

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152530	X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	X3) DATE SURVEY COMPLETED  08/27/2015
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NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART	STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517
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V 0000  Bldg. 00	<p>This was a Federal ESRD [core] recertification survey.</p> <p>Survey Dates: August 25, 26, and 27, 2015</p> <p>Facility #: 007697</p> <p>Medicaid Vendor #: 200032320B</p> <p>QA; LD, R.N.</p>	V 0000		
V 0147  Bldg. 00	<p>494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE</p> <p>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>			

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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	<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 document review, the facility failed to ensure the patient care technician (PCT) provided central venous catheter care in accordance with facility policy in 1 (patient #14) of 1 observations of care of patients with a central venous catheter completed by a patient care technician (employee E).</p> <p>Findings include:</p> <p>1. On 8/27/15 at 10:35 AM, employee E, a patient care technician, was observed in station #8 with patient #14, a patient with a central venous catheter (CVC). The patient had a field under the CVC ports that was visibly stained with a brown substance. The employee failed to place a clean field under the CVC ports prior to discontinuation of dialysis.</p> <p>On 8/27/15 at 10:40 AM, employee E indicated the field was placed under the CVC ports at the time of initiation of</p>	V 0147	<p>The Director of Operations and Clinical Manager will meet with the Medical Director on September 21, 2015 to review the survey statement of deficiencies and plan of correction. The Clinical Manager provided a mandatory in-service to the patient care staff on Friday, August 28, 2015 to review the requirements of the following policy and procedure: #FMS-CS-IC-I-105-028C "Termination of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer Procedure" and #FMS-CS-IC-105-028A "Termination of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer Policy" with emphasis placed on placing a clean barrier under the catheter before termination of treatment and dressing change to protect the work area. The Clinical Manager or designee will audit compliance with this policy and procedure on each Central Venous Catheter patient daily x 2 weeks, followed by weekly on each Central</p>	09/28/2015

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V 0543 Bldg. 00	<p>dialysis treatment and remained under the ports throughout the duration of treatment.</p> <p>2. On 8/27/15 at 2:10 PM, employee J, clinical manager, indicated staff should be changing the field under the CVC ports prior to discontinuation of treatment.</p> <p>3. The facility policy with an effective date as January 6, 2014 titled "Termination of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer" states, "Prior to Termination: Preparation Follow the steps below to prepare for the termination of dialysis: ... Step 5. Ensure that a clean under pad is below the catheter limbs to protect the work area and the clothing. ... ."</p> <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 document review and interview, the facility failed to ensure the patient's blood pressure had been monitored at least every 30 minutes in 4 of 10 in-center hemodialysis patient's</p>	V 0543	<p>Venous Catheter patient x 2 weeks and then monthly until 100% compliance is achieved. Any variance in policy or procedure will be immediately addressed and corrected, including corrective action if warranted. The Clinical Manager is responsible for follow up of audit findings and reporting monthly to the QAI Committee, who will then determine the ongoing audit frequency based on compliance achieved. The Director of Operations is responsible to ensure the Clinical Manager presents all data as defined with the Plan of Correction to the QAI Committee. The QAI Committee is responsible to provide oversight and ensure resolution is occurring.</p> <p>The Director of Operations and Clinical Manager will meet with the Medical Director on September 21, 2015 to review the survey statement of deficiencies and plan of correction.</p>	09/28/2015			

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	<p>records reviewed. (#1, 4, 9, and 10)</p> <p>Findings include:</p> <p>1. Clinical record #1 included hemodialysis treatment flow sheets dated 8/20 and 8/25/15 that evidenced the patient's blood pressure had not been monitored at least every 30 minutes during treatment.</p> <p>A. A hemodialysis treatment flow sheet dated 8/20/15 evidenced vital signs and a safety check had been completed at 9:31 AM and not again until 10:36 AM, a period of 65 minutes between checks. The vital signs and a safety check were then completed at 11:23 AM, a period of 47 minutes between checks.</p> <p>B. A hemodialysis treatment flow sheet dated 8/25/15 evidenced vital signs and a safety check had been completed at 12:00 PM and not again until 12:45 PM, a period of 45 minutes between checks.</p> <p>2. Clinical record #4 included hemodialysis treatment flow sheets dated 8/4 and 8/8/15 that evidenced the patient's blood pressure had not been monitored at least every 30 minutes during treatment.</p> <p>A. A hemodialysis treatment flow</p>		<p>The Clinical Manager provided a mandatory in-service to the patient care staff on Friday, August 28, 2015 to review the requirements of the following policy: #FMS-CS-IC-I-110-133A "Monitoring During Patient Treatment Policy" emphasizing that vital signs will be monitored at the initiation of dialysis and <u>every 30 minutes</u>, or more frequently, as needed. In addition, documentation of the vital signs and machine parameters will be recorded in the patient's medical record within 15 minutes of being performed. The staff members acknowledged understanding of the policy.</p> <p>The Clinical Manager or designee will audit 1 patient flow sheet per PCT daily until 100% compliance is achieved with the policy. After 100% compliance is achieved by all PCT's, the Clinical Manager or designee will continue to audit 1 patient flow sheet per PCT weekly x 2 weeks, followed by 5% of the patient census dialysis flow sheets monthly thereafter. Any evidence of non-compliance will be addressed immediately including corrective action as appropriate.</p> <p>Frequency of ongoing audits will further be determined by the QAI committee upon review of the audit results and resolution of the issue. The Clinical Manager is responsible for reviewing and analyzing all data prior to the QAI meeting and presenting it monthly to the QAI</p>	

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	<p>sheet dated 8/4/15 evidenced vital signs and a safety check had been completed at 1:01 PM and not again until 2:07 PM, a period of 66 minutes between checks.</p> <p>B. A hemodialysis treatment flow sheet dated 8/8/15 evidenced vital signs and a safety check had been completed at 1:00 PM and not again until 2:00 PM, a period of 60 minutes between checks.</p> <p>3. Clinical record #9 included hemodialysis treatment flow sheets dated 8/3 and 8/21/15 that evidenced the patient's blood pressure had not been monitored at least every 30 minutes during treatment.</p> <p>A. A hemodialysis treatment flow sheet dated 8/3/15 evidenced vital signs and a safety check had been completed at 10:12 AM and not again until 11:02 AM, a period of 50 minutes between checks.</p> <p>B. A hemodialysis treatment flow sheet dated 8/21/15 evidenced vital signs and a safety check had been completed at 9:02 AM and not again until 10:07 AM, a period of 65 minutes between checks.</p> <p>4. Clinical record #10 included a hemodialysis treatment flow sheet dated 8/18/15 evidenced the patient's blood pressure had not been monitored at least</p>		<p>team. The Director of Operations is responsible to ensure the Clinical Manager presents all data as defined within the plan of correction to the QAI committee. The QAI committee is responsible to provide oversight and ensure resolution is occurring.</p>	

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V 0550 Bldg. 00	<p>every 30 minutes during treatment.</p> <p>A hemodialysis treatment flow sheet dated 8/18/15 evidenced vital signs and a safety check had been completed at 10:31 AM and not again until 11:28 AM, a period of 57 minutes between checks.</p> <p>5. On 8/27/15 at 2:15 PM, employee J (clinical manager) indicated vital signs should be assessed, according to policy, every 30 minutes during treatment.</p> <p>6. The facility policy with an effective date as August 20, 2014 titled "Patient Monitoring During Patient Treatment" states, "Purpose The purpose of this policy is to provide direction for monitoring dialysis patients during treatment. ... Policy Monitor the patient at the initiation of treatment and every 30 minutes, or more frequently as necessary."</p> <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</p>			

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	<p>consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement.</p> <p>Based on observation and interview, the facility failed to ensure post access care for an arteriovenous fistula (AVF) or graft (AVG) had been completed in accordance with facility policy in 1 of 3 post dialysis access care observations completed. (observation #3 of PT# 13)</p> <p>Findings include:</p> <p>1. On 8/27/15 at 10:25 AM, employee D (patient care technician) was observed to discontinue the dialysis treatment on patient #13. The patient care technician applied gauze and tape and the pressure was held until hemostasis (bleeding had stopped) was achieved on both venous and arterial stick sites. The patient care technician then reinforced the gauze pads with more tape without placement of clean gauze to the insertion sites.</p> <p>On 8/27/15 at 11:00 AM, employee E (patient care technician) indicated the gauze pads should be replaced with clean pads before the patient exits the treatment area.</p> <p>2. On 8/27/15 at 2:10 PM, employee J (clinical manager) indicated staff should be changing the gauze pads, with clean</p>	V 0550	<p>The Director of Operations and Clinical Manager will meet with the Medical Director on September 21, 2015 to review the survey statement of deficiencies and plan of correction. On Friday, August 28, 2015, the Clinical Manager conducted a mandatory in-service to reinforce each employee's obligation for monitoring the patient access including removal of soiled gauze and applying a clean dressing over the needle insertion site. The following policy and procedure: #FMS-CS-IC-I-115-013C "Post Treatment Fistula Needle Removal Procedure" and #FMS-CS-IC-I-115-013A "Post Treatment Fistula Needle Removal Policy" was reviewed with all staff members during the in-service. To prevent reoccurrence and to monitor compliance, the Clinical Manager or designee will monitor the application of a clean dressing on the access weekly x 3 weeks followed by monthly until 100% compliance is achieved. Once compliance is achieved and maintained, ongoing audits will be conducted at the recommendations of the QAI committee. The Clinical Manager will document all findings and actions in the QAI</p>	09/28/2015

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	gauze pads, prior to the patient leaving.		minutes and present them at the monthly to the QAI Committee. The Director of Operations is responsible to ensure the Clinical Manager presents all data as defined with the Plan of Correction to the QAI Committee. The QAI Committee is responsible to provide oversight and ensure resolution is occurring.		