

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

PRINTED: 12/12/2023
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 11/14/2023	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
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E 0000 Bldg. 00	<p>An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62, for a Medicare participating End Stage Renal Disease Supplier.</p> <p>Dates of Survey: 11-13, and 11-14-2023</p> <p>Complaint: IN00421086 with related and unrelated Federal deficiencies cited. Complaint: IN00420131 with related and unrelated Federal deficiencies cited.</p> <p>Facility #: 010516</p> <p>CCN: 152556</p> <p>Stations: 12, with no isolation rooms.</p> <p>Census by Service Type:</p> <p>In Center Hemodialysis Patients: 48 Home Hemodialysis Patients: 4 Home Peritoneal Dialysis Patients: 25 Total Census: 77</p> <p>At this Emergency Preparedness survey, Fresenius Medical Care Noblesville was found not in compliance with Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers, 42 CFR 494.62.</p> <p>QR by Area 3 on 11/27/2023.</p>			E 0000			
E 0018 Bldg. 00	<p>403.748(b)(2), 416.54(b)(1), 418.113(b)(6)(ii) and (v), 441.184(b)(2), 482.15(b)(2), 483.475(b)(2), 483.73(b)(2), 485.625(b)(2), 485.920(b)(1), 486.360(b)(1), 494.62(b)(1)</p>						

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 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>Procedures for Tracking of Staff and Patients §403.748(b)(2), §416.54(b)(1), §418.113(b)(6) (ii) and (v), §441.184(b)(2), §460.84(b)(2), §482.15(b)(2), §483.73(b)(2), §483.475(b)(2), §485.625(b)(2), §485.920(b)(1), §486.360(b)(1), §494.62(b)(1).</p> <p>[(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 minimum, the policies and procedures must address the following:]</p> <p>[(2) or (1)] A system to track the location of on-duty staff and sheltered patients in the [facility's] care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the [facility] must document the specific name and location of the receiving facility or other location.</p> <p>*[For PRTFs at §441.184(b), LTC at §483.73(b), ICF/IIDs at §483.475(b), PACE at §460.84(b):] Policies and procedures. (2) A system to track the location of on-duty staff and sheltered residents in the [PRTF's, LTC, ICF/IID or PACE] care during and after an emergency. If on-duty staff and sheltered residents are relocated during the emergency, the [PRTF's, LTC, ICF/IID or PACE] must document the specific name and location of the receiving facility or other</p>						

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	<p>location.</p> <p>*[For Inpatient Hospice at §418.113(b)(6):] Policies and procedures. (ii) Safe evacuation from the hospice, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s) and primary and alternate means of communication with external sources of assistance. (v) A system to track the location of hospice employees' on-duty and sheltered patients in the hospice's care during an emergency. If the on-duty employees or sheltered patients are relocated during the emergency, the hospice must document the specific name and location of the receiving facility or other location.</p> <p>*[For CMHCs at §485.920(b):] Policies and procedures. (2) Safe evacuation from the CMHC, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.</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>*[For ESRD at § 494.62(b):] Policies and procedures. (2) Safe evacuation from the dialysis facility, which includes staff</p>						

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	<p>responsibilities, and needs of the patients. Based on record review and interview the facility failed to ensure the Emergency totes contained updated patient and staff emergency contact information, and the patient's dialysis orders for all active patients receiving treatments in-center and home dialysis per the facility policy in 2 of 2 Emergency totes observed.</p> <p>Findings Include:</p> <p>1. On 11-14-2023 at 1:30 PM, a dated 07-03-2023, Fresenius Kidney Care policy titled, "Guidelines for Emergency Preparedness" was provided by the Director of Operations (DO). The policy indicated but was not limited to, "... Create and maintain staff, patient and facility emergency information contact lists ..."</p> <p>2. During a flash tour observation on 11-13-2023 at 10:40 AM, the Emergency cart was reviewed. The Emergency cart contained in the top drawer the patient's demographics and dialysis treatment orders which were last updated on 07-08-2023 and did not include the current patients or employees.</p> <p>3. During a flash tour on 11-13-2023 at 10:50 AM, the Emergency box behind the nurse's station was reviewed. The Emergency box failed to evidence an emergency patient contact list, employee emergency contact list, and the patients' dialysis treatment orders.</p> <p>During an interview on 11-13-2023 at 10:50 AM, the Patient Care Technician (PCT) 2, confirmed the in-center patient contact information dated 07-08-2023, did not contain all the current patient's information. PCT 2 further indicated the emergency Code Cart had not been checked off for the month of October 2023.</p>		E 0018	<p>On 12/06/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p> <p>Guidelines for Emergency Preparedness Emphasis was placed on: The facility must develop a communication plan for all patients (in-center and home). This plan includes the following: Create and maintain staff, patient and facility emergency information contact lists: Quarterly, the Director of Operations/Area Manager or designee will review and update: The FKC Facility Emergency Information Directory Quarterly, the CM will review and update The Emergency and Disaster Staff Contact Information Sheet The Emergency and Disaster Patient Contact Information Sheet A current copy of the emergency lists must: Be kept locked in the emergency supply boxes, or cart Effective 12/07/2023, the Clinical Manager will conduct monthly audits utilizing the Emergency Box Contents for Incenter and Emergency Box for Home Audit Tools for 4 weeks or until 100% compliance is achieved. Monitoring for continued compliance will be done monthly</p>		12/14/2023	

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	<p>4. On 11-13-2023 at 12:35 PM, during an observation of the Home Emergency box was reviewed. The Emergency box contained the patient's demographics and dialysis treatment orders which were last updated on 9-27-2023 and did not include the current patients or employees.</p> <p>5. On 11-13-2023 at 12:45 PM, reviewed an agency document titled, "Emergency Box Contents Log Home Therapy (HHD and PD) -Monthly." The document indicated the Emergency box was audited on 11-10-2023 at 3:30 PM.</p> <p>During an interview on 11-13-2023 at 1:00 PM, The Registered Nurse (RN) 2, confirmed the patient list was not accurate. RN 2 indicated they were to check the Emergency box monthly to ensure the patient information was updated and accurate.</p> <p>6. During an interview on 11-14-2023 at 3:30 PM, the DO, confirmed the In-center, Home dialysis patient, and employee contact list and information was to be in the Emergency boxes for In-center and the Home Program. The DO further confirmed the patient and staff information was to be updated monthly.</p>				<p>utilizing the Emergency Box Contents for Incenter and Emergency Box for Home Audit Tools for 4 weeks or until 100% compliance is achieved. The results from the audits will be reviewed each month in QAI with any non-compliance noted in the meeting minutes.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is</p>		

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E 0028 Bldg. 00	<p>494.62(b)(9) Dialysis Emergency Equipment §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 observation, record review, and interview, the facility failed to ensure emergency medications and supplies were checked for expiration dates and failed to complete their monthly itemized log per the facility policy for 2 of 2 Emergency Carts observed.</p> <p>Findings include:</p>	E 0028	<p>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 12/14/2023.</p> <p>On 12/06/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: Emergency Medications, Equipment and Supplies Emphasis was placed on: The emergency cart must</p>	12/14/2023	

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	<p>1. On 11-14-2023 at 1:30 PM, a dated 07-06-2020, Fresenius Kidney Care policy titled, "Emergency Medication, Equipment, and Supplies" was provided by the Director of Operations (DO). The policy indicated but was not limited to, "Emergency Cart ... The emergency cart must be: ... Checked monthly or after use for contents, expiration dates ... 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>2. During the flash tour observation on 11-13-2023 at 10:40 AM, the in-center Emergency Cart contents were reviewed. The emergency Cart contained 2 boxes of Atropine Sulfate (used to treat cardiac arrest) 1 milligram (mg)/10 milliliters (ml) (0.1 mg/ml) 10 ml single dose injections with an expiration date of August 2023, 4 vials of Adrenalin (a medication used for emergency treatment of a severe reaction) 1 mg/ml with an expiration date of September 2023, 1 Intravenous (IV) therapy administration line kit (used for controlled infusion of medications to the needle) with an expiration date of 10-18-2023, and 2 Yankauer suction sets (a rigid catheter designed for emergency airway management) with an expiration date of 10-03-2023.</p> <p>During an interview on 11-13-2023 at 10:45 Am, the Patient Care Technician (PCT) 2, confirmed the medication and supplies were expired, and the Registered Nurse (RN) was to order those. The PCT further indicated the Emergency Cart was to be checked monthly for expired supplies and medications.</p> <p>3. On 11-13-2023 at 12:45 PM, the Emergency Cart of the Home program was reviewed. The</p>				<p>be:</p> <p>Checked monthly or after use for contents, expiration dates, cleanliness, and proper functioning of all equipment.</p> <p>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>Effective 12/07/2023, the Clinical Manager will conduct monthly audits utilizing the Emergency Code Cart, Medications, and Machine Hand Crank Checklist for 4 weeks or until 100% compliance is achieved. Monitoring for continued compliance will be done monthly utilizing the Emergency Code Cart, Medications, and Machine Hand Crank Checklist. The results from the audits will be reviewed each month in QAI with any non-compliance noted in the meeting minutes.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the</p>		

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V 0000 Bldg. 00	<p>Emergency Cart contained 1 Yankauer suction sets (a rigid catheter designed for emergency airway management) with an expiration date of 10-03-2023.</p> <p>4. On 11-13-2023 at 12:45 PM, reviewed an agency document titled, "Emergency Code Cart and Medications Checklist Monthly." The document indicated the Emergency Cart was audited on 11-10-2023 at 3:03 PM and the section titled, "Verify Yankauer is present" was marked yes.</p> <p>During an interview on 11-13-2023 at 1:00 PM, The Registered Nurse (RN) 2, confirmed they were to check the Emergency Cart monthly to ensure supplies and medications had not expired.</p> <p>5. During an interview on 11-13-2023 at 4:15 PM, the Director of Operations (DO), confirmed that the Emergency Cart was to be checked monthly for expired medications and supplies.</p> <p>This visit was for a Federal complaint survey of an ESRD Provider.</p> <p>Complaint: IN00421086 with related and unrelated Federal deficiencies cited.</p> <p>Complaint: IN00420131 with related and unrelated Federal deficiencies cited.</p> <p>Survey Dates: 11-13, and 11-14-2023</p>			V 0000	<p>resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 12/14/2023</p>		

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V 0113 Bldg. 00	<p>Facility #: 010516</p> <p>CCN#: 152556</p> <p>Stations: 12 with no isolation rooms.</p> <p>Census by Service Type: In Center Hemodialysis: 48 Home Hemodialysis Patients: 4 Home Peritoneal Dialysis Patients: 25 Total Census: 77</p> <p>QR completed by Area 3 on 11/27/2023.</p> <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, record review, and interview the facility failed to demonstrate appropriate infection control practices, hand hygiene, and use of Personal Protective Equipment (PPE) appropriately while on the treatment floor by 3 of 3 Patient Care Technicians and 3 of 3 Registered Nurses (RN). (Patients: # 7, 8, 11, 12, 13, 14, 15, 17, 21, 22, and 25) (Employees: PCT 2 (7 times), 3 (3 times), 4 (twice), RN 1, 5 (twice), and 6)</p> <p>Findings include:</p> <p>1. On 11-14-2023 at 1:30 PM, a dated 03-17-2023, Fresenius Kidney Care policy titled, "Hand Hygiene" was provided by the Director of Operations (DO). The policy indicated but was not limited to, "Purpose: The purpose of this policy is to prevent transmission of pathogenic</p>			V 0113	<p>On 12/06/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:</p> <p>Hand Hygiene Policy Hand Hygiene Procedure Emphasis was placed on: Hands will be decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and water: Before and after direct contact with patients Entering and leaving the treatment area Before performing any invasive procedure such as vascular</p>		12/14/2023

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	<p>microorganisms to patients and staff through cross contamination ... Hand Hygiene includes either washing hands with soap and water or using a waterless alcohol-based antiseptic hand rub with 60-90% alcohol content ... Hand Hygiene: Patients. Patients should perform hand hygiene if able, prior to and after each dialysis treatment. As needed, direct patient care staff will demonstrate how to operate the sinks, demonstrate handwashing, to patients who are able to perform hand washing, and explain the risk of contamination with regard to their vascular access and hands to all patients ... holding access sites post treatment to achieve hemostasis ... "</p> <p>2. On 11-13-2023 at 11:00 AM a sign posted on the wall above the sink at the entrance to the treatment area was reviewed. The sign titled, "Hand Hygiene Techniques" provided pictures and written instructions on how to complete a hand wash and how to complete a hand rub with hand sanitizer which indicated the best practice to prevent infection.</p> <p>3. On 11-13-2023 at 2:30 PM, a facility document dated December 2022 through November 2023, titled "Clinic Audit Checklist, Category: Infection Prevention" was provided by the DO. The document indicated a review of the monthly infection prevention audits completed.</p> <p>4. On 11-13-2023 at 2:05 PM, PCT 2 was observed to don gloves without performing hand hygiene answer Station #6's dialysate machine alarm and discarded their gloves in the trash receptacle beside the chair. The PCT donned new gloves without performing hand hygiene and answered the dialysate machine alarm at Station #8, PCT 2 discarded their gloves in the trash receptacle, donned new gloves and began the</p>				<p>access cannulation or administration of parenteral medications Immediately after removing gloves. After contact with body fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly soiled. After contact with inanimate objects near the patient When moving from a contaminated body site to a clean body site of the same patient After contact with the dialysis wall box, concentrate, drain, or water lines. After contact with other objects within the patient station or treatment space Patients should perform hand hygiene if able, prior to and after each dialysis treatment. As needed, direct patient care staff will demonstrate how to operate the sinks, demonstrate hand washing to patients who are able to perform hand washing, and explain the risk of contamination regarding their vascular access and hands to all patients. Gloves must be provided to patients when performing procedures which risk exposure to blood or body fluids, such as when self-cannulating or holding access sites post treatment to achieve hemostasis. Washing Hands with Soap</p>		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 11/14/2023	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP CODE 165 SHERIDAN RD NOBLESVILLE, IN 46060			
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	<p>discontinuation of dialysis treatment for Patient #12 at station #7. PCT 2 failed to perform hand hygiene after they discarded their gloves and prior to donning new gloves.</p> <p>5. During an observation on 11-13-2023 at 3:30 PM, the Registered Nurse (RN) 5, removed the glove from Patient #7's right hand after they held their left vascular access site and discarded the glove in the trash receptacle at Station #8. The RN assisted Patient #7 to the scale to obtain their weight prior to the patient leaving the treatment area. Patient #7 was not offered hand sanitizer or instructed to perform hand hygiene before leaving the treatment floor.</p> <p>6. During an observation on 11-13-2023 at 3:35 PM, RN 6, removed the glove from Patient #14's right hand after they held their left vascular access site and discarded the glove in the trash receptacle at Station #6. The RN assisted Patient #14 to the scale to obtain their weight prior to the patient leaving the treatment area. Patient #14 was not offered hand sanitizer or instructed to perform hand hygiene before leaving the treatment floor.</p> <p>7. During an observation on 11-13-2023 at 3:45 PM, PCT 2, discontinued the treatment for Patient #12, at Station #7. Patient #12 held pressure on the left lower vascular access site with a gloved right hand. Patient #12 discarded their glove in the trash receptacle beside their chair. PCT 2 obtained Patient #12's weight prior to the patient leaving the treatment area. Patient #12 was not offered hand sanitizer or instructed to perform hand hygiene before leaving the treatment floor.</p> <p>8. During an observation on 11-13-2023 at 3:55 PM, PCT 2 was observed cleansing the area around Patient #13's CVC exit site with antiseptic.</p>			<p>and Water - Duration of the entire procedure: 40-60 seconds Decontaminating Hands with Alcohol Based Hand rubs - Duration of the entire procedure: 20-30 seconds. Apply alcohol-based hand rub to the palm of one hand using the amount recommended by the product manufacturer. An adequate amount of product must be used for maximum effectiveness. <i>Rub hands together covering all surfaces of the hands and fingers, until hands are dry.</i> Allowing alcohol to dry completely allows adequate contact time to kill germs, allows alcohol to evaporate and prevents risk of igniting flames due to alcohol's flammable properties.</p> <p>Effective 12/07/23, Clinical Manager will conduct daily audits with focus on ensuring staff and patients perform hand hygiene per policy, as required, utilizing Infection Control Audit Tool for 2 weeks and then weekly for an additional 2 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.</p>			

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	<p>The PCT went to the drawer of the center island obtained a sterile dressing, removed their gloves, and discarded them into the trash receptacle. PCT 2 donned new gloves and applied the sterile dressing to Patient #13's exit site. PCT 2 failed to perform hand hygiene and done new gloves prior to applying the CVC dressing.</p> <p>9. During an observation on 11-14-2023 at 11:59 AM, PCT 4 was placed a clean barrier under the CVC ports of Patient #13. The PCT discarded their gloves, went to the cabinet obtained alcohol pads, donned new gloves, and cleansed the CVC hubs using the alcohol pads. PCT 4 failed to perform hand hygiene and don new gloves prior to disinfecting the hubs of Patient #13's CVC ports.</p> <p>10. During an observation on 11-14-2023 at 8:05 AM, Patient #15 walked to and from the patient bathroom from Station #7 in their socks. Patient #15 made RN 1 aware they needed to use the bathroom prior to initiation of dialysis treatment. The RN failed to instruct or assist Patient #15 with their shoes prior to walking on the treatment floor in their socks.</p> <p>11. During an observation on 11-14-2023 at 10:50 AM, PCT 4, was observed assisted Patient #22, at Station #9, after the patient held pressure on their left vascular access site with a gloved right hand. Patient #22 discarded their glove in the trash receptacle beside their chair. PCT 4 assisted Patient #22 with their belongings to the scale to obtain Patient #22's weight. Patient #22 was not offered hand sanitizer or instructed to perform hand hygiene before leaving the treatment floor.</p> <p>12. During an observation on 11-14-2023 at 10:54 AM, Patient #8, at Station #8, was observed to hold pressure on their left lower vascular access</p>				<p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction.</p> <p>The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 12/14/2023.</p>		

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	<p>site with a right gloved hand. Patient #8 discarded their glove in the trash receptacle beside their chair added more tape to their left lower vascular access dressing, went to the scale and obtained their weight, and left the treatment area. Patient #8 was not offered hand sanitizer or instructed to perform hand hygiene before leaving the treatment floor.</p> <p>13. During an observation on 11-14-2023 at 11:00 AM, PCT 3, was observed assisting Patient #25, at Station #12, after the patient held pressure on their left vascular access site with a gloved right hand. Patient #25 discarded their glove in the trash receptacle beside their chair. PCT 3 obtained Patient #25's weight prior to the patient leaving the treatment area. Patient #25 was not offered hand sanitizer or instructed to perform hand hygiene before leaving the treatment floor.</p> <p>14. During an observation on 11-14-2023 at 11:00 AM, PCT 3, was observed assisted Patient #21, at Station #1, after the patient held pressure on their left vascular access site with a gloved right hand. Patient #21 discarded their glove in the trash receptacle beside their chair. PCT 3 assisted Patient #21 to the scale to obtain their weight. Patient #2 was not offered hand sanitizer or instructed to perform hand hygiene before leaving the treatment floor.</p> <p>15. During an observation on 11-14-2023 at 11:59 AM, PCT 4 was placed a clean barrier under the CVC ports of Patient #13. The PCT discarded their gloves, went to the cabinet obtained alcohol pads, donned new gloves, and cleansed the CVC hubs using the alcohol pads. PCT 4 failed to perform hand hygiene and don new gloves prior to disinfecting the hubs of Patient #13's CVC ports.</p>						

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	<p>16. During an observation on 11-14-2023 at 12:15 PM, PCT 3, Patient #17, at Station #10, was observed to hold pressure on their right vascular access site with a left gloved hand. Patient #17 discarded their glove in the trash receptacle beside their chair. PCT #3 assisted Patient #17 to the scale to obtain their weight prior to the patient leaving the treatment area. Patient #17 was not offered hand sanitizer or instructed to perform hand hygiene before leaving the treatment floor.</p> <p>During an interview on 11-14-2023 at 3:45 PM, RN 1 confirmed hand hygiene should be offered or instructed to the patients after they held their pressure dressing on their vascular assess site.</p> <p>17. On 11-14-2023 at 4:19 PM, a review of the Personnel record for PCT 2, contained a facility document titled, "Fresenius Medical Direct Patient Care-Skills Validation Checklist." The section subtitled, "Infection Control Skill Components" indicated PCT 3 successfully provided cognitive review and demonstrated the following: appropriate Personal Protective Equipment (PPE), hand washing, and correct glove changes on 03-20-2023.18. During an observation on 11-13-2023 at 2:20 PM, RN 5 was observed assisting Patient #11, while they were experiencing symptoms of hypotension (low blood pressure). RN 5 failed to change gloves and perform hygiene prior to touching the patient and after touching the screen of the Dialysis machine.</p> <p>19. During an observation on 11-13-2023 at 3:55 PM, PCT 2 went from touching the screen on the machine to Patient #13. PCT 2 failed to don new gloves and sanitize hands prior to touching the patient. PCT 2 was observed discontinuing the lines from the patient's right upper extremity fistula. PCT 2 failed to perform hand hygiene prior</p>						

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V 0115 Bldg. 00	<p>to donning new gloves after they disconnected the bloodlines. PCT 2 failed to perform hand hygiene prior to donning clean gloves, when the patient's access site was no longer bleeding. Patient #13 held their access site and PCT 2 failed to offer the patient hand sanitizer once hemostasis was achieved.</p> <p>20. During an interview with RN 5 on 11-13-2023 at 4:05 PM, they indicated their hands were to be sanitized before putting the patient on Dialysis, taking them off of Dialysis, after using the restroom, and when soiled. RN 5 indicated they did not have to change their gloves when going from the machine to the patient.</p> <p>21. During an interview with PCT 2 on 11-13-2023 at 4:25 PM, they indicated they were to sanitize their hands after changing gloves, when removing gloves, every time they touch the machine or patient, when soiled, when changing gloves when going from the machine to the patient, and patient to machine.</p> <p>494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. Based on observation, record review, and interview the facility failed to ensure the staff and patients wore masks while on the treatment floor</p>			V 0115	On 12/06/2023, the Clinical Manager held a staff meeting and reinforced the expectations and		12/14/2023

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	<p>for 1 of 1 stand alone in-center dialysis centers. (Employee: Patient Care Technician, PCT 2, (twice) Patient #4, 19 and 20</p> <p>Findings include:</p> <p>1. On 11-14-2023 at 1:30 PM, a dated 03-17-2023, Fresenius Kidney Care policy titled, "Personal Protective Equipment" was provided by the Director of Operations (DO). The policy indicated but was not limited to, "... Facemask creates a physical barrier to help block large particles, splashes, sprays, or splatter from reaching the mouth and nose ..."</p> <p>2. On 11-13-2023 at 9:15 AM a sign posted on the front entrance door to the dialysis treatment facility was reviewed. The sign stated, "Due to the increase in COVID cases. Masks are required to enter the facility."</p> <p>3. During an observation on 11-13-2023 at 3:20 PM, the Patient Care Technician (PCT) 2, was observed improperly wearing their mask below their chin while on the treatment floor at Station #6 discontinuing Patient #12's dialysis treatment.</p> <p>4. During an observation on 11-14-2023 at 7:35 AM, PCT 2 was observed improperly wearing their mask below their nose and mouth while at Station #9 addressing the dialysis machine alarm.</p> <p>5. During an observation on 11-14-2023 at 12:15 PM, Patient #19, was observed at Station #1, not wearing a mask. Patient #4 at Station #6 was observed holding their mask. Patient #20 at Station #12 was observed not wearing a mask.</p> <p>6. During an observation on 11-14-2023 at 1:35 PM, patients at stations 5, 7, and 9 had their</p>				<p>responsibilities of the facility staff on policies:</p> <p>Guidance on Dialyzing and Infection Control Practices of COVID-19 in Fresenius Kidney Care (FKC) Dialysis Clinics</p> <p>Personal Protective Equipment</p> <p>Emphasis was placed on:</p> <p>FKC patients and visitors are required to wear surgical face masks upon entry to the dialysis clinic and throughout the duration of dialysis treatment and discharge from the clinic post-treatment.</p> <p>Patients will not be refused treatment if a mask is not worn during the non-contact portion of treatment. At a minimum, FKC patients are required to wear surgical face masks or N95 mask while in the lobby and when interacting with staff during patient care activities (e.g., cannulation, initiation and termination of treatment, medication administration, central venous catheter care, home therapy clinic visits, etc.).</p> <p>Staff should ensure that the patient's face mask is properly positioned over nose and mouth before approaching the patient.</p> <p>All FKC Staff, physicians and physician extenders are required to wear surgical face masks or wear N95 respirator</p>		

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	<p>masks under their chin.</p> <p>7. During an observation on 11-14-2023 at 2:45 PM, observed the patients at Stations #1, 6, 8, 10 and 12 with no mask on during their treatment.</p> <p>During an interview on 11-14-2023 at 3:00 PM, the South Area Director of Operations, Corp 1, was advised of the patients observed on the treatment floor at Stations #1, 6, 8, 10, and 12 not wearing masks and staff improperly wearing masks during treatment. Corp 1 immediately reminded and reeducated staff to wear masks while on the treatment floor.</p> <p>8. During an observation on 11-14-2023 at 3:30 PM the patients at Stations #1, 6, 8, 10, and 12 not wearing a mask during treatment. The patient at Station #7 was observed with no mask on during treatment with the Medical Social Worker (MSW) 1, on a stool in front of their station.</p> <p>During an interview on 11-14-2023 at 3:45 PM, the Registered Nurse (RN) 1, indicated the staff encourage the patients to wear mask. RN 1 further indicated the staff are to wear mask properly covering their nose and mouth.</p>				<p>while in the treatment area (e.g., during all patient facing activities, at the nursing station, medication preparation area, patient training room, etc.).</p> <p>Effective 12/07/23, Clinical Manager will conduct daily audits with focus on ensuring staff and patients wear face mask per policy, as required, utilizing Infection Control Audit Tool for 2 weeks and then weekly for an additional 2 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.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p>		

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V 0143 Bldg. 00	<p>494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS [The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and Based on observation, record review, and interview, the facility failed to ensure the staff monitored and discarded expired medications and supplies monthly per the facility policies for 1 of 1 In-center dialysis nurse's stations and 1 of 1 Home dialysis nurse's stations.</p> <p>Findings Include:</p> <p>1. On 11-14-2023 at 1:30 PM, a dated 02-06-2023. Fresenius Medical Care policy was provided by</p>	V 0143	<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. 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 12/14/2023.</p> <p>On 12/06/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: Medication Preparation and Administration Expiration Dates Sterile Supplies Emphasis was placed on:</p>	12/14/2023	

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	<p>the Director of Operations (DO). The "Medication Preparation and Administration" policy indicated but was not limited to, " ... When preparing medications if the vial is not used immediately in its entirety, the nurse or PCT (Patient Care Technician) ... must place the date and time the vial was opened on the medication label along with their initials ... Expiration dates for all stored medications are to be monitored on a monthly basis ... Any multi-dose vials must be discarded 28 days after opening or per the manufacturer's expiration date ..."</p> <p>2. On 11-14-2023 at 1:30 PM, a dated 07-04-2012. Fresenius Medical Care policy was provided by the DO. The "Expiration Dates Sterile Supplies" policy indicated but was not limited to, "... This policy provided guidance on checking expiration dates to assure that sterile supplies are taken out of circulation by the expiration date ... Appropriately dispose of sterile items that have reached the expiration date ..."</p> <p>3. During a Flash tour on 11-13-2023 at 10:50 AM, observed in the medicine cabinet behind the in-center nurse's station a box that contained 14 vials of Adrenaline (a medication used for emergency treatment of a severe reaction) 1 milligram (mg)/milliliter (ml) that expired September 2023, 4 boxes of Atropine Sulfate (used to treat cardiac arrest) 1 mg/10 ml (0.1 mg/ml) 10 ml single dose injections that expired August 2023, and 1 box of 2 containers Glucose Control Solution (a solution to do a quality control check on blood sugar monitoring machines) 2.5 ml.</p> <p>During an interview on 11-13-2023 at 10:50 AM, the Patient Care Technician (PCT) 2, confirmed the medications and supplies had expired. The PCT further indicated that the Registered Nurse (RN) 1,</p>				<p>Expiration dates for all stored medications are to be monitored on a monthly basis.</p> <p>Expired medications are to be discarded via Fresenius Kidney Care off-site return program or in accordance with local and/or state law.</p> <p>Any open multi dose vials must be discarded 28 days after opening or per manufacturer's expiration date.</p> <p>Sterile items will be checked before use to ensure that they have not expired. Appropriately dispose of sterile items that have reached the expiration date. Effective 12/07/2023, the Clinical Manager will conduct weekly audits for 4 weeks or until 100% compliance is achieved utilizing Plan of Correction Audit Tool. 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 Tool 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. The Director of Operations is responsible to present the status</p>		

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V 0196 Bldg. 00	<p>orders the medications and supplies after they are checked monthly.</p> <p>4. During a flash tour observation on 11-13-2023 at 12:45 PM, observed on the counter of the Home dialysis nurse's station 3 Bacterial sample vials (vials used to obtain blood samples to test for infections) 30 ml vials expired on 10-07-2023, and 5 red top BD vacutainers tubes (tubes used to obtain blood samples for testing) 6.0 ml expired on 08-31-2023.</p> <p>During an interview on 11-13-2023 at 1:00 PM, RN 2, confirmed the supplies had expired and they were to check medications and supplies monthly.</p> <p>494.40(a) CARBON ADSORP-MONITOR, TEST FREQUENCY 6.2.5 Carbon adsorption: monitoring, testing freq Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours.</p>				<p>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.</p> <p>The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 12/14/2023.</p>		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 11/14/2023	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP CODE 165 SHERIDAN RD NOBLESVILLE, IN 46060			
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	<p>Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet.</p> <p>Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N,N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L].</p> <p>Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly.</p> <p>Based on record review and interview, the agency failed to ensure chlorine checks were performed every 4 hours for 1 of 1 chlorine log sheet reviewed.</p> <p>Findings Include:</p> <p>1. On 11-13-2023 at 1:30 PM, the Area Teams Operation Manager (ATOM) provided a document titled "Log Name: Post Worker Carbon Tank". The document evidenced on 10-23-2023 the test was read at 08:37 and the next time the test was read was at 15:36. The agency failed to ensure the chlorine test was checked and read every 4 hours. The document evidenced on 10-27-2023 the test was read at 04:40 and the next time the test was read at 09:19. The agency failed to ensure the chlorine test was checked and read every 4 hours. The document evidenced on</p>			V 0196	<p>On 12/06/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:</p> <p>Carbon Filtration Monitoring for Incenter Central Water Systems Policy</p> <p>Emphasis was placed on:</p> <p>Prior to the initiation of the first patient treatment of the day and at a minimum of every 4 hours, chlorine test was performed and documented on the Post Worker Carbon Tank - TCL-1 log. Effective 12/07/2023, Clinical Manager will conduct daily audits with focus on ensuring staff conduct and document chlorine testing at a minimum of 4 hours</p>		12/14/2023

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	<p>11-01-2023 the test was read at 05:00 and the next time the test was read was at 14:20. The agency failed to ensure the chlorine test was checked and read every 4 hours.</p> <p>2. During an interview with the ATOM on 11-13-2023 at 11:50 AM, they indicated the chlorine tests were to be completed every 4 hours by 2 qualified individuals, with one having to be a nurse.</p>				<p>per policy, as required, utilizing Plan of Correction Audit Tool for 2 weeks and then weekly for an additional 2 weeks or until 100% compliance is achieved.</p> <p>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 Tool per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction.</p> <p>The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure</p>		

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V 0401 Bldg. 00	<p>494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT</p> <p>The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.</p> <p>Based on observation, record review, and interview, the facility failed to provide a safe and comfortable environment for 1 of 1 stand one dialysis treatment centers.</p> <p>Findings include:</p> <p>1. On 11-14-2023 at 1:30 PM, a dated 02-07-2022, Fresenius Kidney Care policy titled "General Cleanliness and Infection Control Guidelines" was provided by the Director of Operations (DO). The policy indicated but was not limited to, " ... All areas must be kept clean and organized ... treatment area, water/supply room and offices. Walkways must be kept clear of debris and free of clutter ... 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 11-13-2023 at 12:35 PM, noted 3 boxes on the floor of Home dialysis</p>	V 0401	<p>the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 12/14/2023.</p> <p>On 12/06/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:</p> <p>General Cleanliness and Infection Control Guidelines Emphasis was placed on:</p> <p>Facility to provide and maintain a clean, safe, aesthetically pleasant environment for patients, staff, and visitors.</p> <p>All areas must be kept clean and organized, including but not limited to the treatment area, water/supply room and offices. Walkways must be kept clear of debris and free of clutter.</p> <p>Specimens of blood or other potentially infectious materials shall be placed in a container</p>	12/14/2023	

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	<p>office door entry.</p> <p>During an interview on 11-13-2023 at 12:35 PM, the Patient Care Technician and Receptionist, PCT 1, indicated the boxes were full of a patient's supplies.</p> <p>3. During an observation on 11-13-2023 at 1:30 PM, noted 3 boxes of Christmas trees, 6 boxes of Liquacel on the floor of the storage room, in the hallway next to the conference room.</p> <p>During an interview on 11-13-2023 at 1:30 PM, the Area Operation Manager of Biomed Technicians, confirmed no boxes were to be on the floor.</p> <p>4. During an observation on 11-13-2023 at 1:35 PM, observed the patient bathroom with a roll of toilet paper on the floor.</p> <p>5. During an observation on 11-13-2023 at 1:40 PM, observed soiled gauze and gloves on the floor beside the trash receptacle at Station #7.</p> <p>6. During an observation on 11-13-2023 at 2:15 PM, noted 3 gloves on the floor by the clean sink, 2 soiled 2 x 2 gauze dressings, and a normal saline syringe wrapper on the floor in front of Station #9.</p> <p>7. During an observation on 11-13-2023 at 3:20 PM, noted on the surround unit wall shelf a dialysis cap behind Station #7, a blood pressure cuff behind Station #6, a cane behind Station #4, and a tan arm cushion between Station #7 and Station #8.</p> <p>8. During an observation on 11-14-2023 at 7:45 AM, noted a blood pressure cuff on the surround unit wall shelf at Station #6.</p>				<p>which prevents leakage during collection, handling, processing, storage, transport, or shipping. Effective 12/07/2023, Clinical Manager will conduct weekly audits, 3 days per week, utilizing Plan of Correction Audit Tool for 2 weeks and then weekly for an additional 2 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 Tool per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to</p>		

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V 0402 Bldg. 00	<p>During an interview on 11-14-2023 at 3:45 PM, the Registered Nurse (RN) 1, confirmed nothing was to be on the surround unit shelf. On 11-13-2023 at 1:32 PM, it was observed in the storage room next to the offices, 13 cardboard boxes were on the floor and 2 of the boxes were on a black tarp. The agency failed to ensure the hallway was clear of boxes.</p> <p>10. On 11-14-2023 at 11:50 AM, observed a box of gloves behind Station #10 on the chase wall.</p> <p>494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY</p> <p>The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public. Based on observation, record review, and interview, the facility failed to ensure the building was maintained to ensure the safety of patient and staff in 1 of 1 stand one dialysis treatment centers.</p> <p>Findings Include:</p> <p>1. On 11-14-2023 at 1:30 PM, a 04-05-2021 Fresenius Kidney Care policy titled, "Storage of Supplies" was provided by the Director of Operations (DO). The policy indicated but was not limited to, " All clean or sterile supplies ... must be stored off the floor ...".</p> <p>2. On 11-14-2023 at 1:30 PM, a 07-06-2021 Fresenius Kidney Care policy titled, "Equipment Installation-Operation-Maintenance-Repair-And</p>			V 0402	<p>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 12/14/2023.</p> <p>On 12/06/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: Equipment Installation-Operations-Maintenance -Repair-And Disposal Storage of Supplies Emphasis was placed on: The physical plant of the facility should be in good working condition. Any equipment or device that is not fully functioning in accordance with IFU or company policy, must be repaired or replaced as soon as</p>		12/14/2023

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	<p>Disposal" was provided by the DO. The policy indicated but was not limited to, " ... Any equipment or device that is not fully functioning ... must be repaired or replaced as soon as reasonably possible ... Identified issues may include fluid leaks: nonfunctional, broken, or misadjusted parts and components; or aesthetic damages ..."</p> <p>3. On 11-13-2023 at 10:30 AM, during a Flash tour, the water room was found to have crumbled flooring and when stepping around the area water appeared around the carbon filter tanks. There was no sign posted indicating the floor was wet.</p> <p>During an interview on 11-13-2023 11:16 AM, the Biomed Technician, indicated they had a work order for the floor and carbon filter tanks.</p> <p>4. On 11-14-2023 at 10:40 AM, during the Flash tour observation, the black refrigerator in the lab area had dirt and debris on the bottom shelf, and the door facing, and sides had rust showing through the black paint.</p> <p>During an interview on 11-13-2023 at 1:30 PM, the Area Operation Manager of Biomed Technicians, confirmed no boxes were to be on the floor.</p> <p>5. During an observation on 11-13-2023 at 2:08 PM, noted the sink in front of the nurse's station with a green substance surrounding the connections of faucet, handles, and the green build up substance around the white pipe fitting below the sink.</p> <p>6. On 11-13-2023 at 4:13 PM, facility documents titled, "Order No. 3602250300" dated December 23, 2022, and "Order No. 3602442089" dated April 3, 2023, was provided by the Area Operation</p>				<p>reasonably possible.</p> <p>If the faulty equipment poses a risk to the patient or staff, the device will be immediately removed from service.</p> <p>Identified issues may include fluid leaks; nonfunctional, broken, or misadjusted parts and components; or aesthetic damages. Any equipment awaiting repair must be tagged in accordance with the use of Hemodialysis and Ancillary Machine Repair/Return Tag Policy.</p> <p>If any water is identified on the floor, clean and dry the affected area or immediately place If water reappears, obtain, and place a "wet floor" sign in the immediate area and to notify the CM or nurse in charge.</p> <p>All clean or sterile supplies, except drums of concentrate, must be stored off the floor and a minimum of eighteen inches in a sprinklered facility from the ceiling.</p> <p>Area Technical Operations Manager (ATOM) spoke with contractor, at Handy Repair Guys, regarding the scope of work needed. Work to be completed by the contractor will include:</p> <p>Area Technical Operations Manager (ATOM) ordered a new refrigerator to replace refrigerator with rust in lab area, arrival date</p>		

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	<p>Manager of Biomed Technicians. The documents indicated materials needed for repairs for the water room floor.</p> <p>7. During an observation on 11-14-2023 at 11:35 AM, noted Station #3 had 4 floor tiles cracked and cement showing, and the baseboard behind Station #4 was missing.</p> <p>8. During an observation on 11-14-2023 at 11:40 AM, noted behind Station #9 had floor tiles chipped, and behind Station #12 wall paint at the baseboard was peeling.</p> <p>9. During an interview on 11-14-2023 at 9:00 AM, the Area Director of Biomed Technician, confirmed the treatment room sink faucet, handles and drain will need replaced.10. On 11-13-2023 at 10:35 AM, an observation of the treatment room evidenced a black refrigerator behind Patient Care Technician (PCT) station where labs were stored. The refrigerator had yellow rust on the bottom of the door.</p> <p>11. On 11-14-2023 at 11:50 AM, an observation of the treatment room evidenced the wallpaper coming off of the wall at the bottom on the small wall in the corner of the PCT station. The bottom of the cabinet and lower drawer for the cabinet under the PCT station next to the printer had rust on it.</p>				<p>by 12-14-23.</p> <p>ATOM has created a work order (#98240) on 11-14-23 to replace the faucet and handles with green substance on the sink in front of the nurse's station. The green substance on the white pipe fitting below the sink is wiped off clean and does not need to be replaced. The work order will be completed by vendor Handy Repair Guys on or before 12-13-23.</p> <p>ATOM created a work order (#98163) for cracked floor tile and baseboard repairs in treatment room including patient stations 3, 4, 9 and 12. The work order was completed by vendor Handy Repair Guys on 11-21-23.</p> <p>ATOM created a work order (#98163) for repairs to wallpaper lifting at corner of PCT station. The work order was completed by vendor Handy Repair Guys on 11-21-23.</p> <p>ATOM will repair or replace cabinet with rust under the PCT stations next to the printer on or before 12-13.23.</p> <p>Effective 12/07/2023, the Clinical Manager will conduct weekly audits with focus on ensuring the safety and functionality of the facility is maintained for patients and facility staff utilizing Building Interior Physical Environment Inspection Audit for four weeks or until 100% compliance is</p>		

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			<p>achieved. Once compliance is sustained, the Governing Body will decrease frequency to resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Checklist Tool per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution</p>		

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V 0407 Bldg. 00	<p>494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement). Based on observation and interview the facility failed to ensure the patient's access site remained uncovered during dialysis treatments for 1 of 1 stand alone in-center dialysis facilities. (Patients: #15, 18, and 22)</p> <p>Findings Include:</p> <p>1. On 11-14-2023 at 4:45 PM a dated 05-01-2023, Fresenius Kidney Care policy, titled, "Patient Assessment and Monitoring" was provided by the Director of Operations (DO). The policy indicated but was not limited to "Purpose: The purpose of this policy is to provide guidance to the Fresenius Kidney Care direct patient care staff on assessment and monitoring patients before, during, and after treatment ... Access: Ensure access remains uncovered throughout treatment ..."</p> <p>2. During an observation on 11-14-2023 at 7:25 AM, Patient #22 was observed at Station #9. Patient #15's access was fully covered with a maroon and white blanket.</p> <p>3. During an observation on 11-14-2023 at 7:25</p>			V 0407	<p>of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 12/14/2023</p> <p>On 12/06/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: Patient Assessment and Monitoring Emphasis was placed on: Ensure access remains uncovered throughout the treatment Observe and ensure: Tape is secure Needles are intact No bleeding or infiltration is noted Re-educate patient if they continue to cover their access</p> <p>By 12/14/2023, 100% of all patients will be re-educated on the importance of always keeping their access in view. Those patients absent on the day of education will be re-educated on their first treatment back at the facility with documentation noted in the EMR.</p>		12/14/2023

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
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	<p>AM, Patient #18 was observed at Station #3. Patient #18's Central Venous Catheter (CVC) was fully covered with a flowered blanket.</p> <p>4. During an observation on 11-14-2023 at 10:50 AM to 12:35 AM, Patient #15 was observed at Station #7. Patient #15's CVC was fully covered with a pumpkin blanket.</p> <p>During an interview on 11-14-2023 at 3:45 PM, the Registered Nurse (RN) 1, confirmed all patient's accesses were to be visible at all times during their treatment.</p>				<p>Effective 12/07/2023 the Clinical Manager will conduct daily audits with focus on ensuring all patient's access remain uncovered and visible during treatment for 2 weeks and then weekly for an additional 2 weeks or until 100% compliance is achieved utilizing Plan of Correction Audit Tool. Once compliance is sustained, the Governing Body will decrease frequency to resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Checklist with any non-compliance noted in the meeting minutes in eQUIP.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing</p>		

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V 0543 Bldg. 00	<p>494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; Based on record review, and interview, the facility failed to ensure direct patient care staff monitored the patients during their dialysis treatment per the facility policy in 2 of 7 records reviewed. (Patients: #1, and 4)</p> <p>Findings Include:</p> <p>1. On 11-14-2023 at 4:40 PM a dated 05-01-2023, Fresenius Kidney Care policy, titled, "Patient Assessment and Monitoring" was provided by the Director of Operations (DO). The policy indicated but was not limited to "The purpose of</p>	V 0543	<p>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 12/14/2023.</p> <p>On 12/06/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: Patient Assessment and Monitoring Emphasis was placed on: Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulations.</p>	12/14/2023	

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	<p>this policy is to provide guidance ... direct care staff on assessment and monitoring patients before, during and after treatment ... During Treatment: Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulations. Document machine parameters and safety checks every 30 minutes or more often as needed but not to exceed 45 minutes ... "</p> <p>2. The medical record/treatment sheets for Patient #1 were reviewed on 01-14-2023. The treatment sheets from 10-23-2023 through 11-13-2023 evidenced the following:</p> <p>A. Treatment sheet dated 10-27-2023, a blood pressure, and pulse check at 1:32 PM by the Patient Care Technician (PCT). The following patient assessment was completed by the Registered Nurse (RN) at 3:03 PM. No abnormal blood pressure's were noted.</p> <p>B. Treatment sheet dated 10-30-2023, a blood pressure, and pulse check at 2:30 PM by the PCT. The PCT completed the next blood pressure, and pulse check at 4:23 PM. No abnormal blood pressure's were noted.</p> <p>C. Treatment sheet dated 11-06-2023, a blood pressure, and pulse check at 2:07 PM by the PCT. The PCT completed the next blood pressure, and pulse check at 3:04 PM. No abnormal blood pressure's were noted.</p> <p>D. Treatment sheet dated 11-08-2023, a blood pressure, and pulse check at 2:04 PM by the RN. The following patient assessment and machine safety check was completed by the RN at 3:03 PM. No abnormal blood pressure's were noted.</p>				<p>Document machine parameters and safety checks every 30 or more often as needed but not to exceed 45 minutes or per state regulations. Effective 12/07/2023 the Clinical Manager will conduct weekly audits, for 3 days per week for 2 weeks and then weekly for an additional 2 weeks or until 100% compliance is achieved utilizing Plan of Correction Audit Tool. Once compliance is sustained, the Governing Body will decrease frequency to resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Checklist with any non-compliance noted in the meeting minutes in eQUIP.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. 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.</p>		

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	<p>E. Treatment sheet dated 11-10-2023, a blood pressure, pulse, and machine safety check at 1:30 PM by the PCT. The PCT completed the next blood pressure, and pulse check at 2:39 PM. No abnormal blood pressure's were noted.</p> <p>During an interview on 11-13-2023 at 9:30 AM, the Medical Director, indicated the facility had struggled with not enough staff. The Medical Director further indicated they had some staff walk out last week after letting some staff go for not providing quality care after being retrained.</p> <p>3. The medical record/treatment sheets for Patient #4 were reviewed on 01-14-2023. The treatment sheets from 10-21-2023 through 11-11-2023 evidenced the following:</p> <p>A. Treatment sheet dated 10-21-2023, a blood pressure, and pulse check at 12:34 PM by the RN. The RN completed the next blood pressure, pulse, and machine safety check at 1:32 PM. At 3:03 PM the PCT completed a blood pressure, pulse, and machine safety check. The RN completed the next blood pressure, pulse and machine safety check at 4:00 PM. No abnormal blood pressure's were noted.</p> <p>B. Treatment sheet dated 10-24-2023, Patient #4's treatment was initiated at 11:36 AM by the PCT. The RN completed blood pressure, pulse, and machine safety at 12:34 PM. No abnormal blood pressure's were noted.</p> <p>C. Treatment sheet dated 10-28-2023, a blood pressure, pulse, and machine safety check at 2:01 PM by the PCT. The RN completed the next blood pressure, pulse, and machine safety check at 3:03 PM. No abnormal blood pressure's were noted.</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. 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 12/14/2023.</p>		

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	<p>D. Treatment sheet dated 11-04-2023, a blood pressure, pulse, and machine safety check at 11:44 AM by the PCT. The PCT completed the next blood pressure, pulse, and machine safety check at 12:31 PM. No abnormal blood pressure's were noted.</p> <p>E. Treatment sheet dated 11-07-2023, a blood pressure, pulse, and machine safety check at 2:01 PM by the RN. The RN completed the next blood pressure, pulse, and machine safety check at 3:02 PM. No abnormal blood pressure's were noted.</p> <p>F. Treatment sheet dated 11-11-2023, a blood pressure, pulse, and machine safety check at 2:31 PM by the PCT. The PCT completed the next blood pressure, and pulse check at 3:34 PM. No abnormal blood pressure's were noted.</p> <p>During an interview on 11-14-2023 at 4:30 PM, the DO, confirmed Patient #4 was not monitored every 30 minutes with 45 minute maximum per their policy. No further information was provided.</p>						