

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152535	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  12/02/2015
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NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE NEPHROLOGY LAPORTE	STREET ADDRESS, CITY, STATE, ZIP CODE 2910 MONROE ST LA PORTE, IN 46350
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V 0000  Bldg. 00	<p>This visit was an ESRD recertification survey.</p> <p>Survey dates: 11/30/15, 12/1/15, 12/2/15</p> <p>Facility #: 008894</p> <p>Medicare #: 152535</p> <p>Medicaid Vendor #: 200032320D</p> <p>Current census: 12 active patients</p>	V 0000		
V 0122  Bldg. 00	<p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing-</p> <p>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]</p> <p>(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.</p> <p>Based on record review and interview, the facility failed to ensure surfaces were not contaminated with blood for 1 of 1 treatment floor observations on 11/30/15.</p>	V 0122	<p>On 12/23/15, during staff meeting held at 11:30 am the CM educated 100% of the DPC staff on the policy, Dialysis Precautions Policy FMC-CS-IC-II-155-07A.</p>	12/23/2015

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 0229  Bldg. 00	<p>The findings include:</p> <ol style="list-style-type: none"> <li>On 11/30/15 at 8:40 AM, a blood spot about the size of a quarter was noted on a chux under the left arm of patient #5. This patient was at station #9.</li> <li>On 11/30/15 at 8:45 AM, the blood spot was still noted under the left arm of patient #5.</li> <li>On 11/30/15 at 9:10 AM, Employee A, Registered Nurse, indicated patient #5 had just completed the rinse back at the completion of dialysis.</li> <li>The agency policy titled "Dialysis Precautions" with a date of January 4, 2012 stated, "Dialysis Precautions will be followed by all employees with potential exposure to bloodborne pathogens and other potentially infectious material ... in the dialysis setting."</li> </ol> <p>494.40(a) MIXING SYSTEMS-PERM RECORD/VERIF TEST 5.4.4.1 Mixing systems: perm record/verification testing In addition to container labeling, there</p>		<p>Emphasis was placed on the importance of cleaning up all blood spills, splatters immediately with bleach 1:100. The CM or designee will conduct monthly patient treatment area audits to assure compliance to the Dialysis Precaution Policy. Non-compliance to the policy will result in re-education and or corrective action. The CM will summarize the audit findings and report the results to the QAI committee monthly.</p>		

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	<p>should be permanent records of batches produced. These records should include the concentrate formula produced, the volume of the batch, the lot numbers of powdered concentrate packages, the manufacturer of the powdered concentrate, the date and time of mixing, any test results, the person performing the mixing, the person verifying mixing and test results, and the expiration date (if applicable).</p> <p>6.4.1 Mixing systems Acid and bicarbonate concentrates may be tested by using conductivity or by using a hydrometer. Concentrates should not be used or transferred to holding tanks or distribution systems until all tests are completed. The test results and verification that they meet all applicable criteria should be recorded and signed by the individuals performing the tests.</p> <p>Based on interview and record review, the facility failed to ensure an accurate log of bicarbonate mixing disinfection log was completed for 1 of 1 dialysis clinic on 8/31/15.</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>1. A document titled "Bicarbonate Mixing Disinfection Log" with a date of 8/31/15 evidenced multiple entries by Employee B, patient care technician. These entries indicated that bicarb had been mixed 9 times at 4 AM.</li> <li>2. On 12/1/15 at 10:55 AM, Employee</li> </ol>	V 0229	<p>On 12/23/15, the CM educated 100% of the DPC staff on the policy; Acid Concentrate Mixing and Handling Policy and Procedure, FMS-CS-IC-II 140-315A. Emphasis was placed on how to accurately record mixing of the bicarb.</p> <p>The CM/designee will review the water log book for accuracy daily x 2 weeks, if 100% compliance is maintained then audits will be conducted weekly. Any non-compliance to the documentation policy will result in further education and or corrective action.</p> <p>The CM will summarize the results of the audits monthly and report the results to the QAI committee.</p>	01/06/2016

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V 0715 Bldg. 00	<p>E, the biomedical operations manager, indicated that this was a log error and the task written had only occurred once that day and not multiple times as written on the log (in finding #1).</p> <p>3. The agency policy titled "Acid Concentrate Mixing and Handling" with a date of 5/13/05 stated, "Instructions for completing Granuflo dissolution unit log sheet, form DU - 1 ... The Granuflo Dissolution Unit Log Sheet is to be used in conjunction with the Granuflo Dissolution Unit for the functions of mixing and disinfection ... Instruction indicated date of activity ... indicated time of activity ... provides a record of place and time for the activity being performed ... Indicate the initials of person performing the activity ... provides a record of the person responsible for performing the activity."</p> <p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&amp;P The medical director must- (2) Ensure that- (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;</p>			

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	<p>Based on record review and interview, the medical director failed to ensure all new patients had an evaluation by the registered nurse (RN) prior to the start of the first dialysis treatment in accordance with facility policy in 1 (# 3) of 1 records reviewed of patients on service for less than 90 days creating the potential to affect all new patients of the facility.</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>1. Clinical record #3 evidenced the patient's first treatment at the facility was on 9/11/15 and that the treatment was initiated at 9:35 AM. The record failed to evidence a completed evaluation by the Registered Nurse prior to initiation of dialysis.</li> <li>2. On 12/1/15 at 3:30 PM, Employee A, clinical manager, indicated the initial evaluation for patient #3 was not complete.</li> <li>3. The policy titled "Comprehensive Interdisciplinary Assessments and Plan of Care" with a date of July 4, 2012 stated, "A registered nurse must evaluate New to dialysis before initiation of their first treatment to determine immediate needs. Chairside - the RN must at a minimum, complete the nursing evaluation cascade</li> </ol>	V 0715	<p>On 12/23/15, the DO reviewed the results of the survey with the CM. Emphasis was placed on the importance of and RN assessing all new patients prior to initiating the first treatment. The DO educated the CM on policy titled "Comprehensive Interdisciplinary Assessments and Plan of Care. Ongoing, the CM or designee will conduct a comprehensive RN assessment prior to dialysis. The CM will audit 100% of all new patient charts monthly to determine compliance with the policy. The CM will result to the QAI committee monthly. dialysis.</p>	12/23/2015

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	that includes a systems assessment."				