9's ICHD treatment sheets, dated 11/27/24 to 12/13/24, were reviewed and evidenced a physician ordered total run time of 3 hours and 30 minutes during the dialysis treatments.	V 0544	On 12/26/2024, 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 will be placed on: 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. Against Medical Advice forms are	01/15/2025

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	a. On 12/09/24, the ICHD treatment began at 11:20 AM. The total run time was 1 hour and 10 minutes. RN 1 documented the shortened run time reason as patient request and an AMA form was signed by RN 1 and PCT 1. The AMA form was not signed by Patient #9. The clinical record for Patient #9 failed to include documentation that the physician was notified regarding the shortened run time. b. On 12/11/24, the ICHD treatment began at 11:33 AM. The total run time was 1 hour and 4 minutes. RN 1 documented the shortened run time reason as patient request and an AMA form was signed by RN 1 and PCT 1. The AMA form was not signed by Patient #9. The clinical record for Patient #9 failed to include documentation that the physician was notified regarding the shortened run time. 3. During an interview on 12/16/24 beginning at 2:04 PM, the CM relayed verified the clinical record for Patient #9 failed to evidence documentation of the physician being notified when the patient requested to end treatment.		Signed by the patient and witnessed by the supervising nurse. Signed with each early termination event and filed in the patient's medical record. Tracked, trended and reported to the QAI committee monthly Effective 12/31/2024, Clinical Manager or Charge Nurse will conduct 3 days per week on 10 Treatment Sheet Audits with focus on ensuring the facility notifies the doctor if patient treatment is shortened and order not followed as written per policy, as required, utilizing Treatment Sheet Audit Tool for 2 weeks and then weekly on 10% of completed treatments for an additional 2 weeks or until 100% compliance is achieved. 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 QAPI 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	

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			the QAPI 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 QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 01/15/2025.	
V 0556 Bldg. 00	494.90(b)(1) POC-COMPLETED/SIGNED BY IDT & PT	V 0556	On 12/26/2024, the Clinical	01/15/2025

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	Based on record review and interview, the dialysis facility failed to ensure the POC was reviewed and signed by the patient for 2 of 5 ICHD records reviewed (Patient's #4 and 9). Findings include: 1. The facility policy "Comprehensive Interdisciplinary Assessment and Plan of Care," last updated 7/03/23, indicated the patient must sign the plan of care meant to acknowledge the information in the plan. 2. The review of Patient #4's clinical record included a POC dated 9/16/2024. The POC failed to evidence Patient's signature or a statement indicating Patient #4 chose not to sign the POC. 3. The review of Patient #8's clinical record included a POC dated 7/08/24. The POC failed to evidence Patient's signature or a statement indicating Patient #4 chose not to sign the POC. 4. During an interview on 12/16/24 beginning at 2:04 PM, the CM indicated the POC should be reviewed and signed by the patient and she verified the clinical records for Patient's #4 and 8 failed to include POC's that had been signed by the patient.		Manager, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Comprehensive Interdisciplinary Assessment and Plan of Care Emphasis will be placed on: The patient's level of participation is determined by the patient. The patient must sign the plan of care meant to acknowledge the information in the plan. If the patient chooses not to sign their plan of care, the reason for refusal must be documented in the patient's medical record. The interdisciplinary team must ensure the patient signs the completed plan of care after the meeting, or as soon as possible if not held in person. By 01/08/2025 the facility will review 100% of all patients' Plan of Care. Any patients care plan not completed per policy; facility scheduled to re-do patient care plan within 60 days. Effective 12/31/2024 the Clinical Manager will audit monthly to ensure all patients who had a plan of care meeting within that month, signed their plan of care. Audits will continue monthly for 4 months or until 100% compliance is achieved utilizing Plan of	

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			Correction Monitoring Tool. 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 medical record audit with any non-compliance noted in the meeting minutes in eQUIP. The Medical Director will review the results of audits each month at the QAPI 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 QAPI 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 QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly.	

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			The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 01/15/2025.	
V 0715 Bldg. 00	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P Based on record review and interview, the medical director failed to ensure all new employees were screened for tuberculosis (TB, a contagious respiratory infection upon hire for 1 of 1 personnel file reviewed of a PCT (PCT 1). Findings include: 1. The facility policy "Employee Tuberculosis Testing," last updated 2/05/24, indicated all new employees were to be screened for TB upon hire by completing a two-step tuberculin skin test (TST), Interfreon-Gamma Release Assay (IGRA), or chest X-ray. 2. The personnel file for PCT 1 indicated a hire date of 10/17/22 and the employee's duties included direct patient contact. The file for PCT 1 failed to evidence the employee had been screened for TB upon hire.	V 0715	On 12/26/2024, the Clinical Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Employee Tuberculosis Testing Emphasis will be placed on: TB testing using the two-step tuberculin skin test (TST) method is required upon hire. If a new employee has a documented baseline TST result within the previous 12 months, a single TST can be administered as this additional TST represents the second stage of the two-step testing. If an employee provides	01/15/2025

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	3. During an interview on 12/16/24 beginning at 2:50 PM, the Clinical Manager indicated PCT 1'as personnel file failed to include a TB test was performed upon hire.		Interferon-Gamma Release Assay (IGRA) results, these results can be accepted upon hire in lieu of the two-step TST. The results must be within the previous 12 months and reviewed and interpreted by the ordering physician. Examples of IGRAs include: QuantiFERON® - TB Gold IN-tube Test (QFT-GIT) SPOT-TB Test (T-Spot) NOTE: IGRA testing is not performed at FKC. A recent chest x-ray within the previous 6-months can be used as evidence to exclude diagnosis of TB in employees with the following: Previously positive TST or IGRA Newly positive TST or IGRA Evidence of severe scarring at an old TST site (denotes a prior positive reaction) History of previous treatment for latent tuberculosis infection (LTBI) or TB disease The Healthcare Personnel TB Baseline Risk Assessment and TB Risk Assessment Review Questionnaire (TB-RAQ) are required to be completed on all new employees. On 01/06/2025, the Director of Operations reviewed 100% of all staff currently working at the facility to ensure all staff follow	

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	152538	A. BUILDING 00 B. WING	12/17/2024

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			policy and procedure for tuberculosis testing for new hires. Employee records available upon request at the facility for review. Effective 12/31/2024, the Clinical Manager will conduct monthly audit with focus on ensuring all staff currently working at the facility has documented, tuberculosis testing as required for 3 months utilizing the Personnel Staff Tracker, and then an additional 3 months or until 100% compliance is achieved. 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 QAPI 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 QAPI 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 QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 01/15/2025.	