

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

PRINTED: 12/29/2021
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152588	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 09/08/2021
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE IRVINGTON	STREET ADDRESS, CITY, STATE, ZIP CODE 1740 INDUSTRY DRIVE INDIANAPOLIS, IN 46219
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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: 9-07 and 9-08-2021 Facility #: 003639 CCN: 152588 Home Diaylysis Program Patients: PD patients: 54 Home Hemo patients: 16 Total Census: 70 At this Emergency Preparedness survey, Fresenius Medical Care Irvington, 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. Quality Review completed on 9/10/21 by Area 3	E 0000		
V 0000 Bldg. 00	This visit was for a CORE Federal recertification survey of an ESRD provider.	V 0000		

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.

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V 0115 Bldg. 00	<p>Survey dates: 9/07 and 9/08/2021</p> <p>Facility #: 003639</p> <p>CCN#: 152588</p> <p>Home Dialysis Program census total: 70</p> <p>PD patients: 54 Home Hemo patients: 16</p> <p>Quality Review completed on 9/10/21 by Area 3</p> <p>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.</p> <p>Based on record review, observation and interview the facility failed to ensure employees utilized personal protective equipment (PPE) when on the treatment floor in 3 of 3 observations.</p> <p>Findings include:</p> <p>On 9-08-2021 at 12:10 PM the Clinical Manager (employee G) provided a Fresenius Kidney Care policy. Titled, "Coronavirus Disease Screening</p>	V 0115	<p>On September 24, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p> <ul style="list-style-type: none"> · Coronavirus Disease Screening and Infection Control Practices <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> · Personal Protective Equipment (PPE) usage requirements. 	10/07/2021

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	<p>and Infection Control Practices in Fresenius Kidney Care (FKC) Dialysis Clinics", the policy indicates but is not limited to "... All staff, ...must wear full PPE, including gowns, gloves, face shields and facemasks..."</p> <p>On 9-07-2021 at 12:30 PM, Registered Nurse (employee B) was observed entering patient room #4 without wearing a gown or face shield while in the presence of the patient.</p> <p>On 9-08-2021 at 8:15 AM, Registered Nurse (employee E) was observed entering patient room #2 without wearing a gown or face shield while in the presence of the patient.</p> <p>On 9-08-2021 at 1:00 PM, Registered Nurse (employee C) was observed entering and exit the treatment floor next to the scale while wearing a gown and face shield. A sign at the entrance states, "No PPE beyond this point".</p> <p>On 9-07-2021 at 3:10 PM, the Clinical Manager (employee G) when queried about the use of PPE in the patient rooms indicated that PPE should always be worn in the patient care rooms.</p>		<ul style="list-style-type: none"> -Ensure employees utilized full PPE, including gowns, gloves, face shields, and face masks while in the presence of patients. -PPE such as a fluid-resistant gown and shield will be worn to protect and prevent employees from blood or 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. <p>Effective September 27, 2021, the Clinical Manager or designee will conduct infection control audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on PPE usage to promote infection control per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body.</p> <p>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</p>	

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V 0402 Bldg. 00	494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public. Based on observation and interview, the facility failed to maintain the cleanliness of a patient care surface and failed to maintain the safety of staff and patients by preventing a hazard in the building for 2 of 2 days of observations.	V 0402	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 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: October 7, 2021 On September 24, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: ·Housekeeping Policy	10/07/2021

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	<p>Findings include:</p> <p>On 9-07-2021 at 9:30 AM, during the Flash Tour, the cabinet under the dirty sink of room #3 was found to have a splatter (the size of a small hand) of brown, dried liquid on the shelf. The Communication Room located next to the back exit door had a large cardboard box stored on the floor and it was covering a drain. On top of the cardboard box was the emergency preparedness suitcase. The Communication Room stores the information technology servers and the temperature of the room was very warm.</p> <p>On 9-08-2021 at 8:20 AM, the cabinet of room #3 was checked and the brown splatter was still present.</p> <p>On 9-08-2021 at 11:00 AM, the Communication Room drain remained covered with the cardboard box and suitcase.</p> <p>On 9-08-2021 at 1:30 PM, the Communication Room cardboard storage box was pushed to the back wall on the floor. A tall rolling cart was now covering the drain and the emergency preparedness suitcase was on the floor next to the door.</p> <p>On 9-08-2021, at 8:20 AM, the Clinical Manager (employee G) when queried about the splatter and the communication room stated, "Yeah, I didn't get to that last night."</p>		<p>·Dialysis Precautions</p> <p>Education emphasis was placed on:</p> <ul style="list-style-type: none"> ·Maintaining a safe and clean environment. ·Ensuring the patient treatment floor is cleaned appropriately, free of dirt, debris, and fluid stains. ·Drain in communication room will not be covered. ·Prompt cleaning of splatter and discarding cardboard appropriately. <p>Effective September 27, 2021, the Clinic Manager or designee will conduct physical plant audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Physical Environment Monitoring Tool. The focus will be on maintaining a safe and functional treatment environment. The focus will be cleaning all work surfaces with 1:100 bleach solution per policy. 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</p>	
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V 0584 Bldg. 00	<p>494.100(a)(2) H-TRAINING CONDUCTED BY QUALIFIED RN</p> <p>The training must-</p> <p>(2) Be conducted by a registered nurse who meets the requirements of §494.140(b)(2);</p> <p>Based on record review and interview, the facility failed to follow their policy when hiring new employees and failed to ensure they had a qualified home dialysis trainer for 1 of 1 newly hired home peritoneal dialysis trainer.</p>	V 0584	<p>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 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>Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance.</p> <p>Completion Date: October 7, 2021</p> <p>On September 24, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p> <ul style="list-style-type: none"> Staff Home Therapy 	10/07/2021

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	<p>Findings include:</p> <p>On 9-08-2021 at 2:00 PM, a September 2019, Fresenius Medical Care document titled, "Staff Home Therapy RN" was provided by the Clinical Manager (employee G). The document indicates but is not limited to "...Minimum of one year medical-surgical experience preferred... minimum of one year dialysis experience preferred...".</p> <p>On 9-08-2021 at 11:30 AM, the personnel file was reviewed. The file indicates a Registered Nurse (employee B) was hired on August 04, 2020. Employee B's license was issued on 2-03-2020.</p> <p>On 9-07-2021 at 2:20 PM, while reviewing clinical records of patient #5, it was noted that the patient did not record any of their blood pressures or weights for the period 6-19-2021 through 7-21-2021. Further review of the record found no evidence of documentation of educating the patient on the need for the clinical data by employee B during the patients visit on 7-21-2021.</p> <p>On 9-07-2021 at 2:20 PM, the Clinical Manager (employee G) was queried about the missing documentation and the need to include a note regarding education and the importance of taking blood pressures and weights. Employee G stated, "Yes." and noted employee B "Is a new nurse, brand new. She just graduated."</p>		<p>Registered Nurse (RN)</p> <ul style="list-style-type: none"> · Home Therapies Patient Treatment Record Keeping Emphasis was placed on: <ul style="list-style-type: none"> ·Peritoneal Dialysis patient training must be conducted by a RN that meets the requirements of one year experience plus an additional three months in the Peritoneal Dialysis modality. · Ensure all staff understands the importance of proper review and reinforcement of patient responsibilities of complete and correct data reporting. · Ensuring that all patients and/or caregivers understand the importance of complete and accurate documentation of home dialysis treatment data. · Home records will be reviewed by a qualified Home Therapy Registered Nurse (HTRN) during patient monthly clinic visits to identify trends or omissions. Any issues will be addressed by the RN upon receipt and documented in the medical record. Effective September 27, 2021, the Clinical Manager or designee will conduct will conduct home therapy treatment sheet audits on 100% of all current records, then every two weeks for three months upon receipt of treatment sheets utilizing the Medical Records Audit Tool. The focus will be on ensuring a qualified HTRN reviews the records and provides patient training when indicated per policy. 	

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			<p>Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body.</p> <p>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 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>Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: October 7,</p>	

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V 0685 Bldg. 00	<p>494.140(b)(2) PQ-SELF/HOME TRG RN-12 MO RN+3 MO MODALITY (2) Self-care and home dialysis training nurse. The nurse responsible for self-care and/or home care training must-</p> <p>(i) Be a registered nurse; and (ii) Have at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training.</p> <p>Based on record review and interview, the facility failed to ensure they had a qualified home dialysis trainer for 1 of 1 newly hired home peritoneal dialysis trainer.</p> <p>Findings include:</p> <p>On 9-08-2021 at 2:00 PM, a September 2019, Fresenius Medical Care document titled, "Staff Home Therapy RN" was provided by the Clinical Manager (employee G). The document indicates but is not limited to "...Minimum of one year medical-surgical experience preferred... minimum of one year dialysis experience preferred...".</p> <p>On 9-08-2021 at 11:30 AM, the personnel file was reviewed. The file indicates a Registered Nurse (employee B) was hired on August 04, 2020. Employee B's license was issued on 2-03-2020.</p> <p>On 9-07-2021 at 2:20 PM, while reviewing clinical records of patient #5, it was noted that the patient did not record any of their blood pressures or weights for the period 6-19-2021 through 7-21-2021. Further review of the record found no</p>	V 0685	<p>2021</p> <p>On September 24, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p> <ul style="list-style-type: none"> · Staff Home Therapy Registered Nurse (RN) Emphasis was placed on: <ul style="list-style-type: none"> ·Peritoneal Dialysis patient training must be conducted by a RN that meets the requirements of one year experience plus an additional three months in the Peritoneal Dialysis modality. ·Ensure a qualified home dialysis trainer have at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide training. · Home records will be reviewed by a qualified Home Therapy Registered Nurse (HTRN) during patient monthly clinic visits to identify trends or omissions. 	10/07/2021

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	<p>evidence of documentation of educating the patient on the need for the clinical data by employee B during the patients visit on 7-21-2021.</p> <p>On 9-07-2021 at 2:20 PM, the Clinical Manager (employee G) was queried about the missing documentation and the need to include a note regarding education and the importance of taking blood pressures and weights. Employee G stated, "Yes." and noted employee B "Is a new nurse, brand new. She just graduated."</p>		<p>Any issues will be addressed by the RN upon receipt and documented in the medical record. Effective September 27, 2021, the Clinical Manager or designee will conduct will conduct home therapy treatment sheet audits on 100% of all current records, then every two weeks for three months upon receipt of treatment sheets utilizing the Medical Records Audit Tool. The focus will be on ensuring a qualified HTRN reviews the records and provides patient training when indicated per policy. 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</p>	

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