

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152515	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 09/26/2013
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE FORT WAYNE JEFFERSON			STREET ADDRESS, CITY, STATE, ZIP CODE 7838 W JEFFERSON BLVD STE B FORT WAYNE, IN 46804		
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V000000	<p>This was a federal ESRD recertification survey.</p> <p>Survey Dates: 9/23-26, 2013.</p> <p>Facility #: 005160</p> <p>Medicaid Vendor #: 100081860</p> <p>Surveyors: Miriam Bennett, RN, BSN, PHNS Vicki Harmon, RN, PHNS</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN October 2, 2013</p>	V000000			

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 that other safeguards 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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V000113	<p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.</p> <p>Based on observation and policy review, the facility failed to ensure staff followed Centers for Disease Control (CDC) recommendations and facility infection control policies during the initiation of dialysis treatments in 2 of 2 observations of access of arteriovenous fistula (AVF) for initiation of dialysis creating the potential to affect all dialysis patients with AVFs.</p> <p>Findings include:</p>	V000113	<p>On 9/24/13, the Operations Manager and Clinic Manager met with the staff including employees E and G to review the policy Cannulation Site Selection and Skin Preparation (FMS-CS-IS-I-520-005A) with specific focus on skin preparation and the importance of not touching the cleaned site after disinfection due to risk of recontamination of the site.</p> <p>Starting on October 9th, Clinic Manager or designee will conduct an audit daily of proper cleaning of the access sites. Audit will be completed daily for two weeks, weekly for four weeks.</p> <p>Frequency of ongoing audits will be determined through the QAI Committee upon review of audit findings and resolution of the issues. The results of the audit will be documented and reported in the monthly Governing Body meetings and at QAI. Any evidence of non-compliance will be immediately brought to the attention of the Director of Operations by the Clinical Manager. Appropriate intervention and corrective action will be taken for infraction of the policy. The CM is responsible. Any corrective action given can</p>	10/09/2013	

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	<p>1. Employee E was observed to initiate the dialysis treatment on patient number 9 on 9-24-13 at 8 AM. The employee was observed to cleanse the cannulation site with Betadine soaked gauze and then palpated the site. The employee did not cleanse the site again after palpating and inserted the first of 2 needles.</p> <p>2. Employee G was observed to initial the dialysis treatment on patient number 10 on 9-25-13 at 7:40 AM. The employee cleansed the cannulation sites with Betadine soaked gauze and then palpated the first site. The employee did not cleanse the site again after palpating and inserted the first of 2 needles. The employee secured the needle with tape. The employee palpated the 2nd needle insertion site and, without cleansing the insertion site again, inserted the 2nd of 2 needles.</p>		<p>be found in the employee file. The CM is responsible to review and analyze all monitoring data prior to the QAI Meeting and present monthly to the QAI Committee. The Director of Operations is responsible to ensure that the CM presents all data, as required and defined within the POC, to the QAI Committee. The QAI Committee is responsible to provide oversight and ensure resolution is occurring.</p>		

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	<p>3. The facility's 1-16-09 "Cannulation Site Selection and Skin Preparation" procedure number FMS-CS.IS-I-520-005C states, "DO NOT TOUCH THE CLEANED SITE AFTER DISINFECTION. Recontamination of site occurs if touched after cleansing with antiseptic solution."</p>			
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V000115	<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, policy review, and interview, the facility failed to ensure staff removed Personal Protective Equipment (PPE) prior to leaving treatment area and failed to ensure staff changed PPE prior to re-entering the treatment area for 2 of 2 observations involving staff leaving the treatment area with the potential to affect all 78 of the facility's current patients.</p> <p>Findings include</p> <p>1. During observation on 9/23/13 at 2:40 PM, employee I escorted patient # 14 from station out to patient lobby. The employee carried the patient's personal bag holding it against the PPE gown. Employee I failed to remove the gown prior to leaving the treatment area and returned to the treatment area, returning to patient care, without changing the gown.</p>	V000115	<p>On 9/23/13, the Operations Manager and Clinic Manager in-serviced the staff including employee I on Personal Protective Equipment (FMS-CS-IC-II-155-080A) with specific focus on the appropriate uses of PPE including the need to remove prior to leaving the treatment area. Starting on October 9th, Clinic Manager or designee will conduct an audit daily including observation of proper uses of PPE including the need to remove prior to leaving the treatment area.. Audit will be completed daily for a period of 2 weeks then continue weekly for 4 weeks until reviewed by QAI. Frequency of ongoing audits will be determined through the QAI Committee upon review of audit findings and resolution of the issues. The results of the audit will be documented and reported in Governing Body meetings and at QAI. Any evidence of non-compliance will be immediately brought to the</p>	10/09/2013			

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	<p>2. During observation on 9/23/13 at 2:45 PM, employee I escorted patient # 13 from station out to patient lobby and carried the patient's personal bag over employee's shoulder against PPE gown. Employee I failed to remove gown prior to leaving treatment area and returned to treatment area without changing the gown. The employee then engaged in a discontinuation of dialysis on a patient with a Central Venous Catheter.</p> <p>3. On 9/23/13 at 2:50 PM, a sign was observed on the door to the patient lobby that stated, "No PPE beyond this point."</p> <p>4. On 9/23/13 at 4:05 PM, employee W indicated PPE should be removed prior to leaving the treatment area.</p> <p>5. The facility's policy titled "Personal Protective Equipment," #FMS-CS-IC-II-155-080A, revised March 20, 2013 states, "All personal protective equipment shall be removed prior to leaving the treatment area."</p>		<p>attention of the Director of Operations by the Clinical Manager. Appropriate intervention and corrective action will be taken for infraction of the policy. The CM is responsible. Any corrective action given can be found in the employee file.</p> <p>The CM is responsible to review and analyze all monitoring data prior to the QAI Meeting and present monthly to the QAI Committee. The Director of Operations is responsible to ensure that the CM presents all data, as required and defined within the POC, to the QAI Committee. The QAI Committee is responsible to provide oversight and ensure resolution is occurring.</p>		

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V000147	<p>494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE Recommendations for Placement of Intravascular Catheters in Adults and Children</p> <p>I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters.</p> <p>II. Surveillance 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.</p> <p>Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.</p> <p>VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].</p> <p>Based on observation, interview, and facility policy review, the facility failed to ensure central venous catheter (CVC) exit site care was performed per the facility's policy in 2 (#s 1 and 2) of 2 CVC exit site care observations completed creating the</p>	V000147	On 9/25/13, the Operations Manager and Clinic Manager in-serviced the staff including employee E on the procedure Changing the Catheter Dressing (FMS-CS-IC-I-105-032C) with specific focus on cleansing of the	10/09/2013	

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	<p>potential to affect all patients with a CVC.</p> <p>The findings include</p> <ol style="list-style-type: none"> Employee E was observed to change the CVC exit site dressing on patient number 1 on 9-24-13 at 9:00 AM. The employee removed the old dressing and cleansed her hands and changed her gloves. The employee cleansed around the catheter exit site starting approximately 1 to 2 millimeters away from the actual exit site. The employee failed to cleanse the exit site itself. Employee E was observed to change the CVC exit site dressing on patient number 11 on 9-25-13 at 10 AM. The employee removed the old dressing and cleansed her hands and changed her gloves. The employee cleansed around the catheter exit site starting approximately 1 to 2 millimeters away from the actual exit site. The employee failed to cleanse the exit site itself. Observation noted a small amount of dark brown crusting around the catheter at the exit site. The clinic manager, employee A, indicated, on 9-26-13 at 9:15 AM, the employee had not cleansed the catheter exit site in accordance with facility policy. 		<p>site, step #2 which states "Starting at the catheter exit site and working outward to the periphery use gentle friction and back and forth motion to clean for 30 seconds (see figure 1). Use both sides of the swab stick to clean an area the size of the dressing to be applied. Discard swabstick after use." Starting on October 9th, Clinic Manager or designee will conduct an audit daily including observation of cleansing the catheter site per policy and procedure. Audit will be completed daily for a period of 2 weeks then continue weekly for 4 weeks until reviewed by QAI. Frequency of ongoing audits will be determined through the QAI Committee upon review of audit findings and resolution of the issues. The results of the audit will be documented and reported in Governing Body meetings and at QAI. Any evidence of non-compliance will be immediately brought to the attention of the Director of Operations by the Clinical Manager. Appropriate intervention and corrective action will be taken for infraction of the policy. The CM is responsible. Any corrective action given can be found in the employee file.</p> <p>The CM is responsible to review and analyze all monitoring data prior to the QAI Meeting and present monthly to the QAI Committee. The Director of Operations is responsible to</p>				

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	4. The facility's 4-4-12 "Changing the Catheter Dressing" procedure number FMS-CS-IC-I-105-032C states, "Starting at the catheter exit site and working outward to the periphery use gentle friction and back and forth motion to clean for 30 seconds . . . If exudate of crusting is noted, an additional swabstick may be necessary to clean the exit site."		ensure that the CM presents all data, as required and defined within the POC, to the QAI Committee. The QAI Committee is responsible to provide oversight and ensure resolution is occurring.	

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V000543	<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 clinical record review and policy review, the facility failed to ensure it had managed the patients' volume status by addressing those patients that had not attained their physician ordered estimated dry weights in 5 (#s 2, 3, 4, 5, & 6) of 8 records reviewed creating the potential to affect all of the facility's 78 current patients.</p> <p>The findings include</p> <p>1. Clinical record #2 included physician orders dated 6/21/13 that identified the physician ordered estimated dry weight (EDW) as 74.5 kilograms (kg) and orders dated 9/6/13 that identified the physician ordered EDW as 74.1 kg.</p> <p>A. A treatment sheet dated 8/21/13 evidenced the patient's post dialysis weight was 75.3 kg.</p> <p>B. A treatment sheet dated 8/23/13 evidenced the patient's post dialysis weight was 75.4 kg.</p>	V000543	<p>On 9/24/13, the Clinic Manager and Operations Manager in-serviced the staff on the Patient Monitoring During Patient Treatment document FMS-CS-IC-I-110-133A with emphasis on ensuring that the patient's treatment is delivered according to the physician's prescription. If unable to achieve prescribed estimated dry weights, the Patient Care technician will notify the nurse of the inability to achieve the estimated dry weight and document notification on the flowsheet. The nurse will assess the patient's UF Rate/Removal and notify the physician accordingly. Specific assessment/observation, interventions and follow-up including outcome will be documented by the staff on the patient's flowsheet. In addition, the RNs were in-serviced on the Comprehensive Interdisciplinary Assessment and Plan of Care policy document FMS-CS-IC-I-110-125A on 10/7/13 specifically on trending of fluid management and all staff inserviced by 10/12/13 on the document Nursing Supervision and Delegation policy document</p>	10/14/2013			

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	<p>C. A treatment sheet dated 9/9/13 evidenced the patient's post dialysis weight was 77.4 kg.</p> <p>D. A treatment sheet dated 9/12/13 evidenced the patient's post dialysis weight was 73.7 kg.</p> <p>E. B. A treatment sheet dated 9/14/13 evidenced the patient's post dialysis weight was 74.3 kg.</p> <p>F. A treatment sheet dated 9/17/13 evidenced the patient's post dialysis weight was 74.7 kg.</p> <p>G. A treatment sheet dated 9/19/13 evidenced the patient's post dialysis weight was 74.3 kg.</p> <p>2. Clinical record #4 included physician orders dated 8/9/13 that identified the physician ordered EDW as 62.5 kg. A treatment sheet dated 9/9/13 evidenced the patient's post dialysis weight was 59.6 kg.</p> <p>3. Clinical record number 3 included physician orders dated 8-10-13 that</p>		<p>FMS-CS-IC-I-110-149A on when the nurse should be notified specific to fluid management. RN Rounding tool to be implemented starting week of 10/14/13. The Clinical Manager or designee will review treatment sheets daily for 2 weeks, then weekly for 4 weeks to ensure that patient's estimated dry weight is achieved as prescribed (+/- 0.5 kg), or if unable to achieve, notification of the physician and the action taken is documented on the patient treatment sheet and addressed in the patient's plan of care; on-going monthly audits will follow as part of the QAI program. The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body. The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to analyze the results and determine a root cause analysis then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.</p>				

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	<p>identified the desired post treatment target weight was 128.5 kilograms (kg).</p> <p>A. A post treatment flow sheet dated 9-3-13 evidenced the patient's weight at the end of the treatment was 132.1 kg.</p> <p>B. A post treatment flow sheet dated 9-5-13 evidenced the patient's weight at the end of the treatment was 130 kg.</p> <p>C. A post treatment flow sheet dated 9-17-13 evidenced the patient's weight at the end of the treatment was 130.9 kg.</p> <p>4. Clinical record number 5 included physician orders dated 8-9-13 that identified the desired post treatment target weight was 75 kg.</p> <p>A. A post treatment flow sheet dated 9-18-13 evidenced the patient's weight at the end of the treatment was 76.2 kg.</p> <p>B. A post treatment flow sheet dated 9-20-13 evidenced the patient's weight at the end of the treatment was 76.5 kg.</p> <p>C. A post treatment flow sheet dated 9-23-13 evidenced the patient's weight at the end of the treatment was 77 kg.</p> <p>5. Clinical record number 6 included physician orders dated 5-17-13 that</p>				

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	<p>identified the desired post treatment target weight was 66.3 kg.</p> <p>A. A post treatment flow sheet dated 9-18-13 evidenced the patient's weight at the end of the treatment was 69 kg.</p> <p>B. A post treatment flow sheet dated 9-20-13 evidenced the patient's weight at the end of the treatment was 70 kg.</p> <p>6. The facility's policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care" #FMS-CS-IC-I-110-125A, revised July 4, 2012, states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: ... Dose of Dialysis Sustain the prescribed dose of dialysis to meet FMS target HD eKdrt/V of 2.0 ... Provide necessary care and services to manage the patient's volume status."</p>				

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V000544	<p>494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. Based on clinical record review, policy review, and interview, the facility failed to ensure blood flow rates had been maintained as ordered and the correct dialysate was used as ordered for 2 (#s 1 and 4) of 8 records reviewed with the potential to affect all of the facility's 78 current patients.</p> <p>Findings include:</p> <p>1. The facility's policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care" #FMS-CS-IC-I-110-125A, revised July 4, 2012 states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: ... Dose of Dialysis Sustain the prescribed dose of dialysis to meet FMS target HD eKdrt/V of 2.0 ... Provide necessary care and services to manage the patient's volume status."</p> <p>2. The facility's policy titled "Interventions for Sub-optimal Blood Flow," #136-020-225, dated 4/09/03</p>	V000544	<p>On 9/24/13, the Clinic Manager and Operations Manager in-serviced the staff on the Patient Monitoring During Patient Treatment document FMS-CS-IC-I-110-133 with emphasis on ensuring that the patient's treatment is delivered according to the physician's prescription including Blood Flow Rate and correct dialysate. If unable to achieve prescribed Blood Flow Rate, the Patient Care technician will document the reason and interventions taken on the patient's flowsheet. The Patient Care technician will notify the nurse of the inability to achieve the Prescribed Blood Flow Rate and document notification on the flowsheet. The nurse will assess the patient's access and notify the physician. Specific assessment/observation, interventions and follow-up including outcome will be documented by the staff on the patient's flowsheet. In addition, the RNs were in-serviced on the "Comprehensive Interdisciplinary Assessment and Plan of Care" policy document FMS-CS-IC-I-110-125A on 10/7/13 specifically on the</p>	10/14/2013

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152515		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 09/26/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE FORT WAYNE JEFFERSON				STREET ADDRESS, CITY, STATE, ZIP CODE 7838 W JEFFERSON BLVD STE B FORT WAYNE, IN 46804			
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	<p>states, "5. As a last resort, bloodlines may be reversed. ... Due to recirculation which results, a measure of compromise in the adequacy of the dialysis treatment the physician must be informed if this intervention is required in order to achieve an increased blood flow rate. 6. If all other interventions have failed to restore adequate flow, treatment of the catheter with a thrombolytic agent may be attempted, with a physician's order. ... NOTE: If unable to achieve the prescribed blood flow without excessive negative pre-pump arterial pressure or positive venous pressure, blood flow must be reduced until pressure values are within acceptable parameters. Actual blood flow and reason for deviation from prescribed blood flow should be documented and the physician must be informed. ... All observations, assessments and/or interventions and response to those interventions related to poor CVC blood flow should be thoroughly documented in the patient's medical record."</p> <p>3. Clinical record #4 included physician orders dated 8/9/13 that identified the blood flow rate (BFR) was to be 450 milliliters per minute.</p> <p>A. Post dialysis treatment flow sheets dated 9/2, 9/4, and 9/18/13 evidenced the</p>		<p>prescribed dose of dialysis to meet target of Kt/v of 1.2. In addition, all staff inserviced by 10/12/13 on the document Nursing Supervision and Delegation policy document FMS-CS-IC-I-110-149A on when the nurse should be notified. RN Rounding tool to be implemented starting week of 10/14/13. The Clinical Manager or designee will review treatment sheets daily for 2 weeks, then weekly for 4 weeks to ensure that patient's blood flow rate is delivered as prescribed, or if unable to achieve, the action taken is documented in the patient's treatment sheet and addressed in the patient's plan of care. On-going monthly audits will follow as part of the QAI program.; on-going monthly audits will follow as part of the QAI program. The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body. The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to analyze the results and determine a root cause analysis then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be</p>				

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	<p>BFR ran at 350 during the treatment.</p> <p>B. A post dialysis treatment flow sheet dated 9/6/13 evidenced the BFR ranged from 315-350 during the treatment.</p> <p>C. Post dialysis treatment flow sheets dated 9/9, 9/11, 9/13, 9/16, and 9/20/13 evidenced the BFR ranged from 200-350 during the treatment.</p> <p>D. On 9/23/13 at 12:20 PM, employee W indicated if staff cannot run the dialysate at the ordered BFR, they need to obtain a new order to run slower.</p> <p>4. Clinical record number 1 included physician orders dated 9-24-13 that identified the dialysate to be used was a 2.0 potassium and 2.25 calcium mixture. Observation, on 9-24-13 at 2:15 PM, noted the facility does not mix any 2 potassium and 2.25 calcium mixtures.</p> <p>The clinic manager, employee A, indicated, on 9-26-13 at 9:15 AM, patient number 1 transferred from another facility and the order discrepancy was not noted. The manager indicated the patient had received a 2 potassium 2.5 calcium dialysate bath while dialyzing at this facility.</p>		monitored by the QAI committee		

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V000547	<p>494.90(a)(4) POC-MANAGE ANEMIA/H/H MEASURED Q MO</p> <p>The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level.</p> <p>The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs. Based on clinical record review and interview, the facility failed to ensure a hemoglobin was obtained on admission and Epopo was administered as ordered for 2 (#s 1 and 5) of 8 clinical records reviewed with the potential to affect all of the facility's 78 current patients.</p> <p>Findings include</p>	V000547	<p>To specifically address inclusion of managing anemia and monitoring hemoglobin/hematocrit monthly as part of the developed patient care plan, the following has occurred: Reeducation of the IDT and attending physicians to policy FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care on October 10th 2013. Amgen will provide an anemia in-service to Anemia Manager and Clinic Manager on October 3rd 2013 with a follow up meeting scheduled October 28th. Review EPOGEN® IVP Administration (InCenter Only) Version 4.0 Corporate algorithm with Anemia Manager. Effective immediately, the Anemia Manager or Clinic Manager will ensure that all new patients have hemoglobin levels upon admission prior to receiving ESA therapy. The Clinical Manager is responsible to report a summary of findings monthly to the QAI. The QAI Committee is responsible to analyze the results</p>	10/28/2013	

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	<p>1. Clinical record number 1 included physician orders dated 9-17-13 that identified the patient's anemia was to be managed per the facility's corporate anemia algorithm. The record identified the patient had been on Epogen 6600 units 3 times per week at a prior facility upon transfer to this facility and that the order had been continued at this facility. The algorithm identifies for a new patient already on an ESA (erythropoetin stimulating agent) the facility should draw a hemoglobin level upon admission at the patient's first treatment. The record evidenced the patient's first treatment at this facility was 9-17-13. The record failed to evidence the facility had drawn a hemoglobin level upon admission at the patient's first treatment at this facility.</p> <p>A. Post treatment flow sheets, dated 9-17-13, 9-19-13, and 9-21-13, failed to evidence the 6600 units Epogen had been administered during the treatment as</p>		<p>and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee. The Director of Operations is responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body.</p>		

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	<p>ordered.</p> <p>B. The Clinical Operations Manager, employee W, stated, on 9-24-13 at 2:30 PM, "We should have gotten a hemoglobin on [the patient]."</p> <p>2. Clinical record number 5 evidenced the patient's hemoglobin level was 11.8 on 9-4-13 and that the Epogen dose had been held per the corporate algorithm. The record evidenced the patient's hemoglobin level was 11.3 on 9-16-13 and that Epogen had been re-started at 6200 units 3 times per week. The facility's corporate anemia management algorithm identifies dose changes are to be made monthly unless certain exceptions apply. The record failed to evidence the exceptions applied to this patient.</p> <p>The clinic manager, employee A, indicated, on 9-24-13 at 3:50 PM, the Epogen should have been re-started 1 month after the 9-16-13 lab draw.</p>				

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V000550	<p>494.90(a)(5) POC-VASCULAR ACCESS-MONITOR/REFERRALS The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement.</p> <p>Based on clinical record review, interview, and facility policy review, the facility failed to identify the correct vascular access used during dialysis and failed to document catheter care per policy for 5 (#s 1, 3, 4, 5, and 6) of 8 records reviewed creating the potential to affect all 48 current in center patients.</p> <p>The findings include:</p> <p>1. The facility's policy titled "Interventions for Sub-optimal Blood Flow," #136-020-225, dated 4/09/03 states, "To assess and correct flow interruption, strategies outlined below should be attempted: 1. Lowering the patient's head. ... 2. Have the patient cough. ... 3. Change the patient's position from side to side. ... 4. With temporary catheters, it may be possible to rotate the catheter up to 180 degrees. ... 5. As a</p>	V000550	To specifically address inclusion of vascular access monitoring monthly as part of the developed patient care plan, the following has occurred: Reeducation of the IDT and attending physicians to policy FMS-CS-IC-I-110-125A Comprehensive Interdisciplinary Assessment and Plan of Care on October 10th 2013. Staff in-service on September 24th 2013 on the Patient Monitoring During Patient Treatment document FMS-CS-IC-I-110-133 with emphasis on ensuring that the patient's treatment is delivered according to the physician's prescription. If unable to achieve prescribed Blood Flow Rate, the Patient Care technician will document the reason and interventions taken on the patient's flowsheet. The Patient Care technician will notify the nurse of the inability to achieve the Prescribed Blood Flow Rate and document the notification on the flowsheet. The nurse will assess the patient's access and	10/25/2013			

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	<p>last resort, bloodlines may be reversed. ... Due to recirculation which results, a measure of compromise in the adequacy of the dialysis treatment the physician must be informed if this intervention is required in order to achieve an increased blood flow rate. 6. If all other interventions have failed to restore adequate flow, treatment of the catheter with a thrombolytic agent may be attempted, with a physician's order. ... NOTE: If unable to achieve the prescribed blood flow without excessive negative pre-pump arterial pressure or positive venous pressure, blood flow must be reduced until pressure values are within acceptable parameters. Actual blood flow and reason for deviation from prescribed blood flow should be documented and the physician must be informed. ... All observations, assessments and/or interventions and response to those interventions related to poor CVC blood flow should be thoroughly documented in the patient's medical record."</p> <p>2. The facility's policy titled "Administration of Replacement Fluid During Dialysis (Bolus Method)," #FMS CS-IC-I-110-143C, revised July 4, 2012 states, "6 Administer 100 to 200 mls [milliliters] of normal saline depending on patient symptoms or MD order."</p>		<p>notify the physician. Specific assessment/observation, interventions and follow-up including outcome will be documented by the staff on the patient's flowsheet. Staff in-service on October 9th 2013 on the Complications of Hemodialysis: Management and Prevention of Poor Access Blood Flow document FMS-CS-IC-II-125-025A specifically addressing actions to achieve blood flow rates including interventions and documentations of such. RNs also educated on the policy Administration of Replacement Fluid During Dialysis (Bolus Method) document FMS-CS-IC-I-110-143C specifically to notification, obtaining and documentation of physician order. Review of 100% of the patient records by October 25th 2013 to ensure accurate identification of primary and secondary vascular accesses. Any records found out of compliance will have a plan of care update completed and discussed at the care plan meeting on October 25th 2013 including patients #1, 3, 4, 5 and 6. Vascular access champion has been identified and is responsible for reviewing accuracy of primary and secondary vascular accesses on a bimonthly basis. Staff in-service by 10/12/13 on the document Nursing Supervision and Delegation policy document FMS-CS-IC-I-110-149A</p>				

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	<p>3. Clinical record #4 contained physician orders dated 8/9/13 for dialysis with the preferred access: Arterial Venous (AV) Graft-Standard.</p> <p>A. The record evidenced the patient's access was a central venous catheter. Post treatment flow sheets, dated 8-31-13, 9-2-13, 9-4-13, 9-6-13, 9-9-13, 9-11-13, 9-13-13, 9-16-13, 9-18-13, and 9-20-13, state, "Catheter Care." The flow sheets failed to include documentation of any observations of the exit site, observations regarding the integrity of the catheter, or any notifications to the charge nurse of abnormal findings, if any.</p> <p>B. The Quality Status Report dated 8/31/13 states patient #4 has a catheter.</p> <p>C. A treatment sheet dated 9/2/13 evidenced vascular access used was Arterial Venous Graft (AVG) and the lines were reversed at 12:15, 14:03, and 15:03. The record failed to evidence the physician was notified of the need to reverse lines.</p> <p>D. A treatment sheet dated 9/4/13 evidenced vascular access used was AVG and the lines were reversed at 13:04, 14:02, and 15:03. The record failed to evidence the physician was notified of the</p>		<p>on when the nurse should be notified.RN Rounding tool to be implemented starting week of 10/14/13.Treatment sheets will be audited daily for 2 weeks, monthly for 4 weeks until reviewed by QAI for addressing patients not meeting the prescribed blood flow rates, for proper documentation of catheter care including RN/physician interventions and notifications of any abnormal findings.Frequency of ongoing audits will be determined through the QAI Committee upon review of audit findings and resolution of the issues.The results of the audit will be documented and reported in Governing Body meetings and at QAI. The Clinical Manager is responsible to report a summary of findings monthly to the QAI. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee. The Director of Operations is responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body.</p>				

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE FORT WAYNE JEFFERSON	STREET ADDRESS, CITY, STATE, ZIP CODE 7838 W JEFFERSON BLVD STE B FORT WAYNE, IN 46804
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	<p>need to reverse lines.</p> <p>E. A treatment sheet dated 9/6/13 evidenced vascular access used was AVG and Registered Nurse (RN) noted left permcath was accessed without difficulty.</p> <p>F. A treatment sheet dated 9/9/13 evidenced vascular access used was AVG, lines were reversed at 12:05, and RN noted left permcath was accessed without difficulty. The record failed to evidence the physician was notified of the need to reverse lines.</p> <p>G. A treatment sheet dated 9/11/13 evidenced vascular access used was AVG and RN noted left permcath was accessed without difficulty.</p> <p>H. A treatment sheet dated 9/13/13 evidenced vascular access used was AVG. Lines were reversed at 11:19 and multidisciplinary notes state patient was hot and not feeling good. The patient was given 500 milliliters of Normal Saline (NS). The record failed to evidence a written order for the Normal Saline. The record failed to evidence the physician was notified of the need to reverse lines.</p> <p>On 9/23/13 at 1:40 PM, employee W indicated the NS order for this patient was a verbal order from the physician while</p>			

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	<p>on the unit, and the RN should have written the order but did not.</p> <p>I. A treatment sheet dated 9/16/13 evidenced vascular access used was AVG and the lines were reversed at 11:57, 12:36, 15:21, and 15:37. The record failed to evidence the physician was notified of the need to reverse lines.</p> <p>J. A treatment sheet dated 9/18/13 evidenced vascular access used was AVG and the lines were reversed at 11:12, 11:33, 12:02, 12:39, 13:32, 14:05, and 14:40. Multidisciplinary notes written at 12:08 state the lines were reversed due to poor blood flow. The record failed to evidence the physician was notified.</p> <p>K. A treatment sheet dated 9/20/13 evidenced vascular access used was AVG.</p> <p>L. On 9/23/13 at 1:25 PM, employee W indicated the techs reversing lines means they are dialyzing through a catheter. At 1:40 PM, employee W indicated they talked with staff and discovered the techs were dialyzing patient #4 via the perm cath due to the arterial venous fistula was not working, and the staff should have identified the perm cath on the treatment sheets.</p> <p>4. Clinical record number 1 evidenced</p>						

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE FORT WAYNE JEFFERSON	STREET ADDRESS, CITY, STATE, ZIP CODE 7838 W JEFFERSON BLVD STE B FORT WAYNE, IN 46804
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	<p>the patient's access was a central venous catheter. Post treatment flow sheets, dated 9-17-13 and 9-19-13, failed to evidence any access care had been completed. A post treatment flow sheet dated 9-21-13 states, "Catheter Care." The flow sheet failed to include documentation of any observations of the exit site, observations regarding the integrity of the catheter, or any notifications to the charge nurse of abnormal findings, if any.</p> <p>5. Clinical record number 3 evidenced the patient's access was a central venous catheter. Post treatment flow sheets, dated 8-31-13, 9-3-13, 9-5-13, 9-7-13, 9-10-13, 9-12-13, 9-14-13, 9-17-13, 9-19-13, and 9-21-13, state, "Catheter Care." The flow sheets failed to include documentation of any observations of the exit site, observations regarding the integrity of the catheter, or any notifications to the charge nurse of abnormal findings, if any.</p> <p>6. Clinical record number 5 evidenced the patient's access was a central venous catheter. Post treatment flow sheets, dated 8-30-13, 9-4-13, 9-6-13, 9-9-13, 9-11-13, 9-13-13, 9-16-13, 9-18-13, 9-20-13, and 9-23-13, state, "Catheter Care." The flow sheets failed to include documentation of any observations of the</p>			

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	<p>exit site, observations regarding the integrity of the catheter, or any notifications to the charge nurse of abnormal findings, if any.</p> <p>7. Clinical record number 6 evidenced the patient's access was a central venous catheter. Post treatment flow sheets, dated 9-4-13, 9-6-13, 9-16-13, 9-18-13, and 9-20-13, state, "catheter care." The flow sheets failed to include documentation of any observations of the exit site, observations regarding the integrity of the catheter, or any notifications to the charge nurse of abnormal findings, if any.</p>			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152515		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 09/26/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE FORT WAYNE JEFFERSON				STREET ADDRESS, CITY, STATE, ZIP CODE 7838 W JEFFERSON BLVD STE B FORT WAYNE, IN 46804			
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V000628	<p>494.110(a)(2) QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS</p> <p>The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves.</p> <p>Based on quality assurance performance improvement (QAPI) document and facility policy review and interview, the facility failed to ensure its QAPI program included monitoring of fluid management and a review of transplant related information creating the potential to affect all of the facility's 78 current patients.</p> <p>Findings include</p> <p>1. The facility's QAPI meeting minutes failed to evidence the tracking of fluid management and transplant related information.</p> <p>A. On 9/26/13 at 8:55 AM, employee W indicated the facility does not track fluid management as a subject.</p> <p>B. On 9/26/13 at 9:25 AM, employee A indicated the facility does not discuss the percentage of transplant candidates, etcetera in QAPI.</p>	V000628	<p>On 10/10/13, the Director of Operation scheduled a conference call with all participants of the QAI committee for the purpose of reeducation on policy titled Quality Assessment and Performance Improvement Program (QAPI) document FMS-CS-IC-I-101-001A. This education included but was not limited to the following: Monitoring of fluid management Review of transplant related information The Clinical Manager will be responsible for trending/tracking of fluid management and note IDT discussion in Section 1 - Patient Outcomes of the QAI meeting minutes under "ICHHD Adequacy eKt/v>1.2" specifically. The Clinic Manager will be responsible for reporting each month the number of active patients on each of the transplant provider's list and the number of patients in the process of having work ups prior to being placed in active status on the transplant provider list. IDT discussion of transplant status will be documented in Section 5 called</p>	10/25/2013			

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	2. The facility's policy titled "Quality Assessment and Performance Improvement Program (QAPI)," #FMS-CS-IC-I-101-001A, revised April 4, 2012 states, "Elements of QAI Elements to be reviewed in the QAI meeting include: Patient Care Outcomes."		"Other Clinical Issues" for Patient Care Services. The Clinical Manager is responsible to report a summary of findings monthly. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee. The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to analyze the results and determine a root cause analysis then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee		