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	03/23/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE INDIANAPOLIS EAST	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
E 0000 Bldg. 00	An Emergency Preparedness survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62, for a Medicare participating End Stage Renal Disease Supplier. Date of survey: 03-21, 03-22 and 03-23-2022 ICHD census: 165 Total Census: 165 At this Emergency Preparedness survey, Fresenius Medical Care Indianapolis East, was found to have been in compliance with the requirements of Emergency Preparedness Requirements for Medicare participating providers and suppliers, including staffing and implementation of staffing during a Pandemic, at 42 CFR 494.62. QR by Area 3 on 4-1-2022	E 0000	POC accepted on 4-18-2022 Deborah Franco	
V 0000 Bldg. 00	This visit was for a CORE Federal recertification and complaint survey of an ESRD provider . Complaint: IN 00375000, Unsubstantiated; no Federal deficiencies were cited related to the complaint. Survey dates: 03-21, 03-22 and 03-23-2022	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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	ICHD census: 165 Total: 165 QR by Area 3 on 4-1-2022			
V 0115 Bldg. 00	494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. Based on observation, record review, and interview, the facility failed to ensure the proper use of personal protective equipment over 2 of 3 survey days. (Employee: J (two times), Z (two times) M and P) (Patient: 23) Findings include: 1. On 03-23-2022 at 3:00 PM a February 2018, Fresenius Kidney Care policy titled, "Personal Protective Equipment," was provided by the Clinical Manager (CM), Employee AA. A review of the policy indicated but was not limited to, "Remove gloves and wash hands after each patient contact... Designated Patient Care Activities...Full Face Shield or Mask and Protective eyewear...potential contact w/blood (sic), Handling infectious waste, stripping	V 0115	On April 15, 2022, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Personal Protective Equipment Policy Education emphasis was placed on: · Correct Personal Protective Equipment (PPE) usage, including but not limited to utilization of visor during patient care and removal of patient glove and hand hygiene after holding access sites. · Personal protective equipment such as fluid-resistant gown will be worn to protect and prevent employees from blood or	04/22/2022

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	machine after patient treatment, terminating a dialysis, holding needle sites, venipuncture or access procedure..." 2. On 03-22-2022 at 10:15 AM, Patient #23 was observed leaving the treatment floor following their treatment. They continued to wear a glove on their left hand after holding pressure at their access site. They were not offered hand hygiene. 3. On 3-22-2022 at 1:00 PM, the Certified Clinical Hemodialysis Technician (CCHT), Employee J was observed in dialysis station across from the nurses station. Employee J was not wearing a visor. Employee J was corrected by the Clinical Manager (CM), Employee AA. 4. On 3-23-2022 at 8:30 AM, the Certified Clinical Hemodialysis Technician (CCHT), Employee Z was observed in dialysis station # 8. Employee Z was not wearing a visor. 5. On 3-23-2022 at 8:30 AM, CCHT's, Employee M and P were observed in dialysis station # 10. Employee M and P were not wearing a visor. 6. On 3-23-2022 at 10:55 AM, Employee Z at station #8 and Employee J at station #25 were observed not wearing a visor. 7. On 3-23-2022 at 11:00 AM, Employee AA counseled employees not wearing a visor. When queried about the use of PPE, Employee AA indicated the employees should be wearing their visors at all times when in the station.		other potentially infectious materials to pass through to or reach the employee's skin, eyes, mouth, other mucous membranes or work clothes when performing procedures during which spurting and spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood)." Effective April 18, 2022, the Clinic Manager or designee will conduct infection control audits five times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on correct PPE usage, to promote infection control and reduce employee exposure risk to biohazardous waste. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the	

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			resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. 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. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: April 22, 2022	
V 0407 Bldg. 00	494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement). Based on observation, record review, and interview the facility failed to ensure the safety of patients by ensuring their access sites were visible over 3 of 3 survey days. (Patient: 31, 16, 17, 32, 33 and 34) Findings include: 1. On 03-23-2022 at 3:00 PM a September 2018, Fresenius Kidney Care policy titled, "Patient Assessment and Monitoring " was provided by	V 0407	On April 15, 2022, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Monitoring Patients During Treatment Education emphasis was placed on: · All patient connections are secure and visible at all times. · Patients will not cover their	04/22/2022

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	the Clinical Manager (CM), Employee AA. A review of the policy indicated but was not limited to, "... All patients must be under visual observation by clinical staff... Ensure access remains uncovered throughout the treatment ..." 2. On 3-21-2022 at 12:20 PM, Patient #31 was observed at station #33 covered with a green blanket. Their access was not visible. 3. On 3-22-2022 at 8:20 AM, Patient # 16 was observed at station # 17. Their access was not visible when covered by a blanket. 4. On 3-22-2022 at 8:20 AM, Patient #17 was observed at station #16. Their access was not visible when covered by a blanket. 5. On 3-23-2022 at 8:35 AM, Patient # 32 was observed at station #35. Their access was not visible when covered by a blanket. 6. On 3-23-2022 at 8:35 AM, Patient # 33 was observed at station #28. Their access was not visible when covered by a blanket. 7. On 3-23-2022 at 8:35 AM, Patient # 34 was observed at station #29. Their access was not visible when covered by a blanket. 8. On 03-22-2022 at 2:35 PM, Employee AA when queried about a patient's access during treatment indicated that the access should always be visible.		head, dialysis access or bloodlines with blankets or clothing. Effective April 18, 2022, the Clinical Manager or designee will conduct access visibility audits five times weekly for one month, then weekly for one month utilizing the Patient Safety Monitoring Tool. The focus will be on access observations and patient safety checks. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the	

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			Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: April 22, 2022	