

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152691	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 05/11/2023
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NAME OF PROVIDER OR SUPPLIER FRESENIUS KIDNEY CARE SOUTHPORT	STREET ADDRESS, CITY, STATE, ZIP COD 6826 MADISON AVENUE INDIANAPOLIS, IN 46227
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V 0000 Bldg. 00	This visit was for a Federal complaint survey of an ESRD Supplier. Survey Dates: 05-09-2023, 05-10-2023, and 05-11-2023 Complaint#: IN 00407147 Stations: 24 to include 1 isolation room In Center Hemodialysis Patients: 67 Home Hemodialysis Patients: 3 Home Peritoneal Patients: 23 Total Census: 93 QR completed on 05-17-2023 by A3	V 0000	Acceptable POC, 6-1-2023 Melodi Greene, RN	
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 (PPE) for 3 of 3 Registered Nurses (RN) and 2 of 3 Patient Care Technicians (PCT). (RN 1, 2 and 3 and PCT 1 and 2)	V 0115	V 115 On 5/19/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:	06/09/2023

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Elizabeth (Betsey)Farrar-McIntyre	Area Team Lead	05/26/2023

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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	<p>Findings include:</p> <ol style="list-style-type: none"> 1. A policy received from the Administrator on 05-10-2023 at 10:50 PM titled, "Guidance on Dialyzing and Control Practices During a Covid-19 Endemic in Fresenius Kidney Care (FKC) Dialysis Clinics," indicated but was not limited to, "...All FKC staff, physicians..are required to wear gloves, face shields/goggles and ...face masks defined in this section ...full PPE is to be worn when engaging in any direct patient facing activities ... Patient and Visitors PPE: ... All patients and visitors are required to wear surgical masks upon entry to FKC dialysis clinic and throughout the duration of dialysis treatment ...". 2. During an observation on 05-10-2023 at 1:45 PM observed Registered Nurse (RN) 3 at station 23 applying pressure to an active bleeding left arm of a patient with face shield positioned above the eyes on the forehead. 3. During an observation on 05-10-2023 at 1:45 PM observed Patient # 17 with no face mask during dialysis treatment. 4. During an observation on 05-10-2023 at 1:45 PM observed Patient #18 with face mask on forehead during dialysis treatment. 5. During an observation on 05-11-2023 at 10:40 AM observed RN 2 assisting the discontinuation of dialysis treatment while wearing the face shield positioned above the eyes on the forehead. 6. During an observation on 05-11-2023 at 10:55 AM observed PCT 1 initiating a dialysis treatment with the face shield positioned above the eyes on the forehead. 		<ul style="list-style-type: none"> · Guidance on Dialyzing and Infection Control Practices of COVID-19 in Fresenius Kidney Care (FKC) Dialysis Clinics · Personal Protective Equipment <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> · FKC patients and visitors are required to wear surgical face masks upon entry to the dialysis clinic and throughout the duration of dialysis treatment and discharge from the clinic post-treatment. · Patients will not be refused treatment if a mask is not worn during the non-contact portion of treatment. At a minimum, FKC patients are required to wear surgical face masks or N95 mask while in the lobby and when interacting with staff during patient care activities (e.g., cannulation, initiation and termination of treatment, medication administration, central venous catheter care, home therapy clinic visits, etc.). · Staff should ensure that the patient's face mask is properly positioned over the nose and mouth before approaching the patient. · All FKC Staff, physicians and physician extenders are required to surgical face masks or wear N95 respirator during all patient facing activities. Gowns, gloves, and face shields/goggles 	

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	<p>7. On 05/10/23 at 1:30 PM, PCT 2 was observed without a visor while standing at station #2 and documenting on the touch screen of the dialysis machine, which was actively running dialysis. PCT 3 approached and gave PCT 2 a visor, which she donned. PCT 2 and 3 discussed whether a visor was actually needed when facing a dialysis machine. RN 2 indicated a visor should be worn at all times when on the treatment floor.</p> <p>8. On 05/10/23 at 1:35 PM, PCT 2 and 3 were interviewed as to when a visor was required. PCT 2 indicated a visor was only needed during initiation and discontinuation of dialysis, or with direct patient contact. PCT 3 indicated a visor should also be worn when standing at the dialysis machine. RN 2, present during the interview, indicated a visor should be worn at all times when on the treatment floor.</p>		<p>are required based upon the patient care activity being performed.</p> <p>Note: Goggles may be worn in place of face shield when caring for non-COVID-19 positive or PUI patients only.</p> <ul style="list-style-type: none"> Personal protective equipment such as a full-face shield or mask and protective eyewear with full side shield, fluid-resistant gowns and gloves 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 or spattering of blood might occur. Effective 5/25/2023, the Clinical Manager or designee will conduct daily audits with specific focus on ensuring all patients adhere to the requirements for wearing a surgical face mask, as well as ensuring facility staff require the patient to adjust their mask to cover their mouth and nose before approaching the patient. Additional focus will be on staff wearing face shield or goggles when engaged with patient facing activities were blood splatter is possible for 1 week and then weekly for 3 weeks or until 100% compliance is achieved utilizing Infection Control Audit Tool. The Governing Body will determine on-going frequency 	

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			<p>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 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</p>	

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V 0122 Bldg. 00	<p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL</p> <p>[The facility must demonstrate that it follows standard infection control precautions by implementing-</p> <p>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]</p> <p>(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. Based on observation and interview, the facility failed to ensure standards for infection control were followed when cleaning the dialysis station, including cleaning of the prime receptacles for 2 of 2 station cleaning observations. (Patient Care Technician: 2 (two times) and 3 (two times).</p> <p>Findings include:</p> <p>1. On 05/10/23 at 1:45 PM, Patient Care Technician (PCT) 2 was observed cleaning station #2. PCT 2 emptied the prime receptacle during station cleaning and placed it back on the dialysis machine. PCT 2 failed to clean the prime receptacle inside and out with bleach wipes prior to replacing it on the dialysis machine.</p> <p>2. On 05/10/23 at 1:45 PM, PCT was observed cleaning station #1. PCT 3 emptied the prime receptacle during station cleaning and placed it back on the dialysis machine. PCT 2 failed to clean the prime receptacle inside and out with bleach wipes prior to replacing it on the dialysis machine.</p>	V 0122	<p>documentation are available for review at the clinic. Completion 06/09/2023</p> <p><u>V122 IC-Disinfect surfaces/equip/written protocols</u></p> <p>On 05/19/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p> <ul style="list-style-type: none"> · Cleaning and Disinfection of the Dialysis Station Policy · Priming Bucket Disinfection <p>Emphasis will be placed on:</p> <ul style="list-style-type: none"> · Externally disinfect the dialysis machine with 1:100 bleach solutions after each dialysis treatment. · Surface disinfect the prime bucket post treatment <ul style="list-style-type: none"> o Dispose of saline solution down any marked dirty sink o Clean all surfaces of the prime 	06/09/2023

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	3. On 05/10/23 at 1:55 PM, PCT 2 and 3 were interviewed concerning when to clean the prime receptacle and indicated the receptacles should be cleaned inside and out during station disinfection. PCT 2 and 3 failed to follow standards for infection control when disinfecting and cleaning a dialysis station.		<p>bucket or approved receptacle, with 1:100 bleach solution</p> <ul style="list-style-type: none"> o Return clean prime bucket to the machine. <p>Effective 5/25/2023, the Clinic Manager or designee will conduct weekly audits with specific focus on ensuring disinfection of the prime bucket per policy, utilizing Infection Control Audit Tool 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 with any non-compliance noted in the meeting minutes in eQUIP.</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</p>	

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

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			<p>through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing 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 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 Date: 06/09/2023</p>	