STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152502	A. BUILDING 00 B. WING	02/20/2025

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE INDIANAPOLIS EAST	6701 E 21ST STREET INDIANAPOLIS, IN 46219

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V 0000 Bldg. 00	This visit was for a Federal Complaint survey of an ESRD provider. Survey Date: 02/20/2025 Unduplicated Skilled Admissions: 45 Complaint: # IN00451207 was investigated, unrelated findings. Census by Service Type: In-Center Hemodialysis: 166 Home Hemodialysis: No home program. Peritoneal Dialysis: No home program. Total Census: 166 Isolation: 1 Fresenius Medical Care Indianapolis East was found to be in compliance with 42 CFR 494.60, Physical Environment, as it relates to this complaint. Abbreviations RN Registered Nurse ICHD In-Center Hemodialysis PCT Patient Care Technician HHD Home Hemodialysis FA Facility Administrator PD Peritoneal Dialysis MD Medical Doctor CVC Central Venous Catheter RD Registered Dietician CM Clinical Manager MSW Masters Social Worker LPN Licensed Practical Nurse	V 0000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

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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	CCHT Certified Clinical Hemodialysis Technician QR by Area 3 on 2/24/2025.			
V 0117 Bldg. 00	494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS Based on observation, record review, and interview, the facility failed to ensure the proper storage of supplies for 3 of 3 treatment room observations. Findings Include: 1. A review of a Fresenius Kidney Care policy dated 11/04/2024, titled "General Cleanliness and Infection Control Guidelines," indicated but was not limited to, " ... The purpose of this policy is to provide guidance for the FKC staff on preventing the spread of infectious disease and maintaining a clean, safe, and aesthetically pleasant environment for patients, staff, and visitors ... Supplies or patient's belongings should not be kept or stored behind the machine at the patient station ... " 2. During the flash tour on 02/20/2025 at 11:05 AM, the following treatment floor observations were made: An observation at Station 25 evidenced an empty Hemodialysis (a procedure where it filters waste and excess fluids when the kidneys were unable to filter it out of the body) blood tubing bag on top of the dialysis machine. An observation at Station 24 evidenced a tape roll on top of the dialysis machine.	V 0117	**V-117** On 2/27/25, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. General Cleanliness and Infection Control Guidelines Emphasis will be placed on: ·Facility to provide and maintain a clean, safe, aesthetically pleasant environment for patients, staff, and visitors. ·All areas must be kept clean and organized, including but not limited to the treatment area, water/supply room and offices. Walkways must be kept clear of debris and free of clutter. ·Supplies or patient's belongings should not be kept or stored behind the machine at the patient station. Effective 2/28/2025, the Director of Operations or Charge nurse will	03/22/2025

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	An observation at Station 6 evidenced a Citra Clean bottle on top of the wall box behind the chair. An observation at Station 36 evidenced an arm chair cushion on the wall box behind the chair. 3. On 02/20/2025 at 2:37 PM, the following treatment floor observations were made: An observation at Station 17 evidenced a black spiral cord on the wall box behind the chair. An observation at Station 15 evidenced a patient's coat on the wall box behind the chair. An observation at Station 14 evidenced a television remote on the wall box. An observation at Station 12 evidenced a gray, plastic, circular piece, the size of the palm on a hand, on the wall box. An observation at Station 7 evidenced a gray, plastic, circular piece, the size of the palm on a hand, on the wall box. An observation at Station 32 evidenced a Bicarbonate bag on top of the dialysis machine.4. On 02/20/2025 at 10:56 AM, the following flash tour treatment floor observations were made: An observation of a sign posted on the chaise wall box indicated "NO ITEMS ON BACK COUNTER". An observation of a black cord and a blood pressure cuff on the chaise wall box behind Station #32.		conduct bi-weekly audits utilizing specific plan of correction audit tool for 2 weeks, and then weekly for an additional 2 weeks or until 100% compliance is achieved. With a focus on ensuring the facility provides and maintains a clean, safe, aesthetically pleasant environment for patients, staff, and visitors. All areas will be kept clean and organized. 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 Director of Operations 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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	An observation of a gray cushion on the chaise wall box behind Station #30. An observation of a gray cushion on the chaise wall box between Station #27 and 28. An observation of a blood pressure cuff on the chaise wall box behind Station #27. An observation of a gray cushion on the chaise wall box behind Station #12. An observation of a black cord on the chaise wall box behind Station #8. An observation of a blood pressure cuff and gray cushion on the chaise wall box behind Station #7. An observation of a clear bottle labeled "Citric Acid" on the chaise wall box between Station #5 and Station #6. An observation of a blood pressure cuff on the chaise wall box behind Station #19. During an interview on 02/20/2025 at 11:23 AM, LPN 5 indicated that there should be nothing placed on the chaise wall box, and only caps from the dialyzers should be placed on top of the dialysis machine.		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.	
V 0121 Bldg. 00	494.30(a)(4)(i) IC-HANDLING INFECTIOUS WASTE Based on observation, record review, and interview the facility failed to ensure sharps (objects with sharp points or edges that potentially cause injury through puncture or cuts, example needles, scalpels, syringes etc.) were properly disposed of for 1 of 2 trash cans at the	V 0121	V121 On 2/27/25, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities	03/22/2025

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	nurses station attached to handwashing sink B. Findings Include: 1. A review of a Fresenius Kidney Care policy dated 11/04/2024, titled "General Cleanliness and Infection Control Guidelines" indicated but was not limited to, "Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are: clearly identifiable as a sharps container ... Regulated medical waste shall be placed in a container that is ... closeable, leak proof and labeled and/or color coded" 2. On 02/20/2025 at 12:08 PM, the following treatment floor observations were made: An observation of two syringes with needles attached in the trash can next to the handwashing sink B. During an interview on 02/20/2025 at 12:36 PM, PCT 6 indicated sharps should go in the "bio bin". During an interview on 02/20/2025 at 12:45 PM, PCT 11 indicated sharps should go in the biohazard bin. During an interview on 02/20/2025 at 4:36 PM, the Director of Operations 1 indicated "we can't do that, there will be education on that," when queried about sharps being observed in the trash.		of the facility staff on the Policy. General Cleanliness and Infection Control Guidelines Emphasis will be placed on: Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are: clearly identifiable as a sharps container. Regulated medical waste shall be placed in a container that is closeable, leak proof and labeled and/or color coded. Effective 2/28/2025, the Director of Operations or Charge nurse will conduct bi-weekly audits utilizing specific plan of correction audit tool for 2 weeks, and then weekly for an additional 2 weeks or until 100% compliance is achieved. With a focus on ensuring all contaminated sharps will be discarded immediately or as soon as feasible in containers that are: clearly identifiable as a sharps container. Regulated medical waste will be placed in a container that is closeable, leak proof and labeled and/or color coded. 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.	

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			The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly. The Director of Operations 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	

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			documentation, are available for review at the clinic.	
V 0143 Bldg. 00	494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS Based on observations and interviews, the facility failed to ensure all expired medications were removed from 1 of 2 code carts on the treatment floor. Findings Include: 1. A review of a Fresenius Kidney Care policy dated 02/06/2023 titled "Medication Preparation and Administration" indicated but was not limited to, " ... Monitoring Expired Medications: Expiration dates for all stored medications are to be monitored on a monthly basis. Expired medications are to be discarded ..." 2. During a review of the code cart in front of Station 25 on 02/20/2025 at 11:17 PM, Diphenhydramine Hydrochloride 50 milligram (mg)/ milliliter (ml) box had an expiration date of 10/31/2024, Naloxone Hydrochloride 0.4 mg/ml had an expiration date of 11/2024, and Adrenaline 1mg/ml vial had an expiration date of 01/2025. The facility failed to ensure expired medications were disposed. A review of the Automated External Defibrillator checklist evidenced the code cart was checked daily. 3. During an interview with LPN 1 on 02/20/2025 at 11:20 AM, they indicated they thought the code cart was checked monthly. They revealed expired medications were supposed to be disposed and the Facility Administrator would be informed.	V 0143	**V-143** On 2/27/25, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Medication Preparation and Administration Emphasis will be placed on: Monitoring expired medications: Expiration dates for all stored medications will be monitored on a monthly basis. Expired medications will be discarded Effective 2/28/2025, the Director of Operations or Charge nurse will conduct bi-weekly audits utilizing specific plan of correction audit tool for 2 weeks, and then weekly for an additional 2 weeks or until 100% compliance is achieved. With a focus on, monitoring expired medications: Expiration dates for all stored medications will be monitored on a monthly basis. Expired medications will be	03/22/2025

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	4. During an interview with the Director of Operations (DO) on 02/20/2025 at 2:29 PM, they explained how the code cart was to be reviewed daily by the nurse who was assigned to the pod and expired medications were to be discarded.		discarded. 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 Director of Operations 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.	
V 0765 Bldg. 00	494.180(e) GOV-INTERNAL GRIEVANCE SYS ID/IMPLEMENTED Based on record review and interview, the facility failed to ensure an internal grievance was documented for 1 of 1 patient complaints. (Patient #4) Findings Include: 1. A review of a Fresenius Kidney Care policy dated 04/04/2014, titled "Patient Grievance Procedure" indicated but was not limited to, " ... Follow the steps below when a patient or patient representative has a grievance: ... The CM ensure the following details are completed in the Quality Assessment and Performance Improvement (QAI) Patient Grievance Status Report: Date grievance received ... Intake Person, Patient Initials, Nature of the grievance, Findings of the investigation ... Resolution and any corrective actions taken ... Note: Even if a patient's grievance is resolved quickly, the CM must document the complaint and the actions taken to resolve it ..." 2. A review of the "Patient Grievance Report"	V 0765	**V-765** On 2/27/25 the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Patient grievance procedure. Emphasis will be placed on: Within the first 6 treatments after admission to the facility, ands any time as needed the Facility Social Worker (MSW) will provide “What to Do if You Have a Concern” and “Important Numbers” handouts to the patient or patient representative. Note: A Registered Nurse (RN) may assume the responsibility for informing patients if designated by the Clinical Manager (CM)	03/22/2025

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	dated 02/20/2024 to 02/20/2025 failed to evidence the complaint made by Patient #4 to MSW 1. The facility failed to ensure all complaints were investigated, documented, and a resolution was determined. 3. During an interview with the Complainant, Patient #4 on 02/20/2025 at 11:10 AM, they indicated the automatic front door's glass window was boarded up for two months and it was off of the track. They explained how the glass was broken and could have hurt someone. Patient #4 indicated they informed the agency of their concern. They revealed the door had been fixed for about a month. They indicated they had no further issues and if they had further complaints, they knew how to make one. 4. During an interview with the MSW on 02/20/2025 at 1:25 PM, they explained how Patient #4 had approached them and indicated the wood replacement for the glass in the door was embarrassing. They indicated the complaint was not in the complaint log because it was "not a jeopardy" to the patient's treatment. They explained all complaints were to be reported and recorded. They revealed the process of when they received a complaint, they would send an electronic message to the Medical Director, the Director of Operations (DO), or whoever would be in charge of the complaint. They indicated they would document the complaint in their electronic medical record and the complaints were reviewed monthly by the Quality Assurance team. They explained how SW 2 would participate in the meetings and the team would come to a resolution and relay it back to the complainant. 5. During an interview with the DO on 02/20/2025 at 4:35 PM, they indicated the complaint that		After review of the grievance process, MSW will ask the patient to sign the Acknowledgement of Patient Grievance Procedure and file in the patient's medical record. FKC Staff will promptly acknowledge and report all patient grievances to the Nurse in Charge (or Team Leader) as soon as possible. The Nurse in Charge (or Team Leader) will meet with the patient to gather information, and complete as many fields as possible on the Patient Grievance Status Report within 72 hours of being notified and will inform the CM. The DO will review the Patient Grievance Status Report daily. For any new grievances, DO will meet with the patient within 5 business days to acknowledge, investigate and address the grievance. Note: MSW or other staff may also assist in assessing and resolving patient grievances, as appropriate. The DO will report back to the patient when a resolution is attained or considered attained by the facility. Note: When the grievance cannot be immediately resolved, the DO must provide the patient/representative with updates periodically on progress. The DO will ensure the following details are completed in the Quality Assessment and Performance Improvement (QAI)	

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	Patient #4 had made about the front door being broken should have been documented in the complaint log.		Patient Grievance Status Report: Date grievance received Mode of grievance (i.e. meeting, phone call, email, letter, fax) Intake Person Patient Initials Nature of the grievance Findings of the investigation Grievance referred to (if any) Resolution and any corrective actions taken Any follow-up related to the grievance Note: Even if a patient's grievance is resolved quickly, the CM must document the complaint and the actions taken to resolve it. The DO will ensure that all patient grievances are reported to the QAI Committee. By 3/22/25, the Facility Social Worker (MSW) will review with all patients "What to Do if You Have a Concern" and "Important Numbers" handouts and after review of the grievance process, MSW will ask the patient to sign the Acknowledgement of Patient Grievance Procedure and file in the patient's medical record. Effective 2/28/2025, the Director of Operations or Charge nurse will conduct weekly audits utilizing specific plan of correction audit tool for 4 weeks, and then monthly for an additional 2 months or until 100% compliance is achieved.	

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			With a focus on ensuring all patients have had the “What to do if you have a concern” and “Important Numbers” handouts reviewed by the MSW and have signed the Acknowledgment of Patient Grievance procedure. The DO will ensure the Grievance procedure listed above will be followed, monitored and reported in QAI. 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 Director of Operations 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.	