| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING | X3) DATE SURVEY COMPLETED |
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| | 152560 | | 03/06/2014 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| FRESENIUS MEDICAL CARE INDIANAPOLIS MIDTOWN | 3007 DR ANDREW J BROWN AVE<br>INDIANAPOLIS, IN 46205 |

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETION DATE |
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| V000000 | This visit was an ESRD recertification survey.<br><br>Facility: #010914<br><br>Dates: March 4, 5, and 6, 2014<br><br>Medicaid: #**200234630A**<br><br>Surveyors: Bridget Boston, RN, PHNS<br>Ingrid Miller, RN, PHNS<br>Janet Brandt, RN, PHNS<br>Tonya Tucker, RN, PHNS<br><br>FMC Indianapolis Midtown was found to be out of compliance with the Conditions for Coverage 42 CFR 494.30: Infection Control.<br><br>Census: 72 In-center hemodialysis<br><br>Quality Review: Joyce Elder, MSN, BSN, RN<br>March 12, 2014 | V000000 | | |
| V000110 | 494.30<br>CFC-INFECTION CONTROL<br>Based on observations, staff interview, and review of policies and procedures, it | V000110 | As a result of the citations from the March 6, 2014 survey and as | 03/28/2014 |

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

Any defiencystatement ending with an asterisk (*) denotes a deficency which the institution may be excused from correcting providing it is determined that other safegaurds provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days 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 14 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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| | was determined the facility failed to ensure all staff followed infection control policies during provision of care in 2 of 4 observations during the provision of care with the potential to affect all the facility's current in-center patients (See V 113); failed to ensure 1 of 1 patient care technician observation placed lab specimens in a clearly marked area for lab specimen with the potential to affect all the patients, staff, and visitors to the facility (See V 117); and failed to ensure all patients with a central venous catheter received care in compliance with facility policy in 2 of 5 observations of initiation of hemodialysis creating the potential to create an air emboli and spread infectious and communicable disease which could affect all in-center patients (See V 146 and V 147).<br><br>The cumulative effect of these systemic problems resulted in the facility's inability to meet the requirements of the Condition for Coverage 42 CFR 494.30 Infection Control. | | part of the developed plan of correction, the Director of Operations over saw the completion of the following actions:<br>· Reeducation and reinforcement of the mandatory requirement of direct patient care staff to comply with all aspects of the facility's hand hygiene policy. Please refer to V-113<br>· Reeducation and reinforcement of the mandatory requirement of direct patient care staff to comply with all aspects of the facility's PPE program. Please refer to V-115<br>· Reeducation and reinforcement to the separation of clean and contaminated areas. Please refer to V-117<br>· Reeducation and reinforcement of management expectation of staff to comply with the proper wearing and discarding of face mask during central venous catheter procedures. Please refer to V 146 and V 147<br>Documentation of the education, monitoring process, staff and patient assignments document the implemented corrective actions and are available at the facility for review.<br>The Director of Operations and the Governing Body takes seriously its' responsibility to ensure that dialysis and support services are delivered in a manner which – at all times - ensures the health and safety of | |

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| | | | its patients. As such, the Governing Body, which includes the facility's Medical Director, met on March 17, 2014, to review the surveyor's comments made during the exit interview and to formulate a corrective action plan to bring this facility into compliance with the ESRD Conditions of Coverage.<br><br>The Governing Body met again on March 17, 2014, after the receipt of the Statement of Deficiencies, to review the citations and to formulate a corrective action plan to bring this facility into compliance with the ESRD Conditions of Coverage.<br><br>To ensure full implementation of the develop plan of correction, the Governing Body has committed to meet monthly for an additional six months and revert to is routine meeting schedule if no reoccurrence of infection control deficiencies are identified. | |
| V000113 | 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. | V000113 | IC Wear Gloves/Hand Hygiene<br><br>On March 12, 2014, the Clinical Manager conducted a mandatory staff meeting for all Direct Patient Care staff to reinforce both the | 03/28/2014 |

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| | | | expectation and responsibility of facility staff in adhering to the hand hygiene policies of this facility.<br><br>To ensure that all staff understands the importance of proper hand hygiene, the Director of Operations contacted the educational department and arranged for the formal reeducation of all staff to be completed no later than March 28, 2014. This reeducation was inclusive of the following facility policies and procedures:<br>· FMS-CS-IC-II-155-090A & C Hand Hygiene Policy and Procedure<br>· FMS-CS-IC-II-155-070A Dialysis Precautions Policy<br><br>The Staff meeting attendance record and in-service attendance forms document this activity and are available for review at the facility.<br><br>Monitoring of the staff for compliance is the responsibility of the Clinical Manager or assigned Nurse will occur by:<br>·Direct observation of the staff's adherence to infection control policies and procedures.<br>·Immediate intervention, consisting of reeducation up to disciplinary action, to address and correct identified noncompliance with the appropriate staff member. | |

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| | | | Beginning March 19, 2014, the Clinical Manager or assigned nurse utilizes the plan of correction monitoring tool during each patient shift with decreased frequency based upon evaluation of staff compliance as determined by the Governing Body. Any identified staff non-compliance will have an immediate intervention by the Clinical Manager and assigned nurse providing oversight. The noncompliance and intervention will be documented on the Infection Assessment Tool or in the employees personnel file if warranted.<br><br>In the event that a staff member is found to continually not follow the facility procedures for infection control, the Director of Operations will be notified and is responsible to ensure that progressive disciplinary action is applied. Progressive disciplinary action will be structured to reinforce by further education following through as necessary with the application of progressive disciplinary action up to and including termination.<br><br>The Clinical Manager will summarize the findings identified from the monitoring process and report weekly to the Governing Body. The Governing Body will review status of staff compliance and will determine further the | |

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| | | | need of audit frequency and when it determines, decrease the frequency incrementally. Additionally the summaries are compiled and reported to the QAI committee at its monthly meeting. Upon determination of compliance by the Governing Body, the monitoring will revert to the QAI infection control audit schedule.<br><br>The Clinical Manager is responsible to ensure staff compliance to policy and procedure and the Director of Operations will monitor for ongoing compliance through Governing Body oversight and the QAI process. | |
| | Based on observations, staff interview, and review of policies and procedures, the facility failed to ensure all staff followed infection control policies during provision of care in 2 of 4 observations (observations #1 and 2) during the provision of care with the potential to affect all the facility's current in-center patients. (employees H, K, and L)<br><br>Findings<br><br>Observation #1 on 3/4/14:<br><br>1. On 3/4/14 at 10 AM, Employee H, | | | |

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| | patient care technician, was observed to touch patient # 12 at station #1 with ungloved hands and then touch machine #17 at station 4 with patient #16 without sanitizing hands.<br><br>2. On 3/4/14 at 10:04 AM, Employee H was observed to care for patient #13 at station #2. Employee H donned gloves without washing hands and then placed a disposable thermometer in the patient's mouth.<br><br>3. On 3/4/14 at 10:13 AM, Employee H was observed to leave Patient #13 at station #2 and remove gloves. Without washing hands, she obtained gauze in a drawer at the common treatment area across from station #2 and returned with the supplies and washed her hands.<br><br>4. On 3/4/14 at 10:50 AM, Employee H was observed to take Patient #10's shirt off which had a blood splash on it and remove her own protective gown and gloves. Without washing her hands, she donned a new gown and new gloves and continued to care for patient #10.<br><br>5. The agency policy titled "Hand Hygiene" with an effective date of March 20, 2013, stated, "The purpose of this policy is to prevent transmission of pathogenic microorganisms to patients | | | |

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| | and staff through cross contamination ... 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 ... immediately after removing gloves ... after contact with inanimate objects near the patient , when moving from a contaminated body site to a clean body site of the same patient."<br><br>6. On 3/4/15 at 3:30 PM, Employee B, the clinical manager, indicated the infection control policy on handwashing was not followed by Employee H.<br><br>Observation # 2 on 3/4/14:<br><br>8. At 3:15 PM, employee L, a licensed practical nurse, was observed to enter station #17 where a patient was dialyzing, she left station #17, removed her gloves, and entered #16 treatment area where she donned new gloves without completing hand hygiene prior to rendering patient care.<br><br>At 3:30 PM, employee D, a registered nurse, indicated hand hygiene was to be done when entering and when leaving a patient treatment area and was not aware of any breaches related to infection control taking place in | | | |

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| | treatment area.<br><br>7. Employee K, a patient care technician (PCT), was observed to initiate the dialysis treatment on patient number 1 on 3/4/14 at 10:38 AM. The PCT was observed to locate, palpate, and then cleanse the cannulation site. The PCT did not remove gloves and don clean gloves after palpation and before cleansing the cannulation site.<br><br>On 3/6/14 at 1:55 PM, employee A indicated being aware of the need to change gloves after palpating the cannulation site and the staff have not been educated on this yet but will be as soon as their policies and procedures are updated to include this. | | | |

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| V000117 | 494.30(a)(1)(i)<br>IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS<br>Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.<br><br>When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.<br><br>Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.<br>Based on observation, staff interview, and review of policies and procedures, the dialysis failed to ensure 1 of 1 patient care technician observation (Employee H) placed lab specimens in a clearly marked area for lab specimens with the potential to affect all the patients, staff, and visitors to the facility.<br><br>Findings<br><br>1. On 3/4/14 at 11 AM, it was observed | V000117 | IC-Clean/Dirty; Med Prep area: No common Carts<br><br>On March 6, 2014, the Clinical Manager conducted a mandatory staff meeting for all Direct Patient Care staff to reinforce both the expectation and responsibility of facility staff in adhering to facility policies regarding the handling of lab specimens.<br><br>To ensure that all staff understands the importance of proper hand hygiene, the Director | 03/28/2014 |

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| | that Employee H, patient care technician, drew the labs from patient #10 at station #3 and machine #13 and placed the lab specimens into the prime bucket after the labs were drawn.<br><br>2. The facility policy titled "Use of Priming buckets" with an effective date of June 19. 2013, stated, "A priming bucket ... is for the collection of Normal Saline Only."<br><br>3. The facility policy titled "Dialysis Precautions" with an effective date of January 4, 2012, stated, "Clean areas should be clearly separated from dirty areas where used supplies, equipment, blood supplies or biohazard containers are stored or handled."<br><br>4. On 3/4/14 at 2:55 PM, Employee E, the facility educator, indicated the prime bucket was not to be used for lab specimens. | | of Operations contacted the educational department and arranged for the formal reeducation of all staff to be completed no later than March 28, 2014. This reeducation was inclusive of the following facility policies and procedures:<br>· FMS-CS-IC-II-155-070A Dialysis Precautions Policy<br>· FMS-CS-IS-I-510-011 A & C Use of Priming Buckets Policy and Procedure<br><br>The Staff meeting attendance record and in-service attendance forms document this activity and are available for review at the facility.<br><br>Monitoring of the staff for compliance is the responsibility of the Clinical Manager or assigned Nurse will occur by:<br>· Direct observation of the staff's adherence to infection control policies and procedures.<br>· Immediate intervention, consisting of reeducation up to disciplinary action, to address and correct identified noncompliance with the appropriate staff member.<br><br>Beginning March 19, 2014, the Clinical Manager or assigned nurse utilizes the plan of correction monitoring tool during each patient shift with decreased frequency based upon evaluation of staff compliance as determined by the Governing Body. | |

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| | | | Any identified staff non-compliance will have an immediate intervention by the Clinical Manager and assigned nurse providing oversight. The noncompliance and intervention will be documented on the Infection Assessment Tool or in the employees personnel file if warranted.<br><br>In the event that a staff member is found to continually not follow the facility procedures for infection control, the Director of Operations will be notified and is responsible to ensure that progressive disciplinary action is applied. Progressive disciplinary action will be structured to reinforce by further education following through as necessary with the application of progressive disciplinary action up to and including termination.<br>The Clinical Manager will summarize the findings identified from the monitoring process and report weekly to the Governing Body. The Governing Body will review status of staff compliance and will determine further the need of audit frequency and when it determines, decrease the frequency incrementally. Additionally the summaries are compiled and reported to the QAI committee at its monthly meeting. Upon determination of compliance by the Governing Body, the monitoring will revert to the QAI infection control audit | |

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| | | | schedule.<br><br>The Clinical Manager is responsible to ensure staff compliance to policy and procedure and the Director of Operations will monitor for ongoing compliance through Governing Body oversight and the QAI process. | |
| V000146 | 494.30(c)(2)<br>IC-CATHETERS:GENERAL<br>(2) The "Guidelines for the Prevention of Intravascular Catheter-Related Infections" entitled "Recommendations for Placement of Intravascular Catheters in Adults and Children" parts I - IV; and "Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients," Morbidity and Mortality Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection as the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html<br><br>8. On 3/6/14 at 11 AM, employee H was observed in station 4 with patient 5, a patient with a central venous catheter | V000146 | IC-Catheters General<br>On March 6, 2014, the Clinical Manager conducted a mandatory staff meeting for all Direct Patient Care staff to reinforce both the | 03/28/2014 |

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| | (CVC). Employee H was observed to don a mask prior to the initiation of dialysis with patient 5. Following this, she then pulled the mask below her nose and mouth and proceeded to care for another patient with a CVC, patient 10 in station 3. Employee H pulled the same mask back over her nose and mouth and initiated hemodialysis via the patient's CVC access without donning a clean mask. | | expectation and responsibility of facility staff in adhering to the hemodialysis catheter policies of this facility.<br>To ensure that all staff understands the importance of proper hand hygiene, the Director of Operations contacted the educational department and arranged for the formal reeducation of all staff to be completed no later than March 28, 2014. This reeducation was inclusive of the following facility policies and procedures:<br>· FMS-CS-IC-I-105-002 A & C Initiation of Treatment using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer Policy & Procedure<br>· FMS-CS-IC-I-115-025A Eligibility and Performance Requirements for Registered Nurse, Licensed Practical Nurse or Patient Care Technician to Perform Hemodialysis Catheter Care<br>· FMS-CS-IC-II-125-014A Complications of Hemodialysis - Management and Prevention of Air Embolus<br><br>The Staff meeting attendance record and in-service attendance forms document this activity and are available for review at the facility.<br><br>Monitoring of the staff for compliance is the responsibility of the Clinical Manager or assigned Nurse will occur by: | |

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| NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS MIDTOWN | | STREET ADDRESS, CITY, STATE, ZIP CODE 3007 DR ANDREW J BROWN AVE INDIANAPOLIS, IN 46205 | |

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| | | | · Direct observation of the staff's adherence to infection control policies and procedures.<br>· Immediate intervention, consisting of reeducation up to disciplinary action, to address and correct identified noncompliance with the appropriate staff member.<br><br>Beginning March 19, 2014, the Clinical Manager or assigned nurse utilizes the plan of correction monitoring tool during each patient shift with decreased frequency based upon evaluation of staff compliance as determined by the Governing Body. Any identified staff non-compliance will have an immediate intervention by the Clinical Manager and assigned nurse providing oversight. The noncompliance and intervention will be documented on the Infection Assessment Tool or in the employees personnel file if warranted.<br><br>In the event that a staff member is found to continually not follow the facility procedures for infection control, the Director of Operations will be notified and is responsible to ensure that progressive disciplinary action is applied. Progressive disciplinary action will be structured to reinforce by further education following through as necessary with the application of progressive disciplinary action up to and | |

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| | | | including termination<br><br>The Clinical Manager will summarize the findings identified from the monitoring process and report weekly to the Governing Body. The Governing Body will review status of staff compliance and will determine further the need of audit frequency and when it determines, decrease the frequency incrementally. Additionally the summaries are compiled and reported to the QAI committee at its monthly meeting. Upon determination of compliance by the Governing Body, the monitoring will revert to the QAI infection control audit schedule.<br><br>The Clinical Manager is responsible to ensure staff compliance to policy and procedure and the Director of Operations will monitor for ongoing compliance through Governing Body oversight and the QAI process.<br><br>. | |
| | Based on observations, staff interview, and review of policies and procedures, the facility failed to ensure all patients with a central venous catheter (CVC) received care in compliance with facility policy in 2 of 5 observations of initiation | | | |

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| | of hemodialysis creating the potential to create an air emboli and spread infectious and communicable disease which could affect all in-center patients. (Patients 5 and 10)<br><br>Findings<br><br>1. On 3/4/14 at 11:05 AM, Employee H, patient care technician (PCT), was initiating treatment on patient #10 who had a CVC at station #3. The PCT had attached a syringe to the venous catheter limb with the clamp closed. Approximately 10 cc (cubic centimeters) of blood was in the syringe. The PCT withdrew the plunger aggressively causing the plunger to withdraw from the syringe into the PCT's hand. Approximately 5 cc of blood splashed onto the patient's clothes and the PCT. She clamped the line and reinserted the plunger back into the syringe. She took the patient's shirt off which had blood on it and removed her (the employee) gown and gloves where blood had splattered.. She did not notify the Registered Nurse.<br><br>2. On 3/5/14 at 11:45 AM, the clinical manager indicated the PCT did not follow the policy and procedure for CVC care.<br><br>3. The agency policy and procedure | | | |

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| | titled "Initiation of Treatment using a Central Venous Catheter and Optiflux single use ebeam dialyzer" with an effective date of January 6, 2014, stated, "Do not apply excessive force to the catheter with the syringe ... 1. Remove the syringe filled with blood from the arterial catheter limb and immediately attach a 10 ml [milliliter] filled syringe. 2. Discard the syringe with blood into the appropriate hazardous receptacle. 3. Open catheter clamp and gently flush with saline and then reclamp. 4. Repeat steps 1 - 3 for the venous catheter limb.<br><br>4. The agency procedure titled "Patient Care technicians and unlicensed staff" with an effective date of 12/13 stated, "12. Using aseptic technique remove blood - filled syringe from venous limb and immediately attached 10 ml syringe. 13. Opens venous catheter limb clamp and gently flushes limb with sterile saline, closes clamp."<br><br>5. The agency policy titled "Eligibility and Performance Requirements for Registered Nurse, Licensed Practical Nurse or Patient Care Technician to Perform Hemodialysis Catheter Care" with an effective date of Sept. 25, 2013, stated, "RN must implement all nursing judgements and interventions." | | | |

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| | 6. The agency policy titled "Complications of Hemodialysis -- Management and Prevention of Air Embolus" with an effective date of October 3, 2012, stated, "Air embolism occurs when a large quantity of air is introduced into the blood stream ... treatment related causes ... open end of central venous catheter ... To prevent air embolus during hemodialysis treatment ... secure all luer - lok connections through the extracorporeal circuit, return patient's blood with saline."<br><br>7. On 3/6/14 at 11:35 AM, Employee A, the administrator, indicated Employee H would be repeating all training with central venous catheter care and would not care for patients until this was completed and she was observed by the facility educator and demonstrated competency in these tasks again. | | | |

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| V000147 | 494.30(a)(2)<br>IC-STAFF EDUCATION-CATHETERS/CATHETER CARE<br>Recommendations for Placement of Intravascular Catheters in Adults and Children<br><br>I. Health care worker education and training<br>A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections.<br>B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters.<br><br>II. Surveillance<br>A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site.<br><br>Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.<br><br>VI. Catheter and catheter-site care<br>B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections]. | | | |
| | 8. On 3/6/14 at 11 AM, employee H was observed in station 4 with patient 5, a patient with a central venous catheter (CVC). Employee H was observed to don a mask prior to the initiation of | V000147 | IC Staff Education-Catheters/Catheter Care<br><br>On March 6, 2014, the Clinical Manager conducted a mandatory staff meeting for all Direct Patient | 03/28/2014 |

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| | dialysis with patient 5. Following this, she then pulled the mask below her nose and mouth and proceeded to care for another patient with a CVC, patient 10 in station 3. Employee H pulled the same mask back over her nose and mouth and initiated hemodialysis via the patient's CVC access without donning a clean mask. | | Care staff to reinforce both the expectation and responsibility of facility staff in adhering to the hemodialysis catheter policies of this facility.<br><br>To ensure that all staff understands the importance of proper hand hygiene, the Director of Operations contacted the educational department and arranged for the formal reeducation of all staff to be completed no later than March 28, 2014. This reeducation was inclusive of the following facility policies and procedures:<br>· FMS-CS-IC-I-105-002 A & C Initiation of Treatment using a Central VenousCatheter and Optiflux Single Use Ebeam Dialyzer Policy & Procedure<br>· FMS-CS-IC-I-115-025A Eligibility andPerformance Requirements for RegisteredNurse, Licensed Practical Nurse or Patient CareTechnician to Perform Hemodialysis CatheterCare<br>· FMS-CS-IC-II-125-014A Complications ofHemodialysis - Management and Prevention ofAir Embolus<br><br>The Staff meeting attendance record and in-service attendance forms document this activity and are available for review at the facility.<br><br>Monitoring of the staff for | |

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| | | | compliance is the responsibility of the Clinical Manager or assigned Nurse will occur by:<br>· Direct observation of the staff's adherence to infection control policies and procedures.<br>· Immediate intervention, consisting of reeducation up to disciplinary action, to address and correct identified noncompliance with the appropriate staff member.<br><br>Beginning March 19, 2014, the Clinical Manager or assigned nurse utilizes the plan of correction monitoring tool during each patient shift with decreased frequency based upon evaluation of staff compliance as determined by the Governing Body. Any identified staff non-compliance will have an immediate intervention<br>by the Clinical Manager and assigned nurse providing oversight. The noncompliance and intervention will be documented on the Infection Assessment Tool or in the employees personnel file if warranted.<br><br>In the event that a staff member is found to continually not follow the facility procedures for infection control, the Director of Operations will be notified and is responsible to ensure that progressive disciplinary action is | |

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| | | | applied. Progressive disciplinary action will be structured to reinforce by further education following through as necessary with the application of progressive disciplinary action up to and including termination.<br><br>The Clinical Manager will summarize the findings identified from the monitoring process and report weekly to the Governing Body. The Governing Body will review status of staff compliance and will determine further the need of audit frequency and when it determines, decrease the frequency incrementally. Additionally the summaries are compiled and reported to the QAI committee at its monthly meeting. Upon determination of compliance by the Governing Body, the monitoring will revert to the QAI infection control audit schedule.<br><br>The Clinical Manager is responsible to ensure staff compliance to policy and procedure and the Director of Operations will monitor for ongoing compliance through Governing Body oversight and the QAI process | |
| | Based on observations, staff interview, and review of policies and procedures, the facility failed to ensure all patients with a central venous catheter (CVC) received care in compliance with facility policy in 2 of 5 observations of initiation | | | |

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| | of hemodialysis creating the potential to create an air emboli and spread infectious and communicable disease which could affect all in-center patients. (Patients 5 and 10)<br><br>Findings<br><br>1. On 3/4/14 at 11:05 AM, Employee H, patient care technician (PCT), was initiating treatment on patient #10 who had a CVC at station #3. The PCT had attached a syringe to the venous catheter limb with the clamp closed. Approximately 10 cc (cubic centimeters) of blood was in the syringe. The PCT withdrew the plunger aggressively causing the plunger to withdraw from the syringe into the PCT's hand. Approximately 5 cc of blood splashed onto the patient's clothes and the PCT. She clamped the line and reinserted the plunger back into the syringe. She took the patient's shirt off which had blood on it and removed her (the employee) gown and gloves where blood had splattered.. She did not notify the Registered Nurse.<br><br>2. On 3/5/14 at 11:45 AM, the clinical manager indicated the PCT did not follow the policy and procedure for CVC care.<br><br>3. The agency policy and procedure | | | |

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| | titled "Initiation of Treatment using a Central Venous Catheter and Optiflux single use ebeam dialyzer" with an effective date of January 6, 2014, stated, "Do not apply excessive force to the catheter with the syringe ... 1. Remove the syringe filled with blood from the arterial catheter limb and immediately attach a 10 ml [milliliter] filled syringe. 2. Discard the syringe with blood into the appropriate hazardous receptacle. 3. Open catheter clamp and gently flush with saline and then reclamp. 4. Repeat steps 1 - 3 for the venous catheter limb.<br><br>4. The agency procedure titled "Patient Care technicians and unlicensed staff" with an effective date of 12/13 stated, "12. Using aseptic technique remove blood - filled syringe from venous limb and immediately attached 10 ml syringe. 13. Opens venous catheter limb clamp and gently flushes limb with sterile saline, closes clamp."<br><br>5. The agency policy titled "Eligibility and Performance Requirements for Registered Nurse, Licensed Practical Nurse or Patient Care Technician to Perform Hemodialysis Catheter Care" with an effective date of Sept. 25, 2013, stated, "RN must implement all nursing judgements and interventions." | | | |

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| | 6. The agency policy titled "Complications of Hemodialysis -- Management and Prevention of Air Embolus" with an effective date of October 3, 2012, stated, "Air embolism occurs when a large quantity of air is introduced into the blood stream ... treatment related causes ... open end of central venous catheter ... To prevent air embolus during hemodialysis treatment ... secure all luer - lok connections through the extracorporeal circuit, return patient's blood with saline."<br><br>7. On 3/6/14 at 11:35 AM, Employee A, the administrator, indicated Employee H would be repeating all training with central venous catheter care and would not care for patients until this was completed and she was observed by the facility educator and demonstrated competency in these tasks again. | | | |
| V000250 | 494.40(a)<br>DIALYS PROPORT-MONITOR PH/CONDUCTIVITY<br>5.6 Dialysate proportioning: monitor pH/conductivity<br>It is necessary for the operator to follow the manufacturer's instructions regarding dialysate conductivity and to measure approximate pH with an independent method before starting the treatment of the next patient.<br><br>Based on observations, staff interview, and review of policies and procedures, | V000250 | Dialysis Proport-Monitor PH/Conductivity<br>-<br>On March 6, 2014, the Clinical | 03/28/2014 |

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| | the facility failed to ensure that 2 of 4 observations of checking conductivity and pH of Final Dialysate prior to initiating treatment (observations 1 and 4) followed the facility policy creating the potential to not obtain an acceptable range for final dialysate conductivity for all patients receiving incenter hemodialysis at the facility. (Patients 13 and 15)<br><br>Findings<br><br>1. The agency policy titled "Checking Conductivity and pH of Final Dialysate" with a November 5, 2013, stated, "For all dialysis programs: 2 staff members ... will verify the conductivity and pH parameters prior to treatment: to verify conductivity and pH readings, Both staff watch the test being performed at the same time or if the test is not performed and results observed by both people at the same time, the second person [staff or care partner] must perform the test to verify the initial test results."<br><br>2. On 3/4/14 at 10:34 AM, Employee H, patient care technician (PCT), was observed to check the conductivity of the PH on the final dialysate with the Phoenix Meter and then shout out the displayed reading to Employee I, PCT, who was about 10 feet away. Employee | | Manager conducted a mandatory staff meeting for all Direct Patient Care staff to reinforce both the expectation and responsibility of facility staff in adhering to facility requirement that two staff members verify the results of the final dialysate conductivity with the hand held meter.<br><br>To ensure that all staff understands the importance of monitoring the Final Dialysate for conductivity and pH, the Director of Operations contacted the educational department and arranged for the formal reeducation of all staff to be completed no later than March 28, 2014. This reeducation will be inclusive of the following facility policies and procedures:<br>· FMS-CS-IC-II-140-500A Checking Conductivity and pH of Final Dialysate Policy<br>· FMS-CS-IC-II-140-510C1 Checking Conductivity and pH of Final Dialysate with phoenix Meter Procedure<br><br>The Educational Agendas and Attendance Sheets will document the in-services referenced above and, along with the referenced policies, will be available for review at the facility.<br>The Clinical Manager is responsible and the QAI committee monitors to ensure ongoing compliance.<br>Beginning March 19, 2014, the Clinical Manager or assigned | |

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| | I did not look at the reading on the Phoenix meter. This occurred with at Station #2 on machine #6 with patient #13.<br><br>3. On 3/4/14 at 10:34 AM, Employee H indicated the pH reading was 13.6.<br><br>4. On 3/4/14 at 10:34 AM, Employee I indicated that she heard the pH reading.<br><br>5. On 3/6/14 at 11:13 AM, Employee H was observed to check the conductivity of the PH on the final dialysate with the Phoenix Meter and then stated aloud the displayed reading to Employee D, Registered Nurse, who was about 4 feet away. Employee D did not look at the reading on the Phoenix meter. This occurred with at Station #2 on machine #18 with Patient #15.<br><br>6. On 3/6/14 at 11:13 AM, Employee H indicated aloud what the pH reading was.<br><br>7. On 3/6/14 at 11:13 AM, Employee D indicated the reading was verified with Employee H.<br><br>8. On 3/6/14 at 11:14 AM, the facility educator, Employee E, indicated the pH reading should be verified by visually reading the Phoenix meter result with 2 | | nurse utilizes the plan of correction monitoring tool during each patient shift with decreased frequency based upon evaluation of staff compliance as determined by the Governing Body. Any identified staff non-compliance will have an immediate intervention by the Clinical Manager and assigned nurse providing oversight. The noncompliance and intervention will be documented on the Assessment Tool or in the employees personnel file if warranted.<br><br>In the event that a staff member is found to continually not follow the facility procedures for infection control, the Director of Operations will be notified and is responsible to ensure that progressive disciplinary action is applied. Progressive disciplinary action will be structured to reinforce by further education following through as necessary with the application of progressive disciplinary action up to and including termination.<br><br>The Clinical Manager will summarize the findings identified from the monitoring process and report weekly to the Governing Body. The Governing Body will review status of staff compliance and will determine further the need of audit frequency and when it determines, decrease the frequency incrementally. | |

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NAME OF PROVIDER OR SUPPLIER: FRESENIUS MEDICAL CARE INDIANAPOLIS MIDTOWN

STREET ADDRESS, CITY, STATE, ZIP CODE: 3007 DR ANDREW J BROWN AVE INDIANAPOLIS, IN 46205

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| | staff members. | | Additionally the summaries are compiled and reported to the QAI committee at its monthly meeting. Upon determination of compliance by the Governing Body, the monitoring will revert to the QAI infection control audit schedule.<br><br>The Clinical Manager is responsible to ensure staff compliance to policy and procedure and the Director of Operations will monitor for ongoing compliance through Governing Body oversight and the QAI process. | |
| V000401 | 494.60<br>PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT<br>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.<br><br>Based on observations, staff interview, clinical record review, and review of policies and procedures, the dialysis failed to ensure the patient care technician drew up the right dose of medication according to facility policy at 1 of 3 observations of medication administration (Day #1 observation #1) creating the potential to affect all patients receiving medications from this employee (I). | V000401 | PE-Safe/functional/Comfortable Environment<br><br>On March 6, 2014, the Clinical Manager conducted a mandatory staff meeting for all Direct Patient Care staff to reinforce both the expectation and responsibility of facility staff in adhering tothe | 03/28/2014 |

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| | Findings<br><br>1. On 3/4/14 at 10:10 AM, at observation #1 on day #1, Employee I, patient care technician (PCT), was observed to care for patient #11 by administering 2.1 units per milliliter of heparin into the arterial port and 2.2 units per milliliter of heparin into the venous port with two separate syringes each with 3 units per milliliter of heparin. She was observed to waste amounts of heparin into the trash can by the patent's chair and then administer the amounts left in each syringe into the arterial and venous ports.<br><br>2. On 3/4/14 at 10:10 AM, Employee I indicated she always drew up 3 units and then wasted the amount not needed by reading the amount to be given on the patient's arterial and venous port catheter lock and wasting the heparin.<br><br>3. On 3/4/14 at 11:16 AM, the charge nurse, Employee C, indicated the policy is not to draw up more than is needed for medication administration.<br><br>4. On 3/5/14 at 1:20 PM, Employee A, the operations manager, indicated the PCT did not follow the policy of the agency when drawing up the medication. | | medication administration policies of this facility.<br><br>To ensure that all staff understands the importance of medication preparation and administration, the Director of Operations contacted the educational department and arranged for the formal reeducation of all staff to be completed no later than March 28, 2014. This reeducation was inclusive of the following facility policies and procedures:<br><br>· FMS-CS-IC-I-120-040 A & C Medication Preparationand Administration Policy & Procedure<br>The Staff meeting attendance record and in-service attendance forms document this activity and are available for review at the facility.<br><br>Monitoring of the staff for compliance is the responsibility of the Clinical Manager or assigned Nurse will occur by:<br>· Direct observation of the staff's adherence to medication policies and procedures.<br>· Immediate intervention, consisting of reeducation up to disciplinary action, to address and correct identified noncompliance with the appropriate staff member.<br>Beginning March 19, 2014, the Clinical Manager or assigned nurse utilizes the plan of | |

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| | 5. Clinical record #11, with an admission date of 11/26/11, included orders for Heparin 2.2 units per milliliter of heparin / venous port and 2.1 units per milliliter into the arterial port at the onset of dialysis into the catheter lock with the post dialysis treatments.<br><br>6. The facility policy titled "Medication Preparation and Administration" with an effective date of December 30, 2013 stated, "Follow the principles of medication preparation and administration. Follow the '6 Rs' of medication administration when drawing up and giving medications. The '6 Rs' are: Right Drug, Right Dose, Right Route, Right Time, Right Patient, Right Documentation."<br><br>7. The facility procedure titled "Medication Preparation and Administration" with an effective date of September 25, 2013, stated, "[When drawing up medication] Pull plunger back to withdraw the amount of medication ordered by the physician." | | correction monitoring tool during each patient shift with decreased frequency based upon evaluation of staff compliance as determined by the Governing Body. Any identified staff non-compliance will have an immediate intervention by the Clinical Manager and assigned nurse providing oversight. The noncompliance and intervention will be documented on the Infection Assessment Tool or in the employees personnel file if warranted.<br>In the event that a staff member is found to continually not follow the facility procedures for infection control, the Director of Operations will be notified and is responsible to ensure that progressive disciplinary action is applied. Progressive disciplinary action will be structured to reinforce by further education following through as necessary with the application of progressive disciplinary action up to and including termination.<br><br>The Clinical Manager will summarize the findings identified from the monitoring process and report weekly to the Governing Body. The Governing Body will review status of staff compliance and will determine further the need of audit frequency and when it determines, decrease the frequency incrementally. Additionally the summaries are compiled and reported to the QAI | |

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| | | | committee at itsmonthly meeting. Upon determination of compliance by the Governing Body, the monitoring will revert to the QAI infection control audit schedule.<br><br>The Clinical Manager is responsible to ensure staff compliance to policy and procedure and the Director of Operations will monitor for ongoing compliance through Governing Body oversight and the QAI process. | |
| V000543 | 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;<br><br>Based on clinical record and facility policy review, and interview, the facility failed to ensure patients' blood pressures were checked every 30 minutes in 3 of 16 records reviewed (#2, 3, and 7) with the potential to affect all the facility's patients.<br><br>The findings include:<br><br>1. The facility's "Patient Monitoring | V000543 | V543 POC-Manage Volume Status On March 18, 2014, the Clinical Manager met with the facility direct patient care staff to reinforce facility management's expectations that staff will comply with the facility patient care policies to monitor patient vital signs at the required intervals. To ensure that all staff understands the requirements of these polices, the Clinical Manager contacted the educational department and arranged for the formal reeducation of all staff to be | 03/28/2014 |

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| | During Patient Treatment" dated July 4, 2012 states, "Vital signs will be monitored at the initiation of dialysis and every 30 minutes."<br><br>2. On 3/6/14 at 1:50 PM, employee A and B indicated the facility policy is to assess the patient's blood pressure and check the patient every 30 minutes.<br><br>3. Review of clinical record number 2 included twelve post hemodialysis treatment flow sheets dated 1/15/14 through 3/4/14. Four of the twelve post treatment flow sheets failed to evidence the patient's vital signs were checked at least every 30 minutes.<br><br>A.. The treatment flow sheet dated 1/24/14, evidenced the patient was assessed at 1:08 PM and not again until 2:04 PM, a period of 56 minutes between checks.<br><br>B. The treatment flow sheet, dated 2/12/14, evidenced the patient's dialysis treatment was started at 11:15 AM. The documentation indicated a blood pressure was assessed prior to dialysis at an unknown time, standing and sitting. The post treatment record failed to evidence the patient's blood pressure was assessed until 12:39 PM, a period of 1 hour and 14 minutes. | | completed no later than March 28, 2014. This reeducation was inclusive of the following facility policy and procedure: · FMS-CS-IC-I-110-133A Monitoring During Patient Treatment Policy with emphasis on but not limited to o Vital Signs and Mental Status: Vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently as needed · FMS-CS-IC-I-110-141A & C Safety Checks Policy & ProceduresTo prevent reoccurrence and to monitor compliance the following has been implemented: · Clinical Manager or assigned Nurse is responsible to review each patient's treatment sheets by utilization of the Plan of Correction Audit Tool Staff members identified as failing to comply with the implemented process will receive immediate intervention by the nurse providing oversight and/or the Clinical ManagerThe Clinical Manager reports findings of rounding summaries and any non-compliance with reference to the process at the monthly QAI meeting. The QAI Committee will address any variance to the required process by identifying the root cause and developing and implementing a corrective action plan to resolution of the issue. The Clinical Manager is responsible for reinforcing compliance and the QAI | |

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| | C. The treatment flow sheet dated 2/26/14, evidenced the patient's blood pressure was assessed at 11:36 AM and not again until 12:16 PM, assessed at 1:47 PM, and not again until 2:42 PM, and the next assessment was not until 3:34 PM, a period of 40 minutes, 55 minutes, and 52 minutes between checks respectively.<br><br>D. The treatment flow sheet dated 3/4/14, evidenced the patient's blood pressure was assessed at 11:07 AM and not again until 11:47 AM, a period of 40 minutes between checks.<br><br>4. Review of clinical record number 3 included thirteen post hemodialysis treatment flow sheets dated 2/1/14 through 3/1/14. Eight of the thirteen post treatment flow sheets failed to evidence the patient's vital signs were checked at least every 30 minutes.<br><br>A. The treatment flow sheet dated 2/1/14 evidenced the patient was assessed at 9:10 AM and then again at 10:10 AM, a period of 60 minutes between checks.<br><br>B. The treatment flow sheet dated 2/6/14 evidenced the patient was assessed at 8:36 AM and then again at | | Committee will monitor for compliance | |

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| | 9:42 AM, a period of 66 minutes between checks.<br><br>C. The treatment flow sheet dated 2/8/14 evidenced the patient's treatment began at 5:30 AM and then not again until 6:36 AM, a period of 66 minutes between checks.<br><br>D. The treatment flow sheet dated 2/13/14 evidenced the patient was assessed at 5:41 AM and then not again until 6:38 AM, a period of 57 minutes between checks.<br><br>E. The treatment flow sheet dated 2/18/14 evidenced the patient was assessed at 5:56 AM, was not again assessed until 7:08 AM, a period of 1 hour and fourteen minutes, was assessed at 9:05 AM and was not again until 10:22 AM, then the next assessment was 11:11 AM, and then the next assessment was at 12:05 PM, a period of 1 hour and 17 minutes, 49 minutes, and 54 minutes respectively.<br><br>F. The treatment flow sheet dated 2/22/14 evidenced the patient was assessed at 5:46 AM, was not again assessed until 6:30 AM, a period of 44 minutes, and was not assessed again until 7:40 AM, a period of one hour and ten minutes. The patient was assessed at | | | |

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| | 8:41 AM and then not assessed again until 9:53 AM, a period of one hour and 12 minutes, and then was not assessed again until 10:50 AM, a period of 57 minutes.<br><br>G. The treatment flow sheet dated 2/25/14 evidenced the patient was assessed at 7:35 AM, was not again assessed until 8:35 AM, a period of one hour between assessments.<br><br>H. The treatment flow sheet dated 2/27/14 evidenced the patient was assessed at 6:32 AM, then not again until 7:13 AM, and then next assessment was not until 8:14 AM, 41 minutes and one hour and 1 minute respectively between assessments.<br><br>5. Review of clinical record number 7 included nine post hemodialysis treatment flow sheets dated 2/5/14 through 3/3/14. Nine post treatment flow sheets failed to evidence the patient's vital signs were checked at least every 30 minutes.<br><br>A. The treatment flow sheet dated 2/5/14 evidenced the patient was assessed at 1:05 PM and then not again until 2:49 PM, a period of one hour and 44 minutes between checks. | | | |

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| | B. The treatment flow sheet dated 2/7/14 evidenced the patient was assessed at 1:06 PM, then not again until 2:12 PM, and then again at 3:48 PM, a period of one hour and 6 minutes and one hour and 36 minutes respectively between checks.<br><br>C. The treatment flow sheet dated 2/12/14 evidenced the patient's treatment began at 11:45 AM, was assessed at 11:50 AM, and was then not assessed again until 12:36 PM, and period of 46 minutes between assessments. The patient's was assessed at 1:06 PM and was not assessed again until 2:07 PM, a period of 61 minutes between checks.<br><br>D. The treatment flow sheet dated 2/14/14 evidenced the patient was assessed at 12:42 PM and then not again until 1:49 PM, a period of 67 minutes between checks. At 2:36 PM the patient's vital signs were assessed then not again until 3:42 PM, a period of 1 hour and 6 minutes between checks.<br><br>E. The treatment flow sheet dated 2/19/14 evidenced the patient was assessed at 12:42 PM and was not assessed again until 1:54 PM, a period of 1 hour and 12 minutes between checks. | | | |

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| | F. The treatment flow sheet dated 2/22/14 evidenced the patient was assessed at 1 PM and was not assessed again until 2 PM, a period of 1 hour between checks.<br><br>G. The treatment flow sheet dated 2/24/14 evidenced the patient was assessed at 12:47 PM and was not assessed again until 1:37 PM, a period of 50 minutes between checks. The post treatment record failed to evidence a blood pressure was assessed again. the patient's treatment ended at 2:53 PM, a period of 1 hour and 16 minutes since the last time a blood pressure was assessed.<br><br>H. The treatment flow sheet dated 2/28/14 evidenced the patient was assessed at 2:06 PM and was not assessed again until 3:12 PM, a period of 1 hour and 6 minutes between checks.<br><br>I. The treatment flow sheet dated 3/3/14 evidenced the patient was assessed at 12:09 PM and was not again assessed until 1:05 PM, a period of 56 minutes, the next assessment was at 2:26 PM, a period of 1 hour and 21 minutes. | | | |

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| V000637 | 494.110(a)(2)(ix)<br>QAPI-INDICATOR-INF<br>CONT-TREND/PLAN/ACT<br>The program must include, but not be limited to, the following:<br>(ix) Infection control; with respect to this component the facility must-<br>(A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence;<br>(B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and<br>(C) Take actions to reduce future incidents.<br><br>Based on administrative record, facility policy, and clinical record review and interview, the facility failed to ensure a quality assessment and performance improvement (QAPI) program was in place that identified and analyzed infections of all patients to prevent the cross contamination and minimize infection transmission to staff and patients with compromised immune systems creating the potential to affect all of the facility's 72 current patients and all staff.<br><br>The findings include:<br><br>1. The facility's QAPI meeting minutes dated December 2013 and January and February 2014 indicated a patient of the facility had a graft infection identified as MRSA (methicillin resistant staph aureus) in December of 2013. The | V000637 | V637 QAPI-Indicator-INF Cont-Trend/Plan/Act<br><br>As a result of the citations from the March 6th , survey and as is the commitment of the Medical Director to ensure that its Quality Assessment Improvement program provides complete data analysis, tracking and documentation of selected indicators, upon receipt of the Statement of deficiencies and a part of the developed plan of correction, the following actions have occurred<br><br>On March 24, 2014, the Divisional Director of Quality, provided an in-service to the Clinical Manager which included:<br>· CMS QAPI requirements and findings from the March 6th survey<br>· Overview of QAI 2014 Template and Tools Presentation<br>· Review of specific template and tools for data analysis | 03/28/2014 |

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| | patient was identified as a hospitalized patient for a graft pseudo aneurysm in December of 2013, with blood cultures drawn at the hospital prior to the surgery to replace the graft. The blood cultures identified a MRSA infection in the graft that was replaced. The patient was hospitalized in January of 2014 for another MRSA infection identified in the replaced graft.<br><br>The facility administrative QAPI records failed to include awareness of the infection, the infection in their data, and follow through with assessment of infection control precautions, and an assessment of any breaks in infection control protocol.<br><br>2. On 3/7/14 at 3:00 PM Employee A indicated that the infections reviewed in the QAPI meetings were infections that were identified within the facility and where the facility had ordered the blood cultures. Employee A indicated that infections identified outside the facility, as in the case of patient #5, were not reviewed under the facility QAPI process - in this case because the physician at the facility did not have privileges at the hospital where the graft was replaced and the infection identified | | including trending of infections<br>· Review of the previous 6 months of QAPI documentation to identify:<br>o Failure to report all required infections<br>o Inconsistent use of tools<br>o Lack of root cause analysis to identified infections<br><br>The Medical Director as lead of the QAI committee directed the Clinical Manager develop a formal QAI action plan to trend and analyze the incidences of patient infections in the dialysis setting and a second one to review patient hospitalizations. Each new episode of documented infection will require a root cause analysis with the identification of any common factors associated with the incidence and specific actions necessary to prevent reoccurrence.<br><br>The Clinical Manager will present the action plans along with applied interventions at the next scheduled QAI meeting on March 26, 2014<br>.<br><br>The Clinical Manager is responsible to monitor, document and report on the implemented action plans directly to the Medical Director and document on the report to the QAI committee.<br>Going forward, the Clinical Manager will be responsible to | |

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| | Therefore, obtaining the medical record information was difficult, if not impossible, as the hospital was not cooperative in furnishing information to practitioners who did not have privileges to treat patients there. Employee A indicated that discharge physician orders would contain the antibiotic the patient was to be treated with, but obtaining information beyond that was a hardship. Employee A indicated the agency policy was to review facility identified infections in QAPI and the facility staff was following their policy. Employee A indicated that due to risk to other patients in the facility, the infection review process in QAPI should probably be expanded to include all patient infections regardless of the source of identification, even though as staff were expected to follow universal precautions, the risk of infecting a patient or staff member via cross contamination was minimal.<br>3. Agency policy, FMS CS I IOI 001 /A, 4 APRIL 2012: QUALITY ASSESSMENT AND IMPROVEMENT PROGRAM states, "Examples of urgent priorities which could pose a threat to | | compare the treatment data and quality indicator outcomes for each patient infection to determine any potential relationship to treatment provided a the facility. The Clinical Manager is responsible to present a summary of her findings to the QAI committee monthly for review and discussion.<br><br>If sufficient progress to correct the identified deficiencies in not met, the QAI committee will direct the revision of the action plan until resolution is achieved.<br><br>The Clinical Manager is responsible and the QAI committee will monitor for compliance. | |

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| | the health and safety of our patients and require immediate correction include but are not limited to: ... Potential for cross-contamination between infected and non infected patients."<br>4. At 4 PM on 3/7/14, Employee A indicated the facility would need to review all patient infections, not just facility identified infections, in order to successfully complete the quality assurance tasks per quality assurance policy and maintain patient safety.<br>5. Clinical record 5 evidenced the patient was admitted to the hospital on 12/21/13 due to a ruptured pseudoaneurysm of the left upper extremity arteriovenous graft. The hospital summary indicated a blood culture was collected and it was determined the patient had a methicillin resistant staphylococcus aureus (MRSA) infection. The patient's graft was replaced and the facility utilized the graft access for dialysis treatment from 1/3/14 until the patient was identified with an elevated body temperature and sent to the emergency room on 2/12/14. It was determined this graft was also infected with MRSA and was replaced | | | |

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| | on 2/14/14 and a central venous catheter was placed. | | | |
| V000676 | 494.130<br>LAB-CLIA LABS/MEET NEEDS OF PTS<br>The dialysis facility must provide or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. Any laboratory services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter.<br><br>Based on observation, staff interview, and review of policies and procedures, the dialysis failed to ensure 1 of 1 patient care technician observation (Employee H) placed lab specimens in a clearly marked area for lab specimens with the potential to affect all the patients, staff, and visitors to the facility.<br><br>Findings<br><br>1. On 3/4/14 at 11 AM, it was observed that Employee H, patient care technician, drew the labs from patient #10 at station #3 and machine #13 and placed the lab specimens into the prime bucket after the labs were drawn.<br><br>2. The facility policy titled "Use of | V000676 | V676 Lab-CLIA Labs/Meet Needs of PTS<br><br>On March 6, 2014, the Clinical Manager conducted a mandatory staff meeting for all Direct Patient Care staff to reinforce both the expectation and responsibility of facility staff in adhering to facility policies regarding the handling of lab specimens.<br><br>To ensure that all staff understands the importance of the handling of lab specimens, the Director of Operations contacted the educational department and arranged for the formal reeducation of all staff to be completed no later than March 28, 2014. This reeducation was inclusive of the following facility policies and procedures: | 03/28/2014 |

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| | Priming buckets" with an effective date of June 19. 2013, stated, "A priming bucket ... is for the collection of Normal Saline Only."<br><br>3. The facility policy titled "Dialysis Precautions" with an effective date of January 4, 2012, stated, "Clean areas should be clearly separated from dirty areas where used supplies, equipment, blood supplies or biohazard containers are stored or handled."<br><br>4. On 3/4/14 at 2:55 PM, Employee E, the facility educator, indicated the prime bucket was not to be used for lab specimens. | | · FMS-CS-IS-I-510-011A Use of the Priming Buckets<br>· FMS-CS-IC-II-155-070A Dialysis Precautions<br>· Proper Handling of Lab Specimens<br><br>The Staff meeting attendance record and in-service attendance forms document this activity and are available for review at the facility.<br><br>Monitoring of the staff for compliance is the responsibility of the Clinical Manager or assigned Nurse will occur by:<br>· Direct observation of the staff's adherence to infection control policies and procedures.<br>· Immediate intervention, consisting of reeducation up to disciplinary action, to address and correct identified noncompliance with the appropriate staff member.<br><br>Beginning March 19, 2014, the Clinical Manager or assigned nurse utilizes the plan of correction monitoring tool during each patient shift with decreased frequency based upon evaluation of staff compliance as determined by the Governing Body. Any identified staff non-compliance will have an immediate intervention by the Clinical Manager and assigned nurse providing oversight. The noncompliance and intervention | |

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| | | | will be documented on the Infection Assessment Tool or in the employees personnel file if warranted.<br><br>In the event that a staff member is found to continually not follow the facility procedures for infection control or the handling of lab specimens, the Director of Operations will be notified and is responsible to ensure that progressive disciplinary action is applied.<br><br>Progressive disciplinary action will be structured to reinforce by further education following through as necessary with the application of progressive disciplinary action up to and including termination.<br><br>The Clinical Manager will summarize the findings identified from the monitoring process and report weekly to the Governing Body. The Governing Body will review status of staff compliance and will determine further the need of audit frequency and when it determines, decrease the frequency incrementally Additionally the summaries are compiled and reported to the QAI committee at is monthly meeting. Upon determination of compliance by the Governing | |

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| | | | Body, the monitoring will revert to the QAI infection control audit schedule.<br><br>The Clinical Manager is responsible to ensure staff compliance to policy and procedure and the Director of Operations will monitor for ongoing compliance through Governing Body oversight and the QAI process | |
| V000715 | 494.150(c)(2)(i)<br>MD RESP-ENSURE ALL ADHERE TO P&P<br>The medical director must-<br>(2) Ensure that-<br>(i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers;<br><br>Based on clinical record and facility policy review, and interview, the medical director failed to ensure all personnel had adhered to facility policies and procedures relative to patient care in 3 of 16 records reviewed (#2, 3, and 7) with the potential to affect all the facility's patients.<br><br>The findings include:<br><br>1. The facility's "Patient Monitoring During Patient Treatment" dated July 4, 2012 states, "Vital signs will be monitored at the initiation of dialysis | V000715 | V715 MD Resp-Ensure All Adhere to P&P<br>The Medical Director of this facility takes seriously his responsibility to ensure that facility policy and procedures are adhered to by all facility staff. As such, the Medical Director met with the Clinical Manager on March 17, 2014, to emphasize expectations that each member of the staff comply with the requirement to follow policy and procedures written as a requirement of their jobs. Additionally the Medical Director directed the Clinical Manager to educate the facility direct patient care staff and implement a process to monitor adherence to | 03/28/2014 |

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| | and every 30 minutes."<br><br>2. On 3/6/14 at 1:50 PM, employee A and B indicated the facility policy is to assess the patient's blood pressure and check the patient every 30 minutes.<br><br>3. Review of clinical record number 2 included twelve post hemodialysis treatment flow sheets dated 1/15/14 through 3/4/14. Four of the twelve post treatment flow sheets failed to evidence the patient's vital signs were checked at least every 30 minutes.<br><br>A.. The treatment flow sheet dated 1/24/14, evidenced the patient was assessed at 1:08 PM and not again until 2:04 PM, a period of 56 minutes between checks.<br><br>B. The treatment flow sheet, dated 2/12/14, evidenced the patient's dialysis treatment was started at 11:15 AM. The documentation indicated a blood pressure was assessed prior to dialysis at an unknown time, standing and sitting. The post treatment record failed to evidence the patient's blood pressure was assessed until 12:39 PM, a period of 1 hour and 14 minutes.<br><br>C. The treatment flow sheet dated 2/26/14, evidenced the patient's blood | | the following policies and procedures:<br>· FMS-CS-IC-I-110-133A Monitoring During Patient Treatment Policy with emphasis on but not limited to<br>o Vital Signs and Mental Status: " Vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently as needed"<br>· FMS-CS-IC-I-110-141A Safety Checks Policy<br>· FMS-CS-IC-I-110-141C Safety Checks Procedure<br><br>To ensure compliance, the Medical Director instructed the Clinical Manager to monitor the direct patient care staff for compliance to policy and procedure.<br><br>The Clinical Manager discusses findings with the Medical Director weekly providing a status update of any identified issues along with the applied interventions. Additionally, the Clinical Manager summarizes her findings to the QAI committee which the Medical Director chairs. The committee analyzes the data and determines if further action is warranted and following up as it determines is necessary. All reported events are evaluated for trends, and corrective and/or preventative measures implemented as warranted. | |

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| | pressure was assessed at 11:36 AM and not again until 12:16 PM, assessed at 1:47 PM, and not again until 2:42 PM, and the next assessment was not until 3:34 PM, a period of 40 minutes, 55 minutes, and 52 minutes between checks respectively.<br><br>D. The treatment flow sheet dated 3/4/14, evidenced the patient's blood pressure was assessed at 11:07 AM and not again until 11:47 AM, a period of 40 minutes between checks.<br><br>4. Review of clinical record number 3 included thirteen post hemodialysis treatment flow sheets dated 2/1/14 through 3/1/14. Eight of the thirteen post treatment flow sheets failed to evidence the patient's vital signs were checked at least every 30 minutes.<br><br>A. The treatment flow sheet dated 2/1/14 evidenced the patient was assessed at 9:10 AM and then again at 10:10 AM, a period of 60 minutes between checks.<br><br>B. The treatment flow sheet dated 2/6/14 evidenced the patient was assessed at 8:36 AM and then again at 9:42 AM, a period of 66 minutes between checks. | | The committee may recommend procedural or operational changes that are required to prevent reoccurrence of significant events. Target dates for implementation should be included. QAI minutes document this activity and will be available for review at the facility.<br>The Clinical Manager is responsible and the Medical Director through the QAI process monitors for compliance. | |

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| | C. The treatment flow sheet dated 2/8/14 evidenced the patient's treatment began at 5:30 AM and then not again until 6:36 AM, a period of 66 minutes between checks.<br><br>D. The treatment flow sheet dated 2/13/14 evidenced the patient was assessed at 5:41 AM and then not again until 6:38 AM, a period of 57 minutes between checks.<br><br>E. The treatment flow sheet dated 2/18/14 evidenced the patient was assessed at 5:56 AM, was not again assessed until 7:08 AM, a period of 1 hour and fourteen minutes, was assessed at 9:05 AM and was not again until 10:22 AM, then the next assessment was 11:11 AM, and then the next assessment was at 12:05 PM, a period of 1 hour and 17 minutes, 49 minutes, and 54 minutes respectively.<br><br>F. The treatment flow sheet dated 2/22/14 evidenced the patient was assessed at 5:46 AM, was not again assessed until 6:30 AM, a period of 44 minutes, and was not assessed again until 7:40 AM, a period of one hour and ten minutes. The patient was assessed at 8:41 AM and then not assessed again until 9:53 AM, a period of one hour and 12 minutes, and then was not assessed | | | |

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| | again until 10:50 AM, a period of 57 minutes.<br><br>G. The treatment flow sheet dated 2/25/14 evidenced the patient was assessed at 7:35 AM, was not again assessed until 8:35 AM, a period of one hour between assessments.<br><br>H. The treatment flow sheet dated 2/27/14 evidenced the patient was assessed at 6:32 AM, then not again until 7:13 AM, and then next assessment was not until 8:14 AM, 41 minutes and one hour and 1 minute respectively between assessments.<br><br>5. Review of clinical record number 7 included nine post hemodialysis treatment flow sheets dated 2/5/14 through 3/3/14. Nine post treatment flow sheets failed to evidence the patient's vital signs were checked at least every 30 minutes.<br><br>A. The treatment flow sheet dated 2/5/14 evidenced the patient was assessed at 1:05 PM and then not again until 2:49 PM, a period of one hour and 44 minutes between checks.<br><br>B. The treatment flow sheet dated 2/7/14 evidenced the patient was assessed at 1:06 PM, then not again | | | |

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| | until 2:12 PM, and then again at 3:48 PM, a period of one hour and 6 minutes and one hour and 36 minutes respectively between checks.<br><br>C. The treatment flow sheet dated 2/12/14 evidenced the patient's treatment began at 11:45 AM, was assessed at 11:50 AM, and was then not assessed again until 12:36 PM, and period of 46 minutes between assessments. The patient's was assessed at 1:06 PM and was not assessed again until 2:07 PM, a period of 61 minutes between checks.<br><br>D. The treatment flow sheet dated 2/14/14 evidenced the patient was assessed at 12:42 PM and then not again until 1:49 PM, a period of 67 minutes between checks. At 2:36 PM the patient's vital signs were assessed then not again until 3:42 PM, a period of 1 hour and 6 minutes between checks.<br><br>E. The treatment flow sheet dated 2/19/14 evidenced the patient was assessed at 12:42 PM and was not assessed again until 1:54 PM, a period of 1 hour and 12 minutes between checks.<br><br>F. The treatment flow sheet dated 2/22/14 evidenced the patient was assessed at 1 PM and was not assessed | | | |

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| | again until 2 PM, a period of 1 hour between checks.<br><br>G. The treatment flow sheet dated 2/24/14 evidenced the patient was assessed at 12:47 PM and was not assessed again until 1:37 PM, a period of 50 minutes between checks. The post treatment record failed to evidence a blood pressure was assessed again. the patient's treatment ended at 2:53 PM, a period of 1 hour and 16 minutes since the last time a blood pressure was assessed.<br><br>H. The treatment flow sheet dated 2/28/14 evidenced the patient was assessed at 2:06 PM and was not assessed again until 3:12 PM, a period of 1 hour and 6 minutes between checks.<br><br>I. The treatment flow sheet dated 3/3/14 evidenced the patient was assessed at 12:09 PM and was not again assessed until 1:05 PM, a period of 56 minutes, the next assessment was at 2:26 PM, a period of 1 hour and 21 minutes. | | | |