

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	(X3) DATE SURVEY COMPLETED 10/31/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST		STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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	<p>An Emergency Preparedness Survey and was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62 of an ESRD supplier.</p> <p>Survey Dates: 10-27, 10-30, and 10-31-2023</p> <p>Facility #: 005149</p> <p>CCN#: 152502</p> <p>Stations: 36 and 1 isolation room.</p> <p>Census by Service Type: In Center Hemodialysis: 172 Home Peritoneal Dialysis: 0 Home Hemodialysis: 0 Total Census: 172</p> <p>At this Emergency Preparedness survey, Fresenius Medical Care Indianapolis East, was found not in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, with 42 CFR 484.102.</p> <p>QR by Area 3 on 11-01-2023.</p>	E 0000		
E 0028 Bldg. 00	<p>494.62(b)(9)</p> <p>Dialysis Emergency Equipment</p> <p>§494.62(b)(9) Condition for Coverage: [(b) Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this</p>			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined other safeguards 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 disclosed 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.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	(X3) DATE SURVEY COMPLETED 10/31/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST		STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219		
(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
	<p>section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:]</p> <p>(9) A process by which the staff can confirm that emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, are on the premises at all times and immediately available.</p> <p>Based on observation, record review, and interview, the facility failed to ensure emergency medications were checked for expiration and failed to complete their monthly itemized log per the facility policy for 1 of 1 Emergency Carts observed.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. On 10-31-2023 at 8:40 AM, a dated 05-01-2023, Fresenius Kidney Care policy titled, "Emergency Medication, Equipment, and Supplies" was provided by the Clinical Manager. The policy indicated but was not limited to, "Emergency Cart ...The emergency cart must be: ... Checked monthly or after use for contents, expiration dates ... An itemized log must be kept indicating the contents and expiration dates of contents. Items approaching expiration must be reordered and replaced prior to the actual expiration date ...". 2. During an observation on 10-27-2023 at 1:00 PM, the Emergency Cart medications were reviewed. The Emergency Cart contained 23 vials of Sodium Bicarb (a medication used to help maintain adequate acid-base balance) 50 	E 0028	<p>E028</p> <p>By 11/15/2023, the Director of Operations will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure:</p> <p>Emergency Medications, Equipment and Supplies Emergency Code Cart, Medications and Machine Hand Crank Checklist</p> <p>Emphasis was placed on: Importance of ensuring the emergency cart medications will be checked monthly, or after use for expiration dates.</p> <p>An itemized log must be kept indicating the contents and expiration dates of contents. Items approaching expiration must be reordered and replaced prior to the actual expiration date.</p>	11/30/2023

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	(X3) DATE SURVEY COMPLETED 10/31/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST			STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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
	<p>milliequivalents mEq/50 milliliters (ml) that expired February 2023, 25 1 ml vials of Diphenhydramine (a drug used to treat an allergic reaction) 50 milligrams (mg)/50 ml that expired June 2023, 3 bags of 0.9% Sodium Chloride 1,000 ml Intravenous fluid (fluid used to supply water and salt to the body) that expired December 2022, 1 bag of 0.9% Sodium Chloride 1,000 ml Intravenous fluid expired November 2022, 1 bag of 0.9% Sodium Chloride 1,000 ml Intravenous fluid expired July 2023, and 3 vials of Naloxone HCl (a medication used to treat narcotic overdose in an emergency) 0.4 mg/ml that expired February 2023.</p> <p>3. During an interview on 10-27-2023 at 1:55 PM, the Registered Nurse (RN) 2, and RN 1, indicated that the charge clinical manager or charge nurse was to audit the Emergency Cart monthly and reorder supplies needed. The RNs further indicated there was a log in the computer for monthly audits of the contents of the Emergency Cart.</p> <p>During an interview on 10-27-2023 at 5:25 PM, the previous Director of Operations (DO) of the facility, Admin 3, indicated the floor RNs were to check the Emergency Cart monthly to ensure itemswere not expired. Admin 3 to provide the audit logs completed in the computer.</p> <p>During an interview on 10-30-2023 at 4:27 PM, Admin 3, indicated they could not provide copies of the itemized logs for the Emergency Cart as the RN staff had not completed them per the company policy.</p>		<p>On 11/08/2023, Jonathan Lewis CM, removed the expired medications- Sodium Bicarb, Diphenhydramine, 0.9% Sodium Chloride, and Naloxone, and verified that all other medications and supplies are within their expiration dates.</p> <p>Effective 11/16/23, Clinical Manager will conduct weekly audits, utilizing Emergency Code Cart, Medications and Machine Hand Crank Checklist Tool for 4 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.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the</p>	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	(X3) DATE SURVEY COMPLETED 10/31/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST		STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 0000 Bldg. 00	This visit was for a Federal complaint survey of an ESRD Provider. Complaint: IN00418892 with related and unrelated Federal deficiencies cited.	V 0000	<p>resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 11/30/2023. p="" paraid="183430429" paraeid="{73a853a2-7dda-4e30-bd 20-81ab1ba59da2}{194}"></p>	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	(X3) DATE SURVEY COMPLETED 10/31/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST		STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 0113 Bldg. 00	<p>Survey Dates: 10-27, 10-30, and 10-31-2023</p> <p>Facility #: 005149</p> <p>CCN#: 152502</p> <p>Stations: 36 and 1 isolation room.</p> <p>Census by Service Type: In Center Hemodialysis: 172 Home Peritoneal Dialysis: 0 Home Hemodialysis: 0 Total Census: 172</p> <p>QR completed by Area 3 on 11-01-2023.</p> <p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station. Based on observation, record review, and interview the facility failed to demonstrate appropriate hand hygiene in 3 of 4 post dialysis observations. (Patient Care Technicians (PCT) 1, 4, and 5) (Patients: #9, 24, and 25)</p> <p>Findings include:</p> <p>1. On 10-2-2022 at 9:00 AM, a dated 03-17-2023, Fresenius Kidney Care policy titled, "Hand Hygiene" was provided by the Clinical Manager. The policy indicated but was not limited to, "Purpose: The purpose of this policy is to prevent transmission of pathogenic microorganisms to patients and staff through cross contamination ... Hand Hygiene includes either washing hands with</p>	V 0113	<p>V113</p> <p>By 11/15/2023, the Director of Operations will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure:</p> <p>Hand Hygiene Policy and Procedure</p> <p>Emphasis was placed on:</p> <p>Patients should perform hand hygiene prior to and after each dialysis treatment.</p> <p>As needed, direct patient care</p>	11/30/2023

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	(X3) DATE SURVEY COMPLETED 10/31/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST		STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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
	<p>soap and water or using a waterless alcohol-based antiseptic hand rub with 60-90% alcohol content</p> <p>... Hand Hygiene: Patients. Patients should perform hand hygiene if able, prior to and after each dialysis treatment. As needed, direct patient care staff will demonstrate how to operate the sinks, demonstrate handwashing, to patients who are able to perform hand washing, and explain the risk of contamination with regard to their vascular access and hands to all patients ... holding access sites post treatment to achieve hemostasis</p> <p>... "</p> <p>2. A review of a sign on the treatment floor above the entrance scale on 10-27-2023 at 11:15 AM, stated, "Germs all around you. Stay healthy wash your hands."</p> <p>3. During an observation on 10-27-2023 at 1:15 PM, PCT 1, was observed assisting patient #9 after the patient held pressure on their vascular access site with a gloved right hand at Station #11. Patient #9 was not instructed or offered hand hygiene.</p> <p>4. During an observation on 10-31-2023 at 11:15 AM, PCT 4, was observed assisting Patient #25 after the patient held pressure on their vascular access site with a gloved right hand at Station #22. Patient #25 was not instructed or offered hand hygiene.</p> <p>5. During an observation on 10-31-2023 at 11:30 AM, PCT 5, was observed assisting patient #24 after the patient held pressure on their vascular access site with a gloved right hand at Station #32. Patient #24's access bled thru the dressing and PCT 5 handed Patient #24 another glove and reapplied a pressure dressing to their access site. The patient removed their glove and was escorted</p>		<p>staff will demonstrate how to operate the sinks, demonstrate hand washing to patients who are able to perform hand washing, and explain the risk of contamination with regard to their vascular access and hands to all patients. By 11/24/2023, 100% of all patients will be re-educated on hand hygiene with documentation of education noted in each patient's EMR. Those patients absent on the day of education will be re-educated on their first treatment back at the facility with documentation noted in the EMR. Effective 11/16/2023, the Clinical Manager will conduct weekly audits with focus on ensuring 100% of patients are offered and/or perform hand hygiene upon entering and exiting the treatment area for 4 weeks or until 90% compliance is achieved utilizing Infection Control Audit Tool. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Tool per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit</p>	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	(X3) DATE SURVEY COMPLETED 10/31/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST		STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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
	<p>to the scale by PCT 4 and left the treatment area. Patient #24 was not instructed or offered hand hygiene.</p> <p>During an interview on 10-31-2023 at 11:45 AM, the Clinical Manager confirmed the staff were to instruct or offer hand hygiene to the patients after they held the pressure dressing on their access.</p>		<p>results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>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.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 11/30/23. p="" paraid="1358824029" paraeid="{b70a2a02-ef3c-40a3-9e1 2-49246a4cd32b}{87}"></p>	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	(X3) DATE SURVEY COMPLETED 10/31/2023	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST			STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 0117 Bldg. 00	<p>494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS</p> <p>Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.</p> <p>When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.</p> <p>Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.</p> <p>Based on observation, record review, and interview the facility failed to ensure the safety of patients and staff as observed in 22 of 37 dialysis station observations where materials were stored improperly.</p> <p>Findings Include:</p> <p>1. A review of a Fresenius Kidney Care policy dated 04-04-2012, Titled "General Cleanliness and Infection Control Guidelines" was provided by the Clinical Manager on 10-31-2023 at 8:30 AM. The policy indicated but was not limited to, " ... The</p>		V 0117	<p>V 117</p> <p>By 11/15/2023, the Director of Operations will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p> <p>General Cleanliness and Infection Control Guidelines</p> <p>Emphasis was placed on:</p> <p>All areas must be kept clean and organized, including but</p>	11/30/2023

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	(X3) DATE SURVEY COMPLETED 10/31/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST			STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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
	<p>purpose of this policy is to provide guidance for FKC staff ... and maintain a clean, safe and aesthetic environment ... All areas must be kept clean and organized ... "</p> <p>2. During an observation on 10-27-2023 at 11:50 AM, noted at Station #31 and #32, the patient's dialysis prescription, clamps, and glove on the top of the dialysis machines.</p> <p>3. During an observation on 10-27-2023 at 11:55 AM, noted at Station #19 the patient dialysis prescription, and end caps on top of the dialysis machine.</p> <p>4. During an observation on 10-27-2023 at 12:00 PM, noted at Station #18 a tv remote control, the patient's weight strip document, and the patient's dialysis prescription on top of the dialysis machine.</p> <p>5. During an observation on 10-27-2023 at 12:35 PM, noted at Station #25 the patient's dialysis prescription on top of the dialysis machine.</p> <p>6. During an observation on 10-27-2023 at 12:36 PM, noted at Station #26 the patient's weight strip document, and dialysis prescription on top of the dialysis machine.</p> <p>7. During an observation on 10-27-2023 at 4:00 PM, noted at Stations #11, 13, and 14, the patients' weight strip document, and their dialysis prescriptions on top of the dialysis machines.</p> <p>8. During an observation on 10-27-2023 at 4:10 PM, noted at Stations #6, 7, 8, 9, and 10, the patients' weight strip documents, clamps, and their take off kits (saline syringes, dressings, alcohol pads and gloves rolled up in a</p>		<p>not limited to the treatment area, water/supply room and offices. No items should be placed on top of the dialysis machines.</p> <p>Effective 11/16/2023, the Clinical Manager will conduct weekly audits for 4 weeks or until 100% compliance is achieved utilizing Infection Control Audit Tool. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Tool per QAI calendar. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>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.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause</p>	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	(X3) DATE SURVEY COMPLETED 10/31/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST		STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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
	<p>barrier/drape) on top of their dialysis machines.</p> <p>9. During an observation on 10-27-2023 at 4:10 PM, noted at Station #31 a blue chair cushion and blood pressure cuff on the top of the dialysis machine.</p> <p>10. During an observation 10-27-2023 at 4:35 PM, noted at Stations #23, 24, and 25 the patients' dialysis prescription on top of the dialysis machine.</p> <p>11. During an observation 10-30-2023 at 4:30 PM, noted the following; at Stations #15, 27, 28, 29 and 30 take-off kits (saline syringes, dressings, alcohol pads and gloves rolled up in a barrier/drape) a lab specimen tubes in a plastic bag on top of their dialysis machines, at Station #15 a syringe of sodium chloride 10 milliliters (ml) in plastic wrap on top of the dialysis machine, at Station #10 the patient's weight strip documents and end caps, at Station #9 end caps, the patient's weight strip documents, and the patient's dialysis prescription, at Station #32 2 clamps, at Station #22 and 23 the patients' dialysis prescriptions and weight strip documents, and at Station #25 and 26 the patients' dialysis prescriptions were on the top of the dialysis machines.</p> <p>During an interview on 10-30-2023 at 5:00 PM, the Patient Care Technician (PCT) 7, when queried regarding items being on top of the dialysis machines indicated they would take them off and not use them. The PCT further indicated blood does get on the machines, and they would have to clean them.</p> <p>12. During an interview on 10-31-2023 at 11:45 AM, the Clinical Manager and Director of Operations confirmed absolutely nothing should</p>		<p>analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 11/30/2023.</p>	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	(X3) DATE SURVEY COMPLETED 10/31/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST		STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 0143 Bldg. 00	<p>be placed on top of the dialysis machines.</p> <p>494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS [The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and</p> <p>Based on observation, record review, and interview, the facility failed to properly manage the handling of medication and liquid nutrition for 1 of 1 stand alone dialysis treatment centers.</p> <p>Findings Include:</p> <p>1. A review of a Fresenius Medical Care policy dated 02-06-2023, was provided by the Director of Operations, on 10-30-2023 at 9:00 AM. The "Medication Preparation and Administration" policy indicated but was not limited to, " ... When preparing medications if the vial is not used immediately in its entirety, the nurse or PCT (Patient Care Technician) ... must place the date and time the vial was opened on the medication label along with their initials ... Expiration dates for all stored medications are to be monitored on a monthly basis ... Any multi-dose vials must be discarded 28 days after opening or per the manufacturer's expiration date ..."</p> <p>2. During an observation on 10-27-2023 at 11:15 AM, observed on the top of the medication station 5 open 32-ounce containers of Liquacel liquid protein with no opened date or staff initials. The Apple Liquacel with an expiration date of 03-2026, Ginger Ale with an expiration date of 03-2026, the Grape Liquacel with an expiration date of 02-2025, the Watermelon Liquacel with an</p>	V 0143	<p>V 143</p> <p>By 11/15/2023, the Director of Operations will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p> <p>Medication Preparation and Administration</p> <p>Emphasis was placed on:</p> <p>When preparing medications/ or Oral Nutritional Supplements (ONS), if the vial is not used immediately in its entirety, the nurse or PCT (if allowed by state regulations), must place the date and time the vial was opened on the medication label along with their initials.</p> <p>Expiration dates for all stored medications are to be monitored on a monthly basis.</p> <p>Expired medications are to be discarded via Fresenius Kidney Care off-site return program or in accordance with local and/or state law.</p> <p>Any open multi dose vials must be discarded 28 days after</p>	11/30/2023

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	(X3) DATE SURVEY COMPLETED 10/31/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST		STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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
	<p>expiration date of 01-2025, and the Peach Mango Liquacel with an expiration date of 01-2025. The Liquacel container's label for directions indicated to use the product within 3 months of opening.</p> <p>3. During an observation on 10-27-2023 at 11:15 AM, noted in the top drawer of the medication station noted 1 vial of Diphenhydramine (a medication used for allergic reactions)50 milligrams (mg)/milliliters (ml) vial with an expiration date of 06-2023, and an open bottle of Clonidine Hydrochloride (a medication used for increased blood pressure) 0.1 milligrams (mg) ¼ bottle full with an expiration date of 10-2025, with no date opened or staff initials.</p> <p>4. During an observation on 10-30 -2023 at 4:30 PM, observed on the top of the medication station 5 open 32-ounce containers of Liquacel liquid protein with no date opened or staff initials. The Apple Liquacel with an expiration date of 03-2026, Ginger Ale with an expiration date of 03-2026, the Grape Liquacel with an expiration date of 02-2025, the Watermelon Liquacel with an expiration date of 01-2025, and the Peach Mango Liquacel with an expiration date of 01-2025. The Liquacel container's label for directions indicated to use the product within 3 months of opening.</p> <p>5. During an observation on 10-30-2023 at 4:30 PM, noted in the top drawer of the medication station noted 1 vial of Diphenhydramine (a medication used for allergic reactions)50 milligrams (mg)/milliliters (ml) vial with an expiration date of 06-2023, and an open bottle of Clonidine Hydrochloride (a medication used for increased blood pressure) 0.1 milligrams (mg) ¼ bottle full with an expiration date of 10-2025, with no date opened or staff initials.</p>		<p>opening or per manufacturer's expiration date.</p> <p>Floorstock containers of oral solids and oral liquids in bulk bottles per Manufacturer's expiration date.</p> <p>Effective 11/16/2023, the Clinical Manager will conduct weekly audits for 4 weeks or until 100% compliance is achieved utilizing Plan of Correction Audit Tool. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Tool per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>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.</p> <p>The QAI Committee is responsible</p>	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	(X3) DATE SURVEY COMPLETED 10/31/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST			STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 0401 Bldg. 00	<p>6. During an observation on 10-31-2023 at 11:20 AM, observed on the top of the medication station 5 open 32-ounce containers of Liquacel liquid protein with no date opened or staff initials. The Apple Liquacel with an expiration date of 03-2026, Ginger Ale with an expiration date of 03-2026, the Grape Liquacel with an expiration date of 02-2025, the Watermelon Liquacel with an expiration date of 01-2025, and the Peach Mango Liquacel with an expiration date of 01-2025. The Liquacel container's label for directions indicated to use the product within 3 months of opening.</p> <p>During an interview on 10-31-2023 at 11:30 AM the Registered Nurse (RN) 3, indicated they date open and initial all medications and the Liquacel protein drinks at their nurse's station.</p> <p>7. During an interview on 10-31-2023 at 11:45 AM, the Clinical Manager confirmed all Liquacel protein drinks and medication were to be labeled with date opened and staff initials.</p> <p>494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment. Based on observation, record review, and interview, the facility failed to provide a safe and comfortable environment for 1 of 1 stand alone dialysis treatment centers.</p> <p>Findings Include:</p>	V 0401	<p>for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 11/30/2023. p="" paraid="413921542" paraeid="{ec91b0b5-e2c3-4457-b4a5-a0887b49eaf7}{160}"></p> <p>V 401</p> <p>By 11/15/2023, the Director of Operations will hold a staff meeting and reinforced the</p>	11/30/2023

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	(X3) DATE SURVEY COMPLETED 10/31/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST		STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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
	<p>1. A review of a Fresenius Kidney Care policy dated 04-04-2012, Titled "General Cleanliness and Infection Control Guidelines" was provided by the Clinical Manager on 10-31-2023 at 8:30 AM. The policy indicated but was not limited to, " ... The purpose of this policy is to provide the facility management/operations team guidance regarding requirements for contacted cleaning services in maintaining a clean, safe, and aesthetically pleasant environment for patients, staff and visitors ..."</p> <p>2. During an observation upon entering the facility on 10-27-2023 at 10:25 AM, noted a smell of sewer gas in the front lobby patient's bathroom.</p> <p>3. During an interview on 10-27-2023 at 11:45 AM, Patient #10, when queried regarding the cleanliness of the facility, indicated the bathroom sometimes smelled like someone had a blowout.</p> <p>4. During an interview on 10-27-2023 at 12:35 PM, Patient #9, when queried about the cleanliness of the facility, indicated the bathroom sometimes smelled of sewer gas.</p> <p>5. During an interview on 10-27-2023 at 12:00 PM the Patient Care Technician (PCT) 2, indicated there was a smell of sewer gas in the wall boxes and they used bleach in the drains of the wall boxes so the treatment area does not smell.</p> <p>6. During an interview on 10-27-2023 at 4:40 PM, PCT 5, indicated the wall boxes sometimes smell and they used bleach to clean them.</p> <p>7. During an observation on 10-27-2023 at 5:01 PM, noted a smell of sewer gas in the female staff's bathroom.</p>		<p>expectations and responsibilities of the facility staff on policy: General Cleanliness and Infection Control Guidelines Emphasis was placed on: To provide guidance for FKC staff on preventing the spread of infectious disease and maintaining a clean, safe, aesthetically pleasant environment for patients, staff, and visitors.</p> <p>Sewer smell noted in patient and staff rest rooms.</p> <p>On 11/01/2023 Biomedical Tech spoke with contractor(s), DEEM (Women's Restroom); Perfection Group (exhaust fan), regarding the scope of work needed. On Monday, 11/13/2023, the contractor scheduled for on-site visit for repairs. Perfection Group site visit rescheduled due to awaiting parts required. Area Technical Manager (ATOM), spoke with vendor from Perfection Group on 11/15/2023 for follow up and rescheduled site visit by 11/17/2023 for completion of work. DEEM will replace women's rest room toilet's by 11/22/2023. Work to be completed by the contractor(s), will include:</p> <p>Repair for Exhaust fan for the two Patient rest room (Lobby and Treatment Floor) Repair or replacement of the</p>	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	(X3) DATE SURVEY COMPLETED 10/31/2023	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST			STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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
	<p>8. During an observation on 10-30-2023 at 3:30 PM, noted a smell of sewer gas in the female staff's bathroom.</p> <p>9. During an interview on 10-30-2023 at 9:55 AM, the Medical Director, indicated they were aware of the smell in the drains and had discussed the issue with the clinical manager. They were in the process of having a plumber come out.</p> <p>10. During an interview on 10-30-2023 at 3:50 PM, the Clinical Manager, indicated they were aware of the sewer smell and could not provide a work ticket for correcting the issue. The Clinical Manager stated, "I should have followed up on the smell and the drains. I did not."</p> <p>11. During an interview on 10-30-2023 at 5:00 PM, PCT 7, indicated when queried regarding smells at the facility indicated the staff and patient's bathroom smell like sewer gas sometimes.</p> <p>12. During an observation on 10-31-2023 at 8:25 AM, noted the front lobby patient's bathroom smelled of sewer gas.</p> <p>13. During an observation on 10-31-2023 at 8:30 AM, noted the female staff's bathroom smelled of sewer gas.</p> <p>14. During an interview on 10-31-2023 at 9:52 AM, the BioMed Technician, indicated they were to keep water in the traps to help decrease the smell in the bathrooms. The Biomed Technician further indicated they were to use a gel cleaner in the wall box drains to decrease the smell of waste.</p>			<p>women's rest room commodes Repair or replacement for sink/drain near Clinical Manager's Office to prevent odor from re-occurring.</p> <p>Effective 11/20/2023, the Clinical Manager will conduct weekly audits with focus on ensuring the facility is clean and well maintained with no sewer odor present utilizing Building Interior/Exterior Physical Environment Inspection Audit for four weeks or until 100% compliance is achieved. Once compliance is sustained, the Governing Body will decrease frequency to resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Checklist Tool per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>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</p>	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152502	(X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	(X3) DATE SURVEY COMPLETED 10/31/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST		STREET ADDRESS, CITY, STATE, ZIP COD 6701 E 21ST STREET INDIANAPOLIS, IN 46219		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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
			<p>each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 11/30/2023. p="" paraid="1813526040" paraeid="{bbe64245-5bc0-43d7-819f-5edcc4dc1ad3}{228}"></p>	