

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152638	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 PERU	STREET ADDRESS, CITY, STATE, ZIP CODE 25 W 2ND ST PERU, IN 46970
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V 0000 Bldg. 00	<p>This was a federal ESRD recertification survey.</p> <p>Survey Dates: August 24, 25, 26, and 27, 2015</p> <p>Facility #: 012085</p> <p>Medicaid Vendor #: 200942320</p> <p>QR: KH, R.N.</p>	V 0000		
V 0113 Bldg. 00	<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 interview, the facility failed to ensure staff followed facility infection control practices during access of arteriovenous fistula (AVF) for initiation of dialysis in 1 of 2 AVF access observations. (#8)</p> <p>Findings include:</p> <p>1. During observation on 8/26/15 at 10:35 AM, employee F, Certified Clinical Hemodialysis Technician, was</p>	V 0113	<p>On Friday, August 31, 2015, the Education Coordinator conducted a mandatory in-service and return demonstration, inclusive of Employee F, to reinforce each employee's obligation for assessing the patency of the internal access while not contaminating the already cleansed area. The following policy #FMS-CS-IC-I-115-006A "Assessment and Preparation of the Internal Access for Needle Placement" was reviewed with all staff members during the</p>	09/28/2015

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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V 0126 Bldg. 00	<p>observed to access the AVF or Graft for dialysis treatment on patient number 8. The employee cleansed the cannulation sites 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>2. During interview on 8/26/15 at 10:35 AM, employee A, Clinic Manager, indicated the patient techs should be re-washing/preparing the access sites if they touch it again, and should not be touching the sites at the point of needle insertion.</p> <p>494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF Hepatitis B Vaccination</p> <p>Vaccinate all susceptible patients and staff members against hepatitis B. Based on record review and interview, the facility failed to ensure the appropriate documents were in employee files to evidence the employee was offered a Hepatitis B vaccine upon hire</p>	V 0126	<p>in-service. To prevent reoccurrence and to monitor compliance, the Clinical Manager or designee will monitor the assessment and preparation of the internal 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. Any issues related to non-compliance will be addressed immediately and employees will be subject to corrective action. The Clinical Manager will document all findings and actions in the QAI 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.</p> <p>The Education Coordinator provided an in-service to the patient care staff on August 31, 2015. The FMS policy #FMS-CS-IC-II-155-143A "Requirement for Employee</p>	09/10/2015			

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	<p>for 2 of 4 employee files reviewed. (G and N)</p> <p>Findings include:</p> <ol style="list-style-type: none"> Employee file G, Certified Clinical Hemodialysis Technician (CCHT), date of hire (DOH) 8/26/13, failed to evidence the employee was offered and refused the Hepatitis B vaccination and failed to evidence dates a vaccination series was given. The employee file evidenced a lab result dated 3/12/15 for Antibodies. Employee file N, CCHT, DOH 1/26/09, failed to evidence the employee was offered and refused the Hepatitis B vaccination and failed to evidence dates a vaccination series was given. The employee file evidenced a lab result dated 1/14/09 for Antibodies. During interview on 8/27/15 at 11:40 AM, employee A, Clinic Manager, indicated they do not have copies of the Hepatitis B offer/declinations because when she did the hiring she only drew labs for antibody checks on the employees. During interview on 8/27/15 at 12:15 		<p>Testing and Vaccination for Hepatitis B" was reviewed. Staff voiced understanding of this policy. On August 28, 2014, the Clinical Manager completed an audit of 100% of the employee records to determine the presence of consent or declination for Hepatitis B vaccination in each record. On August 31, 2015, Hepatitis B antibodies were drawn on each staff member and labs that were resulted on September 3, 2015. The lab results revealed that all staff members had antibodies > 10. The Clinic Manager then reviewed the declinations with those staff members on September 9, 2015 that had not had a vaccination series and in which, no consent was located in the employee medical file. Completed declination forms were then filed in the appropriate employee medical file. The Clinical Manager or RN designee will ensure that all new employees will be offered the Hepatitis B vaccination upon hiring and a consent or declination will be obtained. The Clinical Manager or designee will also implement use of the QAI employee tracking tool to ensure screenings are completed at the required frequencies and consent or declination is up to date. The Clinical Manager will bring the employee tracking tool to QAI meetings on a quarterly basis for review by the QAI committee. The</p>		

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V 0412 Bldg. 00	<p>PM, employee A indicated she did an audit of the employee files and caught that employee G had not had labs drawn on hire, nor had the Hepatitis B offer/declination, so she did the lab draw when discovered the error in 2015. Employee A indicated the facility has not had any Hepatitis B positive patients in the past 5 years.</p> <p>5. The facility's policy titled "Requirements for employee Testing and Vaccination for Hepatitis B," # FMS-CS-IC-II-155-143A, revised 1/28/15 states, "The Hepatitis B vaccine shall be offered to all employees on hire or rehire. ... Documentation of hepatitis B vaccination or refusal must be present in each employee file."</p> <p>494.60(d)(2) PE-ER PREP-PTS ORIENTED/TRAINED The facility must provide appropriate orientation and training to patients, including the areas specified in paragraphs (d)(1)(i) of this section. Based on record review and interview, the facility failed to ensure all patients receiving in-center hemodialysis (ICHD) received emergency disconnect education for 1 of 4 ICHD patients interviewed. (# 7)</p>	V 0412	<p>QAI committee will monitor ongoing compliance and develop an action plan when warranted.</p> <p>On Friday, August 31, 2015, the Clinic Manager provided an in-service to the staff members on policy #FMS-CS-IC-I-101-007A "Patient Education", emphasizing the requirement to complete patient orientation and training in emergency preparedness within the</p>	09/28/2015	

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	<p>Findings include:</p> <ol style="list-style-type: none"> 1. During interview on 8/24/15 at 10:45 AM, patient # 7 indicated they were also a Peritoneal Dialysis (PD) patient but are doing ICHD temporarily due to recent abdominal surgery. Patient # 7 indicated the ICHD staff did not instruct them on emergency procedures and how to disconnect the blood lines in an emergency situation. 2. Clinical record # 7, start of care date 12/1/14, contained a Note by the physician dated 7/24/15 that stated "Patient had hernia surgery a few days ago and is on in center HD for 4 to 6 weeks." The record failed to evidence ICHD education and take off procedure information had been provided to the patient. 3. During interview on 8/25/15 at 1:45 PM, employee A, the Clinic Manager, indicated they know for a fact this education was not done with patient #7- the patient came to ICHD at the end of July, temporarily from PD, and the education was missed probably due to the modality change. Employee A indicated the emergency take off education is to be done with each patient on admission and then quarterly with all patients. 		<p>1st or 2nd treatment and no later than 6th dialysis treatment.</p> <p>Responsibility for completion of the patient education for emergency preparedness will be delegated to appropriate clinical nursing staff by the Clinical Manager, and the Clinical Manager will be responsible for ensuring it is completed and documented within 6 dialysis treatments. A new process went into place as of August 31, 2015 to ensure that the emergency preparedness training occurs during the 1st treatment that the patient completes in the facility. The emergency preparedness acknowledgement will be placed in the new patient paperwork packet to be signed after the patient has viewed and discussed the emergency preparedness video that will be shown also on the first visit.</p> <p>The Clinical Manager or her designee will complete an audit of 100% of patient charts to identify any patients who do not have emergency preparedness training documented. The IDT and QAI committee will be notified of any patient charts that are missing emergency preparedness education documentation. Any such patients will then be educated within 3 treatments of audit completion. The Clinical Manager or designee will audit all new and transferred in patient charts biweekly x 2 months, then monthly x 3 months to ensure that documentation of patient</p>		

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	<p>4. During interview on 8/26/15 at 10:15 AM, employee E, Registered Nurse, indicated she thought she did provide this education to patient # 7 on admission, but cannot find the paperwork.</p> <p>5. The facility's policy titled "Patient Education," # FMS-CS-IC-I-101-007-A, revised 6/19/13 states, "Document Patient Education- Patient Education must be documented in the Patient's Medical Record as follows: New Patients-Education should be documented in the Education Record for New Patients. ... The required educational materials and usage are as follows: The RN should give new patients a personal copy of the following materials: ... RightStart Power Tools with Facility Specific Information (Important Numbers, Who to Call in a Disaster, Grievance Procedure) Materials should be distributed to new patients within the 1st or 2nd treatment if possible, and no later than the 6th treatment. ... It is the responsibility of the interdisciplinary team (RN, SW, RD, and, if available, the RightStart Case Manager, RSCM) to provide education on all topics listed on the Education record for New Patients. ... Educating Existing Patients."</p>		<p>education of emergency preparedness is present.</p> <p>The Clinical Manager will report audit findings to the IDT and QAI committee. The QAI committee will determine the need for further auditing of new and transfer patient charts based on level of resolution. The Director of Operations is responsible for ensuring that the Clinical Manager presents all data to the QAI committee as defined within the plan. The QAI committee is responsible to provide oversight and ensure resolution is occurring.</p>	

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V 0550 Bldg. 00	<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 observation and interview, the facility failed to ensure staff did not touch cleaned arterial-venous fistula (AVF) sites at point of needle entry for 1 of 2 AVF access observations. (#8)</p> <p>Findings include:</p> <p>1. During observation on 8/26/15 at 10:35 AM, employee F, Certified Clinical Hemodialysis Technician, was observed to access the AVF or Graft for dialysis treatment on patient number 8. The employee cleansed the cannulation sites 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>2. During interview on 8/26/15 at 10:35</p>			V 0550	<p>On Friday, August 31, 2015, the Education Coordinator conducted a mandatory in-service and return demonstration, inclusive of Employee F, to reinforce each employee's obligation for assessing the patency of the internal access while not contaminating the already cleansed area. The following policy #FMS-CS-IC-I-115-006A "Assessment and Preparation of the Internal Access for Needle Placement" 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 assessment and preparation of the internal 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. Any issues related to non-compliance will be addressed</p>		09/28/2015

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	AM, employee A, Clinic Manager, indicated the patient techs should be re-washing/preparing the access sites if they touch it again, and should not be touching the sites at the point of needle insertion.		immediately and employees will be subject to corrective action. The Clinical Manager will document all findings and actions in the QAI 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.		