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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:<br>152504 | X2) MULTIPLE CONSTRUCTION<br>A. BUILDING 00<br>B. WING _____ | X3) DATE SURVEY COMPLETED<br>10/26/2023 |
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| NAME OF PROVIDER OR SUPPLIER<br><br>FRESENIUS MEDICAL CARE SOUTHERN INDIANA | STREET ADDRESS, CITY, STATE, ZIP CODE<br>810 EASTERN BOULEVARD<br>CLARKSVILLE, IN 47129 |
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| E 0000<br><br>Bldg. 00 | An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62<br><br>Survey Dates: October 23 - 26, 2023<br><br>Facility Number: 152504<br><br>Census = 103<br><br>QR completed on 11/01/2023 by A4   | E 0000 |  |  |
| E 0023<br><br>Bldg. 00 | 403.748(b)(5), 416.54(b)(4), 418.113(b)(3), 441.184(b)(5), 482.15(b)(5), 483.475(b)(5), 483.73(b)(5), 484.102(b)(4), 485.625(b)(5), 485.68(b)(3), 485.727(b)(3), 485.920(b)(4), 486.360(b)(2), 491.12(b)(3), 494.62(b)(4)<br><br>Policies/Procedures for Medical Documentation<br>§403.748(b)(5), §416.54(b)(4), §418.113(b)(3), §441.184(b)(5), §460.84(b)(6), §482.15(b)(5), §483.73(b)(5), §483.475(b)(5), §484.102(b)(4), §485.68(b)(3), §485.625(b)(5), §485.727(b)(3), §485.920(b)(4), §486.360(b)(2), §491.12(b)(3), §494.62(b)(4).<br><br>[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years [annually for LTC facilities]. At a |        |  |  |

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| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE                  | (X6) DATE  |
| Paula Rhoten  | Director of Operations | 11/09/2023 |

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>minimum, the policies and procedures must address the following:]</p> <p>[(5) or (3),(4),(6)] A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains availability of records.</p> <p>*[For RNHCIs at §403.748(b):] Policies and procedures. (5) A system of care documentation that does the following:<br/>(i) Preserves patient information.<br/>(ii) Protects confidentiality of patient information.<br/>(iii) Secures and maintains the availability of records.</p> <p>*[For OPOs at §486.360(b):] Policies and procedures. (2) A system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and secures and maintains the availability of records.</p> <p>Based on observation, record review and interview, the facility failed to update the emergency contact information binder for the evacuation box for 1 of 1 evacuation box reviewed with the potential to affect all dialysis patients during an emergency evacuation.</p> <p>Findings include:</p> <p>1. A policy date 07/03/2023, titled "Guidelines for Emergency Preparedness" was provided on 10/23/2023 at 2:50 PM, by Administrator. The policy indicated, but was not limited to, "...The facility must develop a communication plan for all</p> | E 0023        | <p>On 11/16/2023, the Director of Operations in conjunction with the Clinical Manager will meet with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policy:<br/>Guidelines for Emergency Preparedness</p> <p>Emphasis will be placed on:<br/>The Clinical Manager is responsible to review and update the Emergency and Disaster</p> | 12/01/2023           |

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|                    | <p>patients (in-center and home). This plan includes the following: Create and maintain staff, patient, and facility emergency information contact lists: ... Quarterly, the CM will review and update: ... The Emergency and Disaster Patient Contact Information Sheet A current copy of the emergency list must: be kept locked in the emergency supply boxes, or cart ...".</p> <p>2. During an observation on 10/23/2023 at 11:40 AM, an Emergency Preparedness 3-ring binder was found on the counter next to the emergency evacuation box, the binder contained 2 patient evacuation lists one dated 12/28/2022 and the other 03/03/2023.</p> <p>3. During an interview on 10/23/2023 at 12:20 PM, the Clinical Manager indicated the patient evacuation list should be updated quarterly.</p> <p>4. During an interview on 10/23/2023 at 1:15 PM, the Administrator indicated the emergency patient evacuation list should be updated quarterly and should be in the emergency evaluation box.</p> <p>5. During an interview on 10/25/2023 at 3:25 PM, the Medical Director (MD) indicated the emergency patient evacuation list should be kept in the emergency evacuation box.</p> |               | <p>Patient and Staff Contact Information sheets quarterly. A copy of the updated Emergency and Disaster Patient and Staff Contact List will be placed and maintained in the locked emergency supply box.</p> <p>On 10/23/2023, following identification of the findings, the Clinical Manager updated the Emergency and Disaster Patient and Staff Contact Information sheets and placed a copy in the locked emergency supply box.</p> <p>To ensure that the Patient and Staff Contact Information sheets are updated quarterly, and are maintained in the locked Emergency box, beginning 11/16/2023, the Director of Operations will be responsible to verify the Emergency box is securely locked and review the Emergency and Disaster Patient Contact Information sheets quarterly x 2. Once compliance is achieved and sustained, the facility will resume regularly scheduled quarterly updates based on the Guidelines for Emergency Preparedness policy guidelines.</p> <p>It is the expectation of the Governing Body that 100% compliance is achieved. If the review findings fall below 100%, the Governing Body will reconvene</p> |                      |

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|                    |  |               | <p>to determine revision and implementation of the revised action plan.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting. 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 QAPI 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.</p> <p>The QAPI Committee is responsible to provide oversight, review 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 QAPI monthly. 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. The QAPI and Governing Body minutes, education and monitoring documentation, are available for</p> |                      |

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| E 0028<br>Bldg. 00 | <p>494.62(b)(9)<br/>Dialysis Emergency Equipment<br/>§494.62(b)(9) Condition for Coverage: [(b) Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:]</p> <p>(9) A process by which the staff can confirm that emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, are on the premises at all times and immediately available.</p> <p>Based on observations, record review, and interview the facility failed to keep emergency equipment secure and maintain non-expired evacuation medication for 1 of 1 facilities reviewed with the potential to affect all dialysis patients during an emergency evacuation.</p> <p>Findings include:</p> <p>1. A policy dated 05/01/2023, titled "Emergency Medications, Equipment, and Supplies" was provided on 10/26/2023 at 8:15 AM, by Administrator. The policy indicated, but was not limited to, " ... The emergency cart must be:</p> | E 0028        | <p>review at the clinic.</p> <p>On 11/16/2023, the Director of Operations in conjunction with the Clinical Manager will meet with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policy: Emergency Medications, Equipment and Supplies Emphasis will be placed on:</p> <p>The Emergency Cart and Emergency Evacuation Box must be: Locked when not in use</p> | 12/01/2023           |

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|                    | <p>Locked when not in use ...".</p> <p>2. During an observation on 10/23/2023 at 11:40 AM, an Emergency Evacuation Box containing evacuation supplies was observed having 10 bags of 0.9% Sodium Chloride (used for replenishing fluid and for restoring and maintaining the concentrations of sodium and chloride ions) with expiration dates of 08/2023 and 2 stay save caps with expiration dates of 09/2023. The Emergency Cart was found unlocked and unattended.</p> <p>3. During an interview on 10/25/2023 at 12:20 PM, the Clinical Manager indicated, he/she was responsible for Emergency Evacuation Box and Emergency Cart. He/She indicated they both are checked monthly. He/she was not aware of the expired medication in the box.</p> <p>4. During an interview on 10/25/2023 at 2:00 PM, the Administrator indicated the emergency cart should be checked monthly and relocked after being checked. He/She indicated Clinical Manager is responsible for the emergency evacuation box, patient list, and crash cart and would expect supplies in the emergency evacuation box not to be expired.</p> |               | <p>Checked monthly or after use for contents, expiration dates, cleanliness, and proper functioning of all equipment. An itemized log must be kept indicating the contents and expiration dates of contents. Items approaching expiration must be reordered and replaced prior to the actual expiration date.</p> <p>Upon identification of the findings on 10/23/2023, the Clinical Manager discarded and replaced the: 10 bags of 0.9% Sodium Chloride (used for replenishing fluid and for restoring and maintaining the concentrations of sodium and chloride ions) with expiration date 08/2023 2 stay save caps with expiration dates of 09/2023</p> <p>To monitor the Emergency Cart and Evacuation Box to ensure it is maintained locked when not in use and to ensure the Emergency Medications and Supplies are within manufacturer expiration dates, beginning December 2023, the Clinic Manager will be responsible to conduct visual audits of the Emergency Cart and Evacuation Box and contents in conjunction with a Registered Nurse monthly x 3 months.</p> <p>Once compliance is achieved and sustained, the facility will resume regularly scheduled monthly</p> |                      |

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|                    |  |               | <p>Emergency Cart/Box checks based on the policy guidelines.</p> <p>It is the expectation of the Governing Body that 100% compliance is achieved. If the emergency cart and supply monthly audit findings fall below 100%, the Governing Body will reconvene to determine revision and implementation of the revised action plan.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting. 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 QAPI 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.</p> <p>The QAPI Committee is responsible to provide oversight, review 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 QAPI monthly. The Governing Body is responsible to provide</p> |                      |

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| V 0000<br>Bldg. 00 | This visit was for a CORE Federal recertification survey of an ESRD provider.<br><br>Survey dates: October 23 - 26, 2023<br><br>Census by Service Type:<br><br>In-Center Hemodialysis: 80<br><br>Home Hemodialysis: 8<br><br>Home Peritoneal dialysis: 15<br><br>Total Active Census: 103   | V 0000        | 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 QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clini |                      |
| V 0111<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>Based on observation, record review, and interview, the facility failed to ensure patient belongings were not stored at the dialysis station for 2 of 3 treatment floor observations. (Patient | V 0111        | On 11/16/2023, the Director of Operations in conjunction with the Clinical Manager will meet with facility staff to provide reeducation,   | 12/01/2023           |

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|                    | <p>#13)</p> <p>Findings include:</p> <p>1. A 02/07/20232 policy titled General Cleanliness and Infection Control Guidelines was provided by the Administrator on 10/24/2023 at 1:30 PM. The policy indicated, but was not limited to, "preventing the spread of infectious disease and maintaining a clean, safe, aesthetically pleasant environment for patients ... Policy ... Supplies or patient's belongings should not be kept or stored behind the machine at the patient station."</p> <p>2. During an observation on 10/23/2023 at 12:00 PM, Patient #13's personal belongings (blanket, stuffed animal, headrest pillow) were placed on top of the counter directly behind the dialysis machine at station 21 during treatment. At 4:20 PM, Patient #13's personal belongings remained on the countertop after Patient #13 left. At that time, Registered Nurse 2 stated Patient #13's belongings were kept at the station because the nursing home forgot to send the items with the patient.</p> <p>3. During an observation on 10/24/2023 at 8:15 AM, Patient #13's personal belongings remained on top of the counter behind the dialysis machine at station 21 while Patient #14 dialyzed. The facility failed to ensure that the patient's belongings were not stored behind the dialysis machine, as indicated in their policy.</p> <p>4. During an interview on 10/24/2023 at 3:50 PM, the Administrator stated that the patient personal items should not be stored at the treatment station.</p> |               | <p>elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policy:<br/>General Cleanliness and Infection Control</p> <p>Emphasis will be placed on:<br/>Supplies or patient's personal belongings should not be kept or stored behind the machine at the patient station.</p> <p>On 10/23/2023, the Clinical Manager removed the identified patients' belongings (blanket, stuffed animal and headrest pillow) from behind the dialysis machine at the patient station.</p> <p>To ensure patient's personal belongings are not kept or stored behind the dialysis machine at the patient station, beginning 11/10/2023, the Clinic Manager or designee will conduct observational infection control audits of each dialysis station in the treatment area daily x 2 weeks. Once compliance is achieved the Governing Body will decrease frequency to weekly x 2 weeks. Once compliance is sustained, the facility will resume regularly scheduled monthly infection control audits based on the QAPI calendar.</p> <p>Monitoring will be done through the QAI Checklist Audit Tool.</p> |                      |

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|                          |   |                     | <p>It is the expectation of the Governing Body that 100% compliance is achieved. If the infection control audit findings for patient's belongings stored at the dialysis station falls below 100%, the Governing Body will reconvene to determine revision and implementation of the revised action plan.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting. 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 QAPI 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.</p> <p>The QAPI Committee is responsible to provide oversight, review 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 QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of</p> |                            |

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| V 0113<br>Bldg. 00 | <p>494.30(a)(1)<br/>IC-WEAR GLOVES/HAND HYGIENE<br/>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, record review and interview the facility failed to ensure gloves were changed appropriately, and hand hygiene was performed effectively for 5 of 10 patient care observations and 2 of 2 station disinfection (Patient #12, #21, #22, #23, #24) (Station 8, 22)</p> <p>Findings include:</p> <p>1. A policy dated 09/05/2023, titled "Cleaning and Disinfecting the Dialysis Station" was provided on 10/24/2023 at 1:15 PM, by Administrator. The policy indicated, but was not limited to, " ... Electronic Charting Device Integrated into the Dialysis Machine ... The electronic charting device incorporated in the 2008 T dialysis machine is not considered a clean area. Gloves will be required when touching either the screen or keyboard ..."</p> <p>2. During an observation, on 10/23/2023 at 4:45 PM, Registered Nurse (RN) 1 performed a</p> | V 0113        | <p>Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>On 11/16/2023, the Director of Operations in conjunction with the Clinical Manager will meet with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policies:<br/>Hand Hygiene Cleaning<br/>Disinfection of the Dialysis Station</p> <p>Emphasis will be placed on: Dirty gloves will be removed, hand hygiene performed and clean gloves donned including, but not limited to: Before removing needles from arteriovenous (AV) site. After emptying the prime waste receptacle. When moving from the patient to the dialysis machine, and from the dialysis machine to patient contact. Prior</p> | 12/01/2023           |

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|                    | <p>discontinuation of an arteriovenous (AV) fistula (an irregular connection between an artery and a vein) on Patient #23, After disconnecting bloodlines aseptically, RN 1 failed to remove their gloves, failed to perform hand hygiene and failed to don clean gloves before removing needles from AV site.</p> <p>3. During an observation on 10/23/2023 at 5:45 PM, at station 22, RN 1 performed the cleaning and disinfection of the dialysis station. RN 1 failed to remove their gloves, failed to perform hand hygiene and failed to don clean gloves after emptying the prime waste receptacle.</p> <p>4. During an observation on 10/24/2023 at 7:30 AM, RN 2 performed an initiation of a central venous catheter (CVC) (a long, flexible tube your provider inserts into a vein in your neck, chest, arm, or groin), after disinfecting CVC hubs, RN 2 returned to the dialysis machine and touched the screen. RN 2 failed to change gloves or perform hand hygiene before and after touching the screen. He/She then returned to Patient # 21's CVC and connected a sterile syringe to each port to flush with saline and initiate treatment. RN 2 then touched the dialysis machine screen without first performing hand hygiene or donning new gloves between the patient and the machine contact.</p> <p>5. During an observation on 10/24/2023 at 7:15 AM, RN 1 performed an initiation of an arteriovenous (AV) fistula (an irregular connection between an artery and a vein) on Patient #12. RN 1 palpated the AV site and applied antiseptic to the access site without first performing hand hygiene or donning clean gloves.</p> |               | <p>to applying antiseptic to the access site. Gloves will be properly donned prior to touching the dialysis machine to silence alarms.</p> <p>To monitor staff compliance with glove usage and hand hygiene in accordance to FKC policy guidelines, beginning 11/10/2023, the Clinic Manager or designee will conduct observational infection control audits daily x 2 weeks. Once compliance is achieved, the Governing Body will decrease frequency to weekly x 2 weeks. Once compliance is sustained, the facility will resume regularly scheduled monthly infection control audits based on the QAPI calendar.</p> <p>Monitoring will be done through the QAI Checklist Audit Tool.</p> <p>It is the expectation of the Governing Body that 100% compliance is achieved. The Governing Body determined that the facility threshold be 95%. If the infection control audit findings fall below 95%, the Governing Body will reconvene to determine revision and implementation of the revised action plan.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting. The Clinical Manager is responsible to review, analyze and</p> |                      |

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|                    | <p>6. During an observation on 10/24/2023 at 7:45 AM, of Patient #24, License Practical Nurse (LPN) 1 performed an initiation of an arteriovenous (AV) fistula on patient #24. LPN 1 palpated the AV site and applied antiseptic to the access site without first performing hand hygiene or donning clean gloves.</p> <p>7. During an observation on 10/24/2023 at 11:45 AM, RN 2 performed a discontinuation of an arteriovenous (AV) fistula on Patient #22. RN 2 touched the dialysis machine screen with gloves on, he/she then went to the patient and disconnected the bloodlines, then returned to touching the dialysis machine screen. RN 2 failed to remove the dirty gloves, perform hand hygiene, and failed to don clean gloves before touching the patient, or after touching the patient and returning to the dialysis machine.</p> <p>8. During an observation on 10/24/2023 at 12:05 PM, at station 8, Patient Care Technician (PCT) 5 performed cleaning and disinfection of the dialysis station. After PCT 5 emptied the prime waste receptacle, clean gloves were donned without performing hand hygiene.</p> <p>9. During an interview on 10/25/2023 at 3:25 PM, the Medical Director (MD) indicated facility should have protocols in place for hand hygiene and that policy and procedures should be reinforced and followed. 10. During an observation on 10/24/2023 at 8:00 AM, PCT 3 applied a glove to the right fingertips and pushed a button on the dialysis machine to silence the alarm at station 9. PCT 3 wadded up a glove and touched the dialysis machine to silence the alarm at station 12. PCT failed to properly apply gloves prior to touching the dialysis machine.</p> |               | <p>trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI 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.</p> <p>The QAPI Committee is responsible to provide oversight, review 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 QAPI monthly. 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. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> |                      |

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| V 0114<br>Bldg. 00 | <p>11. During an interview on 10/24/2023 at 3:50 PM, the Administrator stated hand hygiene should be performed before and after changing gloves.</p> <p>494.30(a)(1)(i)<br/>IC-SINKS AVAILABLE<br/>A sufficient number of sinks with warm water and soap should be available to facilitate hand washing.</p> <p>Based on observation, record review, and interview, the facility failed to ensure sinks were plumbed with hot water for 2 of 2 observation days and designated as clean/dirty sinks for 1 of 1 treatment room observation day. (Sink Stations 2,3,4)</p> <p>Findings include:</p> <p>1. A 02/07/20232 policy titled General Cleanliness and Infection Control Guidelines was provided by the Administrator on 10/24/2023 at 1:30 PM. The policy indicated, but was not limited to, "preventing the spread of infectious disease and maintaining a clean, safe, aesthetically pleasant environment for patients ... "</p> <p>2. During the flash tour on 10/23/2023 at 11:47 AM, four sinks at stations 3 &amp; 4 were not designated as clean or dirty sinks. One sink at station 3 did not have running water. Two sinks at station 2 were without hot water.</p> <p>3. During a treatment floor observation on 10/24/2023 at 11:00 AM, station 2's sinks were without hot water.</p> <p>4. During an interview on 10/23/2023 at 4:50 PM, the Administrator stated they would have a plumber to fix it. The Administrator was still determining why the sinks were not marked as</p> | V 0114        | <p>On 11/16/2023, the Director of Operations in conjunction with the Clinical Manager will meet with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policies:<br/>General Cleanliness<br/>Infection Control Hand Hygiene<br/>Equipment Installation, Operation, Maintenance Repair and Disposal Policy.</p> <p>Emphasis will be placed on:<br/>Appropriate designation and labeling of "clean and dirty" sinks in the treatment area<br/>Hand washing sinks should be dedicated for hand washing only and should remain clean. A sufficient number of sinks with soap and plumbed with both hot and cold water shall be available to facilitate hand washing.<br/>Ensuring proper functioning and maintenance of the sinks in the treatment area with hot, running water</p> <p>In addition to the education</p> | 12/01/2023           |

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|                    | clean or dirty.   |               | <p>provided:</p> <p>On 10/23/2023 the Administrative Secretary clearly designated and appropriately labeled the four sinks at stations 3 and 4 clean or dirty.</p> <p>On 10/23/2023, Southern Plumbing, a contracted service, repaired/plumbed the one sink at station 3 that did not have running water.</p> <p>On 10/23/2023, Southern Plumbing, a contracted service repaired/plumbed the 2 sinks at station 2 that were without hot water.</p> <p>To monitor sinks in the treatment area for clear designation with appropriate labeling as "clean" or "dirty", the Clinical Manager or designee will be responsible to visualize the labeling for each sink in the treatment area daily x 2 weeks. To ensure that all sinks in the treatment area are plumbed with hot, running water, beginning 11/10/2023, the Clinical Manager or designee will be responsible to physically turn the water on to test each sink in the treatment area daily x 2 weeks. Once compliance is achieved, the Governing Body will decrease frequency to weekly x 2 weeks. Once compliance is sustained, the facility will resume regularly scheduled preventative maintenance of the sinks based on the Total Maintenance System (TMS) Preventative Maintenance</p> |                      |

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|                    |   |               | <p>Calendar.</p> <p>Monitoring will be done through the Total Maintenance System and the monthly QAI Infection Control Audit Checklist.</p> <p>It is the expectation of the Governing Body that 100% compliance is achieved. If the audit findings fall below 100%, the Governing Body will reconvene to determine revision and implementation of the revised action plan. The Medical Director will review the results of audits each month at the QAPI Committee meeting. 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 QAPI 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.</p> <p>The QAPI Committee is responsible to provide oversight, review 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</p> |                      |

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| V 0122<br>Bldg. 00 | <p>494.30(a)(4)(ii)<br/>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, record review and interview the facility failed to follow infection control procedures when cleaning and disinfecting contaminated equipment for 2 of 2 patient assessments. (Patient #2, #12)</p> <p>Findings include:</p> <p>1. A policy dated 07/05/2022, titled "Access Assessment and Cannulation" was left on the desk on 10/25/2023 and retrieved at 8:00 AM. The policy indicated, but was not limited to, " ... Clean stethoscope after assessing a patient ...".</p> | V 0122        | <p>in QAPI monthly. 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. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic</p> <p>On 11/16/2023, the Director of Operations in conjunction with the Clinical Manager will meet with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policy:</p> <p>Cleaning and Disinfecting the Dialysis Station<br/>Access Assessment and Cannulation</p> <p>Emphasis will be placed on:</p> | 12/01/2023           |

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|                    | <p>2. A policy dated 09/05/2022, titled "Cleaning and Disinfecting the Dialysis Station" was provided on 10/24/2023 at 1:15 PM, by Administrator. The policy indicated, but was not limited to, " ... If equipment is brought into the patient station or becomes contaminated follow cleaning and disinfection procedures ...".</p> <p>3. During an observation of an assessment of patient #24 on 10/21/2023 at 07:45 AM, the License Practical Nurse (LPN)1 did not clean/disinfect the stethoscope, pre- or post-use of assessing the patient's arteriovenous (AV) fistula (an irregular connection between an artery and a vein).</p> <p>4. During an observation on 10/24/2023 at 7:50 AM, PCT 3 assessed Patient #12's arteriovenous (AV) site with a stethoscope. PCT 3 then placed the stethoscope around their neck. PCT 3 failed to disinfect the stethoscope diaphragm/bell end pre and post-use of assessing an AV site.</p> <p>5. During an interview on 10/24/2023 at 3:55 PM, the Administrator indicated staff should clean stethoscopes between use and before placing them back in the common area.</p> |               | <p>After use, any non-disposable equipment and supplies brought into the dialysis station (ex. Stethoscope) must be disinfected with 1:100 bleach or EPA registered disinfectant before being removed from the dialysis station.</p> <p>To monitor staff cleaning and disinfection of the stethoscope, beginning 11/10/2023, the Clinic Manager or designee will conduct observational infection control audits daily x 2 weeks. Once compliance is achieved, the Governing Body will decrease frequency to weekly x 2 weeks. Once compliance is sustained, the facility will resume regularly scheduled monthly infection control audits based on the QAPI calendar.</p> <p>Monitoring will be done through the QAPI Checklist Audit Tool.</p> <p>It is the expectation of the Governing Body that 100% compliance is achieved. The Governing Body determined that the facility threshold be 95%. If the infection control audit findings for cleaning and disinfection of the stethoscope falls below 95%, the Governing Body will reconvene to determine revision and implementation of the revised action plan. The Medical Director will review the results of audits</p> |                      |

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| V 0143<br>Bldg. 00 | 494.30(b)(2)<br>IC-ASEPTIC TECHNIQUES FOR IV MEDS<br>[The facility must-]   |               | <p>each month at the QAPI Committee meeting. 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 QAPI 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.</p> <p>The QAPI Committee is responsible to provide oversight, review 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 QAPI monthly. 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. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> |                      |

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|                    | <p>(2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and</p> <p>Based on observation, record review, and interview, the facility staff failed to ensure facility policy was followed regarding medication preparation for 1 of 2 medication observations. (LPN 1, RN 2)</p> <p>Findings include:</p> <p>1. A 02/06/2023 policy titled Medication Preparation and Administration was provided by the Administrator on 10/23/2023 at 2:50 PM. The policy indicated, but was not limited to, " ... The person who prepares the medication must be the person who will administer the medication. ..."</p> <p>2. During a medication observation on 10/24/2023 at 7:12 AM, Licensed Practical Nurse 1 (LPN) administered Hecoral (vitamin D medication) 8 micrograms intravenous (IV) to Patient #6. Registered Nurse 2 (RN) drew up Micera (medicine for low red blood count) 50 milligrams and then handed LPN 1 the syringe to give to Patient #6 while at chairside. Both nurses failed to follow facility policy regarding medication administration.</p> <p>3. During an interview on 10/24/2023 at 3:50 PM, the Administrator stated the nurse who draws the medication up into a syringe should be the one to administer to the patient.</p> | V 0143        | <p>Please Note: Mircera is a single-use, pre-filled and pre-packaged syringe. Registered Nurse (2) did not "draw up" the medication and hand it to the LPN for administration during the survey process.</p> <p>On 11/16/2023, the Director of Operations in conjunction with the Clinical Manager will meet with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policy:</p> <p>Medication Preparation and Administration</p> <p>Emphasis will be placed on:<br/>Ensuring the person who prepares the medication is the person that will administer the medication.</p> <p>To monitor staff compliance with medication preparation and administration, beginning 11/10/2023, the Clinic Manager or designee will conduct medication preparation and administration audits daily x 2 weeks. Once compliance is achieved, the Governing Body will decrease frequency to weekly x 2 weeks.</p> | 12/01/2023           |

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|                    |   |               | <p>Once compliance is sustained, the facility will resume regularly scheduled monthly infection control audits based on the QAPI calendar.</p> <p>Monitoring will be done through the QAPI Checklist Audit Tool.</p> <p>It is the expectation of the Governing Body that 100% compliance is achieved. If the Medication Preparation and Administration audit findings fall below 100%, the Governing Body will reconvene to determine revision and implementation of the revised action plan.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting. 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 QAPI 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.</p> <p>The QAPI Committee is responsible to provide oversight, review findings, and take actions</p> |                      |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:<br><br>152504 | X2) MULTIPLE CONSTRUCTION<br>A. BUILDING 00<br>B. WING _____ | X3) DATE SURVEY COMPLETED<br><br>10/26/2023 |
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| NAME OF PROVIDER OR SUPPLIER<br><br>FRESENIUS MEDICAL CARE SOUTHERN INDIANA | STREET ADDRESS, CITY, STATE, ZIP COD<br>810 EASTERN BOULEVARD<br>CLARKSVILLE, IN 47129 |
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| V 0403<br>Bldg. 00 | <p>494.60(b)<br/>PE-EQUIPMENT<br/>MAINTENANCE-MANUFACTURER'S DFU<br/>The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.<br/>Based on observation, record review, and interview, the facility failed to ensure all acid line equipment was maintained for 1 of 1 water room observations and failed to ensure water outlets were free from crystallization prior to dialysis machine hook-up for 1 of 3 wall box station observations. (Station 14)</p> <p>Findings include:</p> <p>1. A 02/07/2023 policy titled General Cleanliness and Infection Control Guidelines was provided by the Administrator on 10/24/2023 at 1:30 PM. The</p> | V 0403        | <p>as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. 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. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>On 11/16/2023, the Director of Operations in conjunction with the Clinical Manager will meet with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policy:</p> <p>General Cleanliness and Infection Control</p> <p>Emphasis will be placed on:</p> | 12/01/2023           |

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|                    | <p>policy indicated, but was not limited to, "preventing the spread of infectious disease and maintaining a clean, safe, aesthetically pleasant environment for patients, staff, and visitors. ... Policy · All areas must be kept clean and organized, including but not limited to the treatment area, water/supply room ... Facility staff are accountable for cleaning and rooms/areas not assigned to contracted cleaning staff. ... Detergents Germicides and Cleaning Supplies ... Solutions will be stored and labeled per policy."</p> <p>2. During the water treatment room observation along with Patient Care Technician 5 (PCT) on 10/23/2023 at 11:30 AM, an open bag of salt was found directly on the floor. During an observation along with Bio Med 1 on 10/24/2023 at 10:00 AM, the same opened salt bag was found directly on the floor. At that time, Bio Med 1 stated the bag probably busted open and should have been thrown away.</p> <p>3. During a treatment floor observation on 10/23/2023 at 11:47 AM, a large amount of white crystallization buildup was found on the acid line in the wall box chasic located between stations 14 and 15. White crystallization was found on the floor behind the treatment chair at station 14.</p> <p>4. During a water room observation along with Bio Med 1 personnel on 10/25/2023 at 1:20 PM, standing water was found in the corner of the room, and a large piece of white crystallization was found underneath the acid mixer tank. Bio Med 1 stated the water was not cleaned up as a result of maintenance and was unsure why the crystallization buildup was not cleaned up.</p> |               | <p>Ensuring staff maintain all areas including, but not limited to the treatment area and the water treatment room clean, safe and aesthetically pleasant for patients, staff and visitors.</p> <p>Ensuring supplies are not maintained directly on the floor.</p> <p>In addition to the education provided:</p> <p>On 10/24/2023, the Bio-Medical Technician removed and discarded the open bag of salt that was found directly on the floor in the water treatment room.</p> <p>On 10/23/2023, the Bio-Medical Technician cleaned and removed the large amount of white, crystallized buildup found on the acid line in the wall box chassic located between stations 14 and 15 in the treatment area.</p> <p>On 10/23/2023, a Patient Care Technician cleaned and removed the white crystallization found on the floor behind the treatment chair at station 14 in the treatment area.</p> <p>On 10/25/2023, the Patient Care Technician/Ward Clerk mopped and cleaned the standing water found in the corner of the room and cleaned the white crystallization found underneath</p> |                      |

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|                          |   |                     | <p>the acid mixer tank in the water treatment room.</p> <p>To monitor staff compliance with ensuring a clean, organized, safe and aesthetically pleasant environment for patients, staff and visitors, beginning 11/10/2023, the Clinic Manager or designee will conduct a physical environment observational walk through audit of the treatment area and the water treatment room daily x 2 weeks. Once compliance is achieved the Governing Body will decrease audit frequency to weekly x 2 weeks. Once compliance is sustained, the facility will resume regularly scheduled monthly interior and exterior physical plant audits based on the QAPI calendar.</p> <p>Monitoring will be done through the QAPI Checklist Audit Tool.</p> <p>It is the expectation of the Governing Body that 100% compliance is achieved. If the physical plant audit findings fall below 100%, the Governing Body will reconvene to determine revision and implementation of the revised action plan. The Medical Director will review the results of audits each month at the QAPI Committee meeting. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to</p> |                            |

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| V 0543<br><br>Bldg. 00 | 494.90(a)(1)<br>POC-MANAGE VOLUME STATUS<br>The plan of care must address, but not be limited to, the following:<br>(1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; |               | <p>this Plan of Correction prior to presenting to the QAPI 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.</p> <p>The QAPI Committee is responsible to provide oversight, review 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 QAPI monthly. 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. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> |                      |

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|                    | <p>Based on record review and interview the facility failed to monitor, report, and treat elevated blood pressures for 2 of 5 records reviewed (Patient #3, #9), failed to maintain a ultrafiltration rate (UFR) of less than 13 mL/kg/hour for 1 of 5 records reviewed (Patient #9), and failed to consistently meet estimated dry weights (EDW) for 1 of 5 records reviewed(Patient #3).</p> <p>Findings include:</p> <p>1. A 05/01/23 policy titled "Patient Assessment and Monitoring" was provided on 10/24/23 at 1:15 PM, by the Administrator. The policy indicated, but was not limited to, " ... Data Collection ... The RN will notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instructions ... Pre - Treatment ... Record blood pressure. Verify: Systolic blood pressures greater than 180 mm/HG and/or diastolic blood pressure greater than 100 mm/Hg ... 3. Document findings and interventions in medical record. Contact the physician as needed for additional orders ... During Treatment ... Report to the nurse: Systolic blood pressure greater than 180 mm/Hg Diastolic blood pressure greater than 100 mm/Hg ... Monitor UF rate. Note: Ultrafiltration rates greater than 13 ml/kg/hr. should be avoided if possible ... Machine parameters and Extracorporeal Circuit ... Check prescribed blood flow is being achieved or reason is documented in medical record if unable to meet prescribed blood flow ... Weight Obtain the patients post weight. Ensure the post weight is consistent with the goal set of machine ...".</p> <p>2. A 05/01/23 policy titled "Nursing Supervision and Delegation" was provided on 10/24/23 at 2:00 PM, by the Administrator. The policy indicated,</p> | V 0543        | <p>On 11/16/2023, the Director of Operations in conjunction with the Incenter Clinical Manager will meet with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policies:</p> <p>Patient Assessment and Monitoring<br/>Nursing Supervision and Delegation</p> <p>Emphasis will be placed on:<br/>Ensuring all staff including Patient Care Technician, Licensed Practical Nurse /Licensed Vocational Nurse, and Registered Nurse appropriately notifies the Charge Nurse/Team Leader or Clinical Manager of:</p> <p>Blood Pressure: (Patient #9)<br/>Systolic blood pressures greater than 180 mm/Hg · Diastolic blood pressure greater than 100 mm/Hg · Blood Pressure less than or equal to 100 mm/hg systolic pre, during or post treatment.</p> <p>Ultrafiltration Rate: (Patient #9)<br/>Ultrafiltration rates greater than 13 ml/kg/hr should be avoided if possible, by providing adequate prescribed dialysis duration, and scheduling of additional treatments if medically necessary.</p> | 12/01/2023           |

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|                    | <p>but was not limited to, " ... Prior to discharge, the RN must review the treatment records to: Confirm patient is stable for discharge ... The record must be reviewed for: ... Blood pressures ... greater than 180 diastolic address by registered nurse with or documentation present ... guideline to identify when a PCT/LPN/LVN or RN shall refer a patient to a Team Leader/ Charge Nurse for further assessment pre, during or post treatment ... Blood Pressure A systolic blood pressure greater than 180 mm/hg and /or diastolic blood pressure greater than 100 mm/Hg at any time before, during or after treatment ...</p> <p>3. A 09/05/23 policy titled "Cleaning and Disinfecting the Dialysis Station" was provided on 10/24/23 at 1:15 PM, by Administrator. The policy indicated, but was not limited to, " ... All dialysis patient must be clinically stabilized (i.e. stable blood pressure, ...) following their dialysis treatments before being moved from dialysis station ...)</p> <p>4. A document dated 07/12/22, titled "Job title: PCT II" was provided on 10/26/23 at 8:00 AM, by the administrator. The policy indicated, but was not limited to, " ... Report any significant information and/or change in patient condition directly to the registered nurse or supervisor ...".</p> <p>5. The clinical record for Patient #3 was reviewed on 10/25/2023 and evidenced the following:</p> <p>A transfer sheet for Patient #3 indicating an estimated dry weight (EDW) of 71.5 kg.</p> <p>A treatment record dated 10/01/2023 indicating a post-treatment EDW of 76.0 kg.</p> <p>A treatment record dated 10/02/2023 indicating a</p> |               | <p>The Charge Nurse/Team Leader or Clinical Manager is responsible to notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instruction. The Charge Nurse/ Team Leader is responsible to assess/re-assess any findings addressed pre, during, or post treatment as needed.</p> <p>The Clinical Manager is scheduled to meet with (Patient #9) physician on 11/13/2023 to review: Average intra-treatment blood pressure elevations. Any orders received from the physician to assist in the management of the patient's hypertension will be appropriately documented in the electronic health record.</p> <p>Ultrafiltration rates greater than 13ml/kg/hour. The physician determined and provided a standing order, effective immediately patients at the facility will not be dialyzed with a UFR greater than 13ml/kg/hour without specific physician order to include documented medical justification. Patient(s) requiring a UFR greater than 13ml/kg/hour will be immediately escalated to the Charge Nurse/Team Leader or Clinical Manager who will be responsible to schedule the patient(s) to receive additional</p> |                      |

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|                    | <p>post-treatment EDW of 76.0 kg.</p> <p>A treatment record dated 10/05/2023 indicating a post-treatment EDW of 75.0 kg.</p> <p>A treatment record dated 10/06/2023 indicating a post-treatment EDW of 76.1 kg.</p> <p>A treatment record dated 10/10/2023 indicating a post-treatment EDW of 76.8 kg.</p> <p>A treatment record dated 10/12/2023 indicating a post-treatment BP of 200/79 mm/hg and post-treatment EDW of 76.1 kg.</p> <p>A treatment record dated 10/06/2023 indicating a post-treatment EDW of 75.8 kg.</p> <p>A treatment record dated 10/16/2023 indicating a post-treatment BP of 194/81.</p> <p>A treatment record dated 10/19/2023 indicating a post-treatment BP of 184/74 and a post-treatment EDW of 76.0 kg.</p> <p>A treatment record dated 10/21/2023 indicating a post-treatment BP of 150/102.</p> <p>A 10/17/2023 Clinical Notes Report indicating an interdisciplinary team meeting with the MD, RN, Patient #3's family member, and Patient #3. The clinical note failed to indicate the interdisciplinary team addressed the consecutive failure of the patient to meet EDW and failed to address BP readings consistently outside of normal parameters.</p> <p>6. The clinical record for Patient #9 was reviewed on 10/23/2023 and evidenced the following:</p> |               | <p>dialysis treatments to ensure adequate fluid removal.</p> <p>Home Therapies: On 11/10/2023 the Home Training Clinical Manager will meet with facility Home Therapies staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the Home Therapy staff on the following FKC Policies:</p> <p>Patient Assessment and Monitoring<br/>Nursing Supervision and Delegation</p> <p>Emphasis will be placed on:</p> <p>Ensuring Home Therapy staff appropriately notifies the Charge Nurse or Home Therapy Clinical Manager of:</p> <p>Fluid Status: (Patient #3) Any weight gains greater than 4 kg pre-treatment. Any swelling in the facial area, and lower extremity edema. Any post treatment weight with a variance from the estimated dry weight (EDW) of 0.5 kg. Any weight loss or no change in weight from a patient's last treatment post weight.</p> <p>Blood Pressure: (Patient # 3) Systolic blood pressures greater than 180 mm/Hg · Diastolic blood pressure greater than 100 mm/Hg</p> |                      |

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|                    | <p>A treatment record dated 09/30/2023 indicating intra-treatment blood pressures of 152/106, 144/113, and 148/103.</p> <p>A treatment record dated 10/03/2023 indicating intra-treatment blood pressures of 162/105, 160/107, 159/102, and a UFR of 25.7.</p> <p>A treatment record dated 10/05/2023 indicating intra-treatment blood pressures of 156/106, 176/105, 178/113, 185/113, 172/119, a post-treatment BP of 174/105, and a UFR of 18.0.</p> <p>A treatment record dated 10/07/2023 indicating intra-treatment blood pressures of 162/112, 171/105, 164/107, 185/109, 176/120, 172/125, and a UFR of 18.7.</p> <p>A treatment record dated 10/10/2023 indicating intra-treatment blood pressures of 174/121, 180/1558, 180/100, 188/90, 190/130, and a UFR of 18.3.</p> <p>A treatment record dated 10/12/2023 indicating intra-treatment blood pressures of 188/84, 173/117, 182/116, 171/118, 163/109, 171/120, and a UFR of 21.7.</p> <p>7. During an interview on 10/24/2023 at 2:10 PM, the Clinical Manager indicated blood pressures with a diastolic over 180 or a systolic over 100, should be evaluated by a nurse, the physician should be notified if a PRN (as needed medication) is not available to be given. The Clinical manager was unable to locate special orders for the patient to continue dialysis with high blood pressure, nor was he/she able to locate orders for PRN medication to manage hypertension for patient #9. The Clinical manager indicated she would not have let the patient leave</p> |               | <p>· Blood Pressure less than or equal to 100 mm/hg systolic pre, during or post treatment.</p> <p>The Charge Nurse/Team Leader or Clinical Manager is responsible to notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instruction. The Charge Nurse/ Team Leader is responsible to assess/re-assess any findings addressed pre, during, or post treatment as needed.</p> <p>The Home Therapy Clinical Manager is scheduled to meet with (Patient #3) physician on 11/14/2023 to review:</p> <p>Average post weight variances from the prescribed EDW over a 1-month period. Prescribed changes in the patients prescribed EDW ordered by the physician will be appropriately documented in the electronic health record.</p> <p>Average post treatment blood pressure elevations (Patient #3). Any orders received from the physician to assist in the management of the patient's hypertension will be appropriately documented in the electronic health record.</p> <p>To monitor Incenter and Home</p> |                      |

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|                    | <p>with a post-dialysis blood pressure above the given parameters without notifying the physician and requesting a PRN medication.</p> <p>8. During an interview on 10/25/2023 at 2:00 PM, the Clinical Manager indicated the primary physician should be notified when patients are not meeting EDW. The Clinical Manager also confirmed patient # 9's UFR was greater than 13 mL/kg/ hour.</p> <p>9. During an interview on 10/25/2023 at 11:10 AM, the Home Therapy Clinical Manager indicated no documentation found in patient #3's records addressing EDW or elevated blood pressure during the monthly meeting on 10/17/23.</p> <p>10. During an interview on 10/24/2023 at 12:05 PM, the Patient Care Technician (PCT) 5 indicated nurses should make a note if blood pressures are outside of ranges set by the facility and the doctor would be notified.</p> <p>11. During an interview on 10/25/2023 at 3:25 PM, the Medical Director (MD) indicated the primary physician of a patient with a blood pressure over 180 systolic should be notified. He/She also indicated if EDW is not met during treatment, a reason should be documented, and the primary physician should be notified.</p> |               | <p>Therapy staff compliance with appropriate Charge Nurse/Team Leader, Clinical Manager notifications of abnormal patient findings including, but not limited to hyper/hypotension pre, during or post treatment, patients requiring additional fluid removal in order to maintain ultrafiltration goals at or less than 13ml/kg/hour, and post weight variances greater than 0.5kg, and to monitor appropriate escalation of abnormal patient findings to the physician by the Registered Nurse, as applicable, beginning 11/10/2023, the Incenter Clinical Manager and the Home Therapy Clinical Manager or designated Registered Nurse will review 10% treatment sheet documentation daily x 2 weeks.</p> <p>Once compliance is achieved, the Governing Body will decrease the treatment sheet audit frequency to weekly x 2 weeks. Once compliance is sustained, the facility will resume regularly scheduled monthly medical record audits based on the QAPI calendar.</p> <p>Monitoring will be done through the Medical Record QAI Checklist Audit Tool. It is the expectation of the Governing Body that 100% compliance is achieved. If the treatment sheet audit findings fall below 100%, the Governing Body</p> |                      |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:<br><br>152504 | X2) MULTIPLE CONSTRUCTION<br>A. BUILDING 00<br>B. WING _____ | X3) DATE SURVEY COMPLETED<br><br>10/26/2023 |
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| NAME OF PROVIDER OR SUPPLIER<br><br>FRESENIUS MEDICAL CARE SOUTHERN INDIANA | STREET ADDRESS, CITY, STATE, ZIP COD<br>810 EASTERN BOULEVARD<br>CLARKSVILLE, IN 47129 |
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|                    |   |               | <p>will reconvene to determine revision and implementation of the revised action plan. The Medical Director will review the results of audits each month at the QAPI Committee meeting. The Incenter Clinical Manager and the Home Therapy Clinical Manager are responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI 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.</p> <p>The QAPI Committee is responsible to provide oversight, review 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 QAPI monthly. 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. The QAPI and Governing Body minutes, education and monitoring documentation, are available for</p> |                      |

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| V 0544<br>Bldg. 00 | <p>494.90(a)(1)<br/>POC-ACHIEVE ADEQUATE CLEARANCE<br/>Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. Based on observation, record review, and interview, the facility failed to ensure blood flow rates (BFRs) were maintained per orders throughout dialysis treatments for 3 of 5 record reviews (Patients #2,#3,#9); the facility failed to ensure licensed nurse and/or physician was notified of bloodlines being reversed on 3 of 5 patients (#2,#9,#10).</p> <p>Finding include:</p> <p>1. A policy dated 11/01/21 titled "Unable to Achieve Prescribed Blood Flow Rate" was provided on 10/25/23 at 4:07 PM by the Administrator. The policy indicated, but was not limited to, " Staff, patient, and/or care partner will recognize and report to the nurse in charge the inability to achieve prescribed blood flow rate ... Notification Notify physician/extender if unable to achieve prescribed blood flow rate ...".</p> <p>2. A 05/01/2023 policy titled "Patient Assessment and Monitoring" was provided on 10/24/2023 at 1:15 PM by the Administrator. The policy indicated, but was not limited to, "If the PCT/LPN note any changes or abnormal findings in the patient's condition or vascular assess ... the registered nurse must assess the patient. The RN will notify the patient's physician/physician extender of any abnormal findings ... 3. Document</p> | V 0544 | <p>review at the clinic.</p> <p>On 11/16/2023, the Director of Operations in conjunction with the Clinical Manager will meet with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policy:</p> <p>Patient Assessment and Monitoring (Machine Parameters and Extracorporeal Circuit) Unable To Achieve Prescribed Blood Flow Rate</p> <p>Emphasis will be placed on:</p> <p>Staff responsibility to monitor that the prescribed blood flow is being achieved during the dialysis treatment every 30 minutes, not to exceed 45 minutes.</p> <p>If the patient is unable to meet the prescribed Blood Flow Rate, staff will appropriately document the reason in the electronic health record. Staff responsibility to report abnormal findings in the patients vascular access and</p> | 12/01/2023 |
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|                    | <p>findings and interventions in the medical record."</p> <p>3. A document dated 07/12/22, titled "Job title: PCT II" was provided on 10/26/23 at 8:00 AM, by the Administrator. The policy indicated, but was not limited to, " ... Report any significant information and/or change in patient condition directly to the registered nurse or supervisor ...".</p> <p>4. During an observation on 10/24/2023 at 7:35 AM, Personal Care Technician (PCT) 4 was accessing Patient #10's central venous line ports when they asked Patient #10 if they were to run the lines in reverse. Patient #10 stated they were not sure.</p> <p>5. A review of Patient #10's treatment sheets dated 10/06/2023 and 09/27/2023 evidenced that reversed lines were initiated by PCT 2 without Registered Nurse (RN) notification. There was no documentation in Patient #10's plan of care (POC) or physician orders indicating reverse line use. 6. The clinical record for Patient #2 was reviewed on 10/24/2023 and evidenced the following:</p> <p>Treatment records dated 10/02, 10/09, 10/13, 10/16, and 10/18 of 2023 that indicated a prescribed blood flow rate (BFR) of 450 mL/min but a treatment BFR of 400 mL/min.</p> <p>A treatment record dated 10/04/2023 that indicated a prescribed BFR of 450 mL/min but a treatment BFR of 400 mL/min. The treatment record subsequently indicated the arterial and venous lines were reversed for treatment.</p> <p>A treatment record dated 10/11/2023 with a prescribed BFR of 450 mL/min but a treatment BFR of 300 mL/min.</p> |               | <p>inability to achieve prescribed Blood Flow Rate to the Charge Nurse/Team Leader or Clinical Manager. The Registered Nurse, Charge Nurse/Team Leader or Clinical Manager's responsibility to notify the physician/extender if the patient is unable to achieve the prescribed blood flow rate.</p> <p>To monitor staff compliance beginning 11/10/2023, the Clinic Manager or designee will review 10% Treatment sheets daily x 2 weeks.</p> <p>Once compliance is achieved, the Governing Body will decrease frequency to weekly x 2 weeks. Once compliance is sustained, the facility will resume regularly scheduled monthly medical record audits based on the QAPI calendar.</p> <p>Monitoring will be done through the Medical Record Checklist Audit Tool.</p> <p>It is the expectation of the Governing Body that 100% compliance is achieved. The Governing Body determined that the facility threshold be 95%. If the treatment sheet audit findings fall below 95%, the Governing Body will reconvene to determine revision and implementation of the revised action plan.</p> |                      |

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|                    | <p>The record failed to evidence the physician was notified of the inability to treat with prescribed BFR or notified of the need to reverse the lines.</p> <p>7. The clinical record for Patient #3 was reviewed on 10/25/2023 and evidenced the following:</p> <p>Treatment sheets dated 10/01/2023 and 10/09/2023 with a prescribed BFR of 450 mL/min but a treatment BFR of 350 mL/min.</p> <p>Treatment sheets dated 10/02/2023 and 10/05/2023 with a prescribed BFR of 450 mL/min but a treatment BFR of 400 mL/min.</p> <p>The record failed to evidence the physician had been notified of the inability to achieve the prescribed BFR.</p> <p>8. The clinical record for Patient #9 was reviewed on 10/23/2023 and evidenced the following:</p> <p>Treatment sheets dated 9/30/2023, 10/03/2023, and 10/05/2023 indicating the arterial and venous lines were reversed.</p> <p>The record failed to evidence the physician had been notified of the need to reverse the central lines.</p> <p>9. During an interview on 10/25/2023 at 3:20 PM, the Medical Director stated the expectation was for PCTs to notify the nurse when lines are reversed and for staff to follow facility policies. On 10/26/2023 at 10:35 AM, PCT 4 stated the nurse was to be notified when reversing lines and documented on the treatment sheet. At 10:40 AM, RN 1 stated the PCT should report and document RN notification on line reversal on the treatment sheet.</p> |               | <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting. 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 QAPI 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.</p> <p>The QAPI Committee is responsible to provide oversight, review 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 QAPI monthly. 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. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> |                      |

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

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