

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152501	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 05/16/2024
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NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE GARY	STREET ADDRESS, CITY, STATE, ZIP COD 3290 GRANT ST GARY, IN 46408
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V 0000  Bldg. 00	<p>This visit was for a Federal complaint survey of an ESRD Provider.</p> <p>Survey Dates: May 15 and 16, 2024</p> <p>Complaint: IN00433948 was investigated; Federal deficiencies, related, were cited.</p> <p>Census by Service Type: In-Center Hemodialysis Patients: 88 Home Peritoneal Dialysis Patients: 15 Home Hemodialysis Patients: 0 Total Active Census: 103 Isolation Room/Waiver: 1</p> <p>QR: 5/30/24</p>	V 0000		
V 0113  Bldg. 00	<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.</p> <p>Based on observation and interview, the dialysis clinic failed to ensure patient care was provided per policy during 1 of 1 on site observation of care.</p> <p>Findings include:</p> <p>1. A policy dated 11/06/2023, titled, "Hand Hygiene," indicated alcohol based hand rub or hand washing with antimicrobial soap and water should be used before and after direct contact</p>	V 0113	V 113 On 5/9/24 & 5/10/24, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: • Hand Hygiene version 8 After receipt of the Statement of Deficiencies, on 5/13/24, the Clinical Manager provided staff reeducation on: • Hand Hygiene version 8 • Personal Protective Equipment version 6 Emphasis	06/14/2024

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Holly Marty	CM/RN	06/05/2024

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>with patients, immediately after removing gloves, after contact with inanimate objects near the patient.</p> <p>2. During an observation on 05/15/2024:</p> <p>A. Beginning at 10 AM, Patient Care Technician (PCT) 3 was at dialysis station 4 with Patient #9; PCT 3 was observed wearing gloves on both hands and touching the computer screen and keyboard as they checked and entered Patient information. PCT then moved to station 3 with Patient #2 present and while wearing the same gloves, touched the computer screen and keyboard in station 3, then without changing gloves or hand sanitizing, returned to station 4 with Patient #9 and then removed gloves and sanitized hands.</p> <p>B. Beginning at 10:10 AM, PCT 3 was observed with a glove on their right hand and touched the computer screen for station #3, PCT 3 then removed the right hand glove and walked Patient to the scale and pressed the scale button to weigh Patient; PCT failed to sanitize hands after they removed their gloves and before providing direct patient care.</p> <p>C. During an interview on 05/16/2024, beginning at 9:40 AM, PCT 4 indicated gloves are to be removed between patients and hands sanitized.</p> <p>D. During an interview on 05/15/2024, beginning at 12:30 PM, PCT 2 indicated he/she has had infection control training and should change gloves and sanitized hands between patients.</p> <p>E. During an interview on 05/15/2024, beginning at 12:45 PM, PCT 3 indicated they have had infection control training and inservices. PCT 3 indicated</p>		<p>was placed on: • Staff must remove gloves and wash hands after:</p> <ul style="list-style-type: none"> <li>o Patient care</li> <li>o Exposure to blood and body fluids</li> <li>o Touching any surfaces within the patient station</li> <li>• If hands are not visibly soiled, an alcohol-based hand sanitizer may be used. • Always perform hand hygiene after glove removal. • Avoid touching surfaces with gloved hands that will be touched with ungloved hands (for ex. patient charts and computers.)</li> <li>• Hand hygiene includes either washing hands with soap and water or using a waterless alcoholbased antiseptic hand rub with 60-90% alcohol content. • Hand will be washed with antimicrobial soap and water when: <ul style="list-style-type: none"> <li>o Hands are visibly dirty or contaminated with proteinaceous material, blood, or other body fluids</li> <li>o Before eating</li> <li>o After using a restroom</li> <li>o Anthrax or C-difficile exposure</li> <li>• Hands will be decontaminated using alcohol-based hand rub or by washing with antimicrobial soap and water: <ul style="list-style-type: none"> <li>o Before and after direct contact with patients</li> <li>o Entering and leaving the treatment area</li> <li>o Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medications</li> <li>o Immediately after removing gloves</li> <li>o After contact with body fluids or excretion, mucous membranes, non-intact</li> </ul> </li> </ul> </li> </ul>	

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	gloves should be changed between patients and hands sanitized and hand sanitizing should occur after gloves removed and after each patient interaction.		skin, and wound dressings if hands are not visibly soiled o After contact with inanimate objects near the patient o When moving from a contaminated body site to a clean body site of the same patient o After contact with the dialysis wall box, concentrate, drain, or water lines o After contact with other objects within the patient station or treatment space Effective 5/13/24, Clinical Manager will conduct audits twice daily with focus on ensuring staff complete hand hygiene according to hand hygiene policy's utilizing Clinic Audit Tool for 1 week, and then daily for 1 week and then weekly for an additional 3 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. 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	

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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 and interview, the facility	V 0115	deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. 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. 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. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 6/14/24  V 115 On 5/30/24, the Clinical Manager held a staff meeting and	06/28/2024	

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	<p>failed to ensure the treatment area was free from possible contaminates in 1 of 1 observation of the incenter hemodialysis treatment floor.</p> <p>Findings include:</p> <p>During an observation on 05/15/2024, beginning at 9:15 AM, a nature sweet, sweet and salty granola bar was noted at the south workstation on the treatment floor next to the dialyzers and saline bags.</p> <p>During an observation on 05/15/2025, at 10:55 AM, the granola bar remained on the south workstation.</p> <p>During an interview on 05/15/2024, beginning at 10:55 AM, Patient Care Technician (PCT) 5 indicated the granola bar at the workstation should not be at the workstation and it did not belong to a patient.</p> <p>During an interview on 05/15/2024, beginning at 11:40 AM, Registered Nurse 1 indicated there should be no food at the workstations on the dialysis floor.</p>		<p>reinforced the expectations and responsibilities of the facility staff on policies: • General Cleanliness and Infection Control Guidelines version 6 Emphasis was placed on: • Eating, drinking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there V 115</p> <p>On 5/30/24, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:</p> <ul style="list-style-type: none"> <li>• General Cleanliness and Infection Control Guidelines version 6</li> </ul> <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> <li>• Eating, drinking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.</li> <li>• Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.</li> </ul> <p>Effective 6/3/24, Clinical Manager or designee will conduct weekly audits with focus on ensuring the treatment area remains free from possible contaminations (i.e. food) utilizing Clinic Audit Tool for 4 weeks or until 100% compliance is achieved. The Governing Body</p>	

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			<p>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. 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</p>	

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			<p>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 6/28/24.is a reasonable likelihood of occupational exposure. • Food and drink shaV 115 On 5/30/24, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: • General Cleanliness and Infection Control Guidelines version 6 Emphasis was placed on: • Eating, drinking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure. • Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present. Effective 6/3/24, Clinical Manager or designee will conduct weekly audits with focus on ensuring the treatment area remains free from possible contaminations (i.e. food) utilizing Clinic Audit Tool for 4 weeks or</p>	

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			<p>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. 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 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. 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. The QAI and</p>	

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			Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 6/28/24. It not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present. Effective 6/3/24, Clinical Manager or designee will conduct weekly audits with focus on ensuring the treatment area remains free from possible contaminations (i.e. food) utilizing Clinic Audit 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. 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	

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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.</p> <p>Based on observation, interview, and record review, the dialysis clinic failed to ensure dialysis equipment was decontaminated between each patient use.</p>	V 0122	<p>identified issues. 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. 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. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 6/28/24.</p> <p>V 122 On 5/9/24 &amp; 5/10/24, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: • Cleaning and Disinfection of the</p>	06/14/2024	

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	<p>Findings include:</p> <p>A policy dated 09/05/2023, titled, "Cleaning and Disinfecting the Dialysis Station," indicated the dialysis station included the chair, reusable equipment to include IV pole and blood pressure cuff should be disinfected with bleach solution after completion of a dialysis (removal of toxins from people whose kidneys no longer worker normally) procedure.</p> <p>During an observation on 05/15/2024, beginning at 10:25 AM, Patient Care Technician (PCT) 2 was observed as they cleaned dialysis station #23. Noted the stations' blood pressure cuff was lying on the floor. PCT 2 picked the cuff from the floor and hung the blood pressure cuff back on to the IV pole without decontamination.</p> <p>During an interview on 05/15/2024, beginning at 12:45 PM, PCT 3 indicated during station cleaning, the blood pressure cuff should be cleaned with bleach solution and hung on the IV pole, if a blood pressure cuff were to touch the floor it should be re-cleaned.</p>		<p>Dialysis Station version 14 After receipt of the Statement of Deficiencies, on 5/30/24, the Clinical Manager provided staff reeducation to reinforce completion of thorough disinfection/decontamination of the dialysis equipment (i.e. Blood Pressure Cuff) between each patient use. Emphasis was placed on:</p> <ul style="list-style-type: none"> <li>• Area including the dialysis machine, chair/bed and other reusable equipment or supplies utilized during dialysis treatment, patient training, and/or patient clinic visits. Equipment in the dialysis station may include (but is not limited to) the following: <ul style="list-style-type: none"> <li>o Dialysis machine/cycler and attachments such as IV pole, BP cuff and hand sanitizer/holder, organizer</li> <li>o Chair</li> <li>o Place in Trendelenburg</li> <li>o Open side door panels</li> <li>o Lower side tray tables</li> <li>o Pureflow SL</li> <li>o Individual television and remote</li> </ul> </li> <li>• The dialysis station could become contaminated with blood and other body fluids during treatment. After use, any non-disposable equipment and supplies brought into the dialysis station must be disinfected with 1:100 bleach or EPA registered disinfectant before being removed from the dialysis station</li> <li>• All work surfaces shall be cleaned and disinfected with 1:100 bleach solution after completion of procedures. Make the surface glisteningly wet and allow to air</li> </ul>	

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			dry unless otherwise specified by the manufacturer. Effective 5/13/24, Clinical Manager will conduct audits twice daily with focus on ensuring dialysis equipment is decontaminated between each patient use utilizing Clinic Audit Tool for 1 week, and then daily for 1 week and then weekly for an additional 3 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. 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 for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to	

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

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