

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152502	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 06/24/2013
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST			STREET ADDRESS, CITY, STATE, ZIP CODE 6635 E 21ST ST STE 400 INDIANAPOLIS, IN 46219		
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V000000	<p>This visit was a Federal ESRD complaint investigation survey.</p> <p>Complaint number: IN00130622 - Substantiated: Deficiencies related to the allegation are cited.</p> <p>Survey dates: June 24, 2013</p> <p>Facility number: 005149</p> <p>Surveyor: Kelly Ennis, BSN, RN, Public Health Nurse Surveyor</p> <p>QA: Linda Dubak, R.N. 06/27/13</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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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.</p> <p>Based on policy and procedure review, clinical record review, and staff interview, the facility failed to ensure patients had achieved and sustained the prescribed dose of dialysis by failing to ensure saline flushes had been administered as ordered in 1 (#2) of 1 records reviewed of patients that had saline flushes ordered; failed to ensure blood flow rates had been administered as ordered in 2 (#2 and #3) of 3 records reviewed; and failed to ensure the patient's scheduled treatment time was achieved in 1 (#2) of 3 records reviewed creating the potential to affect all of the facility's current patients.</p> <p>The findings include:</p> <p>1. Facility policy titled "Pre-Treatment Safety Checks" document number FMS-CS-IC-I-110-141C, revision date 7/04/2012 states, "The following information is accurately entered in the dialysis machine: ... prescribed</p>	V000544	<p>V 544 A mandatory in-service with the Clinic Manager is scheduled for all staff on July 15 th 2013 to review policies of "Pre-Treatment Safety Checks" FMS-CS-IC-I-110-141C, "Initiation of Treatment using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer" FMS-CS-IC-I-105-002C, "Initiation of Treatment using an Arteriovenous Graft or Fistula and Optiflux Single Use Ebeam Dialyzer" FMS-CS-IC-I-105-001C, and "Patient Monitoring During Patient Treatment" FMS-CS-IC-I-110-133A. Special emphasis was placed on ensuring that the patient's prescribed blood flow rate and treatment time are delivered according to the physician's prescription. Also that appropriate documentation and delivery of saline flushes as ordered by the physician.</p> <p>This will be monitored daily by the Charge Nurse using the Rounding Tool. Frequency of</p>	07/22/2013			

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	<p>blood flow rate."</p> <p>2. Facility procedure titled "Initiation of Treatment using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer" document number FMS-CS-IC-I-105-002C, IS-1-520-021C, HT N/A, revision date 4/4/2012 states, "If no problems are noted, turn up the blood flow to the rate prescribed by the physician to achieve optimal clearances. Once again, monitor arterial and venous pressures carefully during this process to note any possible flow restrictions or inappropriate pressure readings."</p> <p>3. Facility procedure titled "Initiation of Treatment using an Arteriovenous Graft or Fistula and Optiflux Single Use Ebeam Dialyzer" document number FMS-CS-IC-I-105-001C, IS-1-520-020C, HT N/A, revision date 4/4/2012, states, "If no problems are noted, turn up the blood flow to the rate prescribed by the physician to achieve optimal clearances. Once again, monitor arterial and venous pressures carefully during this process to note any possible flow restrictions or inappropriate pressure readings."</p> <p>4. Facility policy titled "Patient</p>		<p>ongoing monitoring will be determined by the QAI Committee upon review of monitoring results and resolution of the issue. Any issues found out of compliance will be corrected immediately and corrective action will be taken as appropriate.</p> <p>The Clinical Manager will monitor the results of the Rounding Tool audits weekly for 4 weeks and ongoing monitoring will be determined by the QAI Committee upon review of monitoring results and resolution of the issue.</p> <p>The Clinical Manager is responsible to report a summary of findings monthly in QAI. If resolution is not evident, the QAI Committee will complete a root cause analysis and the Plan of Correction will be revised as necessary.</p> <p>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>Monitoring During Patient Treatment" document number FMS-CS-IC-I-110-133A, revision date 7/4/12 states, "Monitor the patient at the initiation of treatment and every 30 minutes, or more frequently as necessary ... Check machine settings and measurements and document at the initiation of dialysis and at every safety check blood flow rate: Check prescribed blood flow is being achieved. Make adjustments as needed... Unusual observations, findings and the inability to reach prescribed orders must be promptly reported to the charge nurse/team leader ... Documentation of monitoring will be completed on the treatment record."</p> <p>5. Clinical record number 2, start of care 10/12/12, evidenced the following:</p> <p>A. The patient's prescribed blood flow rate of 400 was not achieved as ordered. The hemodialysis flow sheets that failed to achieve the prescribed blood flow rate were dated 5/11/13, 5/14/13, 5/16/13, and 5/25/13.</p> <p>B. The patient's prescribed treatment time of 4 hours was not achieved as ordered and no AMA [Against Medical</p>			

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	<p>Advice] form was completed, or explanation given. The hemodialysis flow sheets that failed to achieve the prescribed treatment time were dated 5/14/13, 5/16/13, and 5/25/13.</p> <p>C. On 5/14/13, employee C, Registered Nurse (RN) wrote "Saline Flush line started at 100 mL/hr per [doctor] due to ECP [extracorporeal circuit] clotting." Review of the record failed to evidence the saline flush was given.</p> <p>6. Clinical record number 3, start of care 2/10/12, evidenced the patient's prescribed blood flow rate of 450 was not achieved as ordered. The hemodialysis flow sheets that failed to achieve the prescribed blood flow rate were dated 6/10/13, 6/12/13, 6/14/13, 6/17/13, 6/19/13, and 6/21/13.</p> <p>7. On 6/24/13 at 10:00 AM, the following interview with employee A, RN, took place:</p> <p>A. The RN was asked by the surveyor to explain to them the process of how the dialysis machine is set up and monitored throughout the dialysis process?</p> <p>B. Employee A indicated the Patient Care Technician (PCT) obtains the</p>			

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	<p>treatment orders for each patient and sets up the machine. Employee A indicated that once the prescription is entered into the machine, the prescription is then verified by a second person, who may be a PCT or a RN. Employee A indicated the RN then makes rounds and verifies the prescription in the machine a third time.</p> <p>C. Employee A was asked by the surveyor how they ensure that patients are receiving the ordered amount of saline, and/or other medications?</p> <p>D. Employee A indicated if the patient is to receive saline, this would be noted in the special notes section of the treatment orders sheet. This added saline would then be added to the total fluid volume.</p> <p>8. During an interview on 6/24/13 at 2:00 PM, employee B, interim Administrator was asked if there was any reason why a Blood Flow Rate would not be followed as prescribed by the physician.</p> <p>Employee B indicated the blood flow rate may not be followed if the arterial or venous pressure is high. Employee B indicated the reason the</p>				

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	blood flow rate was not achieved should be noted in the comments section.			