| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 152634 | A. BUILDING 00<br>B. WING | 11/16/2020 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP COD |
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| FRESENIUS MEDICAL CARE MUNCIE | 4021 W KILGORE AVE<br>MUNCIE, IN 47304 |

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| E 0000<br><br>Bldg. 00 | An Infection Control Focused Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62.<br><br>Survey Date: November 16th of 2020<br><br>Facility Number: 012067<br>Provider Number: 152634<br><br>Census: 65 in-center hemodialysis<br>15 home peritoneal dialysis<br>1 home hemodialysis<br><br>At this Focused Infection Control Emergency Preparedness survey, in regards to staffing and implementation of staffing, Fresenius Medical Care Muncie was found to be in compliance with 42 CFR 494.62 Emergency Preparedness requirements for Medicare participating Providers and Suppliers for ESRD facilities.<br><br>Quality Review completed on 12/9/2020 A4 | E 0000 | | |
| V 0000<br><br>Bldg. 00 | This visit was for a federal ESRD complaint survey in conjunction with an Infection Control COVID-19 focused survey .<br><br>Complaint IN00341428 - Substantiated with related and unrelated findings.<br>Complaint IN00342420 - Unsubstantiated due to lack of evidence. | V 0000 | | |

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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| | Survey Date: November 16th of 2020<br><br>Facility Number: 012067<br>Provider Number: 152634<br><br>Census: 65 in-center hemodialysis<br>15 home peritoneal dialysis<br>1 home hemodialysis | | | |
| V 0111<br><br>Bldg. 00 | 494.30<br>IC-SANITARY ENVIRONMENT<br>The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.<br><br>Based on observation, record review, and interview the facility failed monitor the environment to prevent infectious material being transmitted between adjacent areas in 1 of 2 dialysis treatment chairs observed post treatment.<br><br>Findings include:<br><br>A document titled "Housekeeping Policy", with an effective date of 3-20-2013 was provided by Employee A on 11/16/2020. The policy indicated, but was not limited to, "Regulated waste. . . contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed . . . microbiological wastes containing blood . . . All regulated waste shall be contained in red plastic bags or specially labeled cartons designed for regulated waste storage. Regulated waste must be kept separate from regular waste . . ."<br><br>Observations on 11/16/2020 from 12:00 p.m. to | V 0111 | The Clinic Manager educated staff on 11/18/20 & 11/19/20 and reinforced education on 12/21/20 on the expectations and responsibilities to comply with the following policies:<br>·Housekeeping V4, Effective 3/20/2013<br><br>Education emphasis was placed on:<br>· Handling, storage and disposal of potentially infectious waste.<br>· All regulated waste shall be contained in red plastic bags or specially labeled cartons designed for regulated waste storage.<br>· Immediate disposal of blood saturated items, including paper towels and gauze into biohazard container. | 01/10/2021 |

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| | 12:30 p.m. evidenced a blood soiled paper towel and blood soiled gauze on the treatment floor in front of treatment station 8. The soiled biohazardous waste remained on the floor for 30 minutes after the previous patient had left the chair before it was picked up and properly disposed of into a biohazardous waste bin.<br><br>During an interview on 11/16/2020 at 3:56 p.m. the clinical manager was made aware of the finding and indicated it should have been taken to the biohazard bin immediately after patient left the treatment chair. | | Effective December 22, 2020, the Clinic Manager or designee will conduct infection control audits daily for one week, then weekly for two weeks, then monthly utilizing the Infection Control Monitoring Tool. The focus will be on immediate disposal of blood saturated items into bio-hazard bins. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body.<br>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 | |

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| | | | the Statement of Deficiency, is effective and is providing resolution of the issues.<br>Documentation of education, monitoring, QAI, and Governing Body is available for review.<br>The Clinic Manager is responsible for overall compliance. | |
| V 0121<br><br>Bldg. 00 | 494.30(a)(4)(i)<br>IC-HANDLING INFECTIOUS WASTE<br>[The facility must demonstrate that it follows standard infection control precautions by implementing-]<br>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-<br>(i) Handling, storage and disposal of potentially infectious waste;<br><br>Based on observation, record review, and interview, the facility failed to follow proper infection control precautions in handling and disposal of potentially infectious waste for 1 of 1 facilities reviewed.<br><br>Findings include:<br><br>A document titled "Housekeeping Policy", with an effective date of 3-20-2013 was provided by Employee A on 11/16/2020. The policy indicated, but was not limited to, "Regulated waste. . . contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed . . . microbiological wastes containing blood . . . All regulated waste shall be contained in red plastic bags or specially labeled cartons designed for regulated waste storage. Regulated waste must be kept separate | V 0121 | The Clinic Manager educated staff on 11/18/20 & 11/19/20 and reinforced education on 12/21/20 on the expectations and responsibilities to comply with the following policies:<br>· Housekeeping, V4 Effective 3/20/2013<br>Education emphasis was placed on:<br>·Handling, storage and disposal of potentially infectious waste.<br>·Removal and replacement of biohazard bin when full.<br>·Bloody lines will not drape over the side of biohazard container.<br><br>Effective December 22, 2020, the Clinic Manager or designee will conduct infection control audits | 01/10/2021 |

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| | from regular waste . . ."<br><br>The Center for Disease Control published a document titled, Regulated Medical Waste: Guidelines for Environmental Infection Control in Health-Care Facilities, accessible at https://www.cdc.gov/infectioncontrol/guidelines/environmental/background/medical-waste.html. The document indicated, but was not limited to, "Medical wastes require careful disposal and containment before collection and consolidation for treatment. OSHA (Occupational Safety and Health Administration) has dictated initial measures for discarding regulated medical-waste items. These measures are designed to protect the workers who generate medical wastes and who manage the wastes from point of generation to disposal ... Both federal and state regulations address the safe transport and storage of on- and off-site regulated medical wastes ... Health-care facilities are instructed to dispose medical wastes regularly to avoid accumulation."<br><br>Observations on 11/16/2020 from 11:32 a.m. to 12:09 p.m. evidenced the biohazard waste bin overflowing with used blood lines and dialyzers. The used blood line draped over of the container. The container was located directly in front of dialysis patient treatment chairs in the center of pod 4. The overflowing hazardous waste bin continued to accumulate waste until it was emptied at 12:09 p.m.<br><br>During an interview on 11/16/20 at 3:56 p.m. employee A, Clinical Manager, stated the dialysis PCT for Pod 4 had lifting restrictions and was unable to empty the biohazard bin when full. She stated the PCT (Patient Care Technician) had to rely on other staff to keep biohazard bin empty and they did not always notice it was full. | | daily for one week, then weekly for two weeks, then monthly utilizing the Infection Control Monitoring Tool. The focus will be on appropriate handling infectious waste and timely replacement of biohazard bins when full. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body.<br>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. | |

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| | | | Documentation of education, monitoring, QAI, and Governing Body is available for review.<br>The Clinic Manager is responsible for overall compliance. | |
| V 0122<br><br>Bldg. 00 | 494.30(a)(4)(ii)<br>IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL<br>[The facility must demonstrate that it follows standard infection control precautions by implementing-<br>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]<br>(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.<br><br>Based on observation and interview, the agency failed to ensure all staff demonstrated proper infection control procedures for cleaning and disinfection of contaminated surfaces and equipment to safeguard against potential transmission of COVID-19 in 3 of 3 patient weight observations (4, 6, and 7).<br><br>Findings include:<br><br>1. A document titled, Coronavirus Disease Screening and Infection Control Practices in Fresenius Kidney Care (FKC) Dialysis Clinics, was provided by the clinical manager on 11/16/2020 a.m. at 3:00 p.m. The document indicated, but was not limited to, "...Clean AND disinfect frequently touched surfaces ... this includes tables, doorknobs, light switches, countertops, flat surfaces, handles ... Thoroughly clean ... using a 1:100 bleach disinfectant." | V 0122 | The Clinic Manager educated staff on 11/18/20 & 11/19/20 and reinforced education on 12/21/20 on the expectations and responsibilities to comply with the following policies:<br>·Coronavirus Disease Screening and Infection Control Practices in Fresenius Kidney Care (FKC) Dialysis Clinics, V10 Effective 12/2/20<br>·Hand Hygiene, V6 Effective 11/4/19<br><br>Education emphasis was placed on:<br>·Clean and disinfect frequently touched surfaces, including door knobs and buttons on weight scales.<br>·Change gloves and practice hand hygiene after handling | 01/10/2021 |

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| | 2. Review of a facility policy titled "Hand Hygiene" indicated, but was not limited to, "Hands will be decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and water before an after direct contact with patient, entering and leaving the treatment area, ... Immediately after removing gloves ... after contact with inanimate objects near the patient ..."<br><br>3. During an observation on 11/16/2020 at 12:29 p.m., observed patient 4 enter the treatment room, step on the scale and push the button on the scale to obtain current weight.<br><br>4. During an observation on 11/16/2020 at 12:31 p.m., observed patient 6 leave treatment chair, step on the scale, and push the button on the scale to obtain current weight. Patient 6 then exited the treatment floor opening the door with bare hand.<br><br>5. During an observation on 11/16/2020 at 12:35 p.m., observed employee E open the treatment floor door using a gloved hand to allow patient 7 to enter. Employee E obtained patient 7 temperature and recorded on facility log. Patient 7 step on the scale and Employee E pushed the button to obtain the patient's weight using the same gloved hand.<br><br>6. During an observation on 11/16/2020 at 12:40 p.m. the scale button was disinfected.<br><br>7. Observations on 11/16/2020 from 12:29 p.m. to 12:40 p.m. evidenced 5 instances of cross contamination between patients, the door handle, and the weight scale.<br><br>8. During an interview on 11/16/2020 at 3:56 p.m. | | potentially contaminated equipment.<br>·Treat all supplies and equipment used for a patient's treatment as if they are contaminated.<br><br>Effective December 22, 2020, the Clinic Manager or designee will conduct infection control audits daily for one week, then weekly for two weeks, then monthly utilizing the Infection Control Monitoring Tool. The focus will be on hand hygiene and cleaning all work surfaces with 1:100 bleach solution. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body.<br>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 | |

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| | the clinical manager was notified of the infection control concerns and acknowledged more education was needed. | | Committee is responsible to provide oversight, review findings, and take actions as appropriate.<br>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.<br>Documentation of education, monitoring, QAI, and Governing Body is available for review.<br>The Clinic Manager is responsible for overall compliance. | |