

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152585	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 06/07/2012
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE SHADELAND STATION			STREET ADDRESS, CITY, STATE, ZIP CODE 7155 SHADELAND STATION STE 130 INDIANAPOLIS, IN 46256		
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V0000	<p>This was a federal ESRD recertification survey.</p> <p>Facility #: 003483</p> <p>Survey Dates: 6-5-12, 6-6-12, and 6-7-12</p> <p>Medicaid Vendor : 200424460</p> <p>Surveyor: Vicki Harmon, RN, PHNS</p> <p>Facility census: 111 incenter hemodialysis patients, 0 peritoneal, and 0 home hemodialysis</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN</p> <p>June 12, 2012</p>	V0000			

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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V0196	<p>494.40(a) CARBON ADSORP-MONITOR, TEST FREQUENCY 6.2.5 Carbon adsorption: monitoring, testing freq Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours.</p> <p>Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet.</p> <p>Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N.N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L]. Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly.</p> <p>Based on observation, interview, and facility policy review, the facility failed to ensure chlorine testing had been completed in accordance with facility policy in 1 of 1 water test observed creating the potential to affect all of the facility's 111 current patients.</p>	V0196	<p>On June 19 th 2012 the Governing Body met to review the statement of deficiencies and to make certain that all identified deficiencies are being addressed both immediately and with long term resolution.</p> <p>The Clinic Manager will hold staff meeting and an in-service for all employees that perform the Chlorine/ Chloramines testing on June 18 th</p>	06/19/2012	

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	<p>The findings include:</p> <ol style="list-style-type: none"> 1. On 6-6-12 at 4:30 PM, employee J, a patient care technician, was observed to complete a total chlorine water test. The employee was not observed to wear gloves while performing the test. 2. The facility administrator, employee C, stated, on 6-6-12 at 5:00 PM, "They are supposed to be wearing gloves when doing the water testing." 3. Employee N, a patient care technician, stated, on 6-6-12 at 5:00 PM, "We are supposed to wear gloves when doing the water test. There are special vinyl ones back there just to be used for water testing." 4. The facility's 7-31-08 "Chlorine/Chloramine Testing of Water Using a Hach Colorimeter" procedure number FMS-132-110-103 states, "Disinfect hands and don appropriate PPE to protect hands and ensure integrity of testing." 		<p>2012 to review the procedure of Chlorine/Chloramines Testing of Water Using a hach Colorimeter FMS-132-110-103, with all staff members. Special emphasis to step #1 which states "Disinfect Hands and don appropriate PPE to protect hands and ensure integrity of testing"</p> <p>The Clinical Manager will ensure that all staff members follow this procedure using the infection control audit tool via the QAI Calendar and ensure the integrity of the testing is not compromised.</p> <p>The Clinic Manager is responsible for reporting her findings of these audits to the QAI committee during the QAI monthly meetings</p> <p>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.</p>		

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V0544	<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 clinical record review and interview, the facility failed to ensure patients achieved the prescribed dose of dialysis by ensuring heparin had been administered as ordered in 3 (#s 3, 9, and 10) of 3 records reviewed of patients with mid-treatment heparin ordered creating the potential to affect all of the facility's patients that receive mid treatment heparin.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Clinical record number 3 included physician orders dated 5-10-12 that state, "Heparin 2000 units mid treatment bolus every sched [scheduled] dialysis trmt [treatment]." The orders identified the treatment length as 4 hours. <p>A. A post treatment flow sheet dated 5-10-12 evidenced the dialysis treatment had been initiated at 10:47 AM and the 2000 units of mid-treatment heparin had been administered at 3:15 PM.</p> <p>B. A post treatment flow sheet dated</p>	V0544	<p>A mandatory in-service was scheduled for all staff on June 19 th 2012 with emphasis on ensuring that the patient's heparin is delivered according to the physician's prescription.</p> <p>This will be monitored monthly by the Clinical Manager during the medical record audits via the QAI calendar schedule. Any heparin dosages found out of compliance will be corrected immediately and corrective action will be taken as appropriate</p> <p>The Clinical Manager is responsible to report a summary of findings in QAI.</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>	06/19/2012			

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	<p>5-11-12 evidenced the dialysis treatment had been initiated at 10:31 AM and the 2000 units of mid-treatment heparin had been administered at 1:04 PM.</p> <p>C. A post treatment flow sheet dated 5-15-12 evidenced the dialysis treatment had been initiated at 9:10 AM and the 2000 units of mid-treatment heparin had been administered at 1:46 PM.</p> <p>D. A post treatment flow sheet dated 5-19-12 evidenced the dialysis treatment had been initiated at 10:35 AM and the 2000 units of mid-treatment heparin had been administered at 11:39 AM.</p> <p>E. A post treatment flow sheet dated 5-26-12 evidenced the dialysis treatment had been initiated at 10:52 AM and the 2000 units of mid-treatment heparin had been administered at 2:08 PM.</p> <p>F. A post treatment flow sheet dated 5-29-12 evidenced the dialysis treatment had been initiated at 11:14 AM and the mid-treatment heparin had been administered at 3:34 PM.</p> <p>G. A post treatment flow sheet dated 5-31-12 evidenced the dialysis treatment had been initiated at 10:10 AM and the mid-treatment heparin had been administered at 2:16 PM.</p>				

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	<p>H. A post treatment flow sheet dated 6-2-11 evidenced the dialysis treatment had been initiated at 11:11 AM and the mid-treatment heparin had been administered at 12:42 PM.</p> <p>2. Clinical record number 9 included physician orders dated 4-20-12 that identified 2000 units of heparin were to be administered mid-treatment "every sched dialysis trmt." The orders identified the treatment length as 4 hours.</p> <p>A. A post treatment flow sheet dated 5-14-12 evidenced the dialysis treatment had been initiated at 3:51 PM and the mid-treatment heparin had been administered at 4:30 PM.</p> <p>B. A post treatment flow sheet dated 5-16-12 evidenced the dialysis treatment had been initiated at 4:02 PM and the mid-treatment heparin had been administered at 7:17 PM.</p> <p>C. A post treatment flow sheet dated 5-18-12 evidenced the dialysis treatment had been initiated at 3:39 PM and the mid-treatment heparin had been administered at 7:46 PM.</p> <p>D. A post treatment flow sheet dated 5-21-12 evidenced the dialysis treatment</p>			
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	<p>had been initiated at 3:45 PM and the mid-treatment heparin had been administered at 7:48 PM.</p> <p>E. A post treatment flow sheet dated 5-25-12 evidenced the dialysis treatment had been initiated at 3:50 PM and the mid-treatment heparin had been administered at 4:48 PM.</p> <p>F. A post treatment flow sheet dated 5-28-12 evidenced the dialysis treatment had been initiated at 3:10 PM and the mid-treatment heparin had been administered at 7:15 PM.</p> <p>G. A post treatment flow sheet dated 5-30-12 evidenced the dialysis treatment had been initiated at 3:20 PM and the mid-treatment heparin had been administered at 6:45 PM.</p> <p>H. A post treatment flow sheet dated 6-1-12 evidenced the dialysis treatment had been initiated at 3:26 PM and the mid-treatment heparin had been administered at 7:58 PM.</p> <p>I. A post treatment flow sheet dated 6-4-12 evidenced the dialysis treatment had been initiated at 3:49 PM and the mid-treatment heparin had been administered at 3:54 PM.</p>						

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	<p>3. Clinical record number 10 included physician orders dated 5-7-12 that identified 2000 units of heparin were to be administered mid-treatment. The orders identified the treatment length as 4 hours.</p> <p>A. A post treatment flow sheet dated 5-14-12 evidenced the dialysis treatment had been initiated at 3:50 PM and the mid-treatment heparin had been administered at 4:29 PM.</p> <p>B. A post treatment flow sheet dated 5-16-12 evidenced the dialysis treatment had been initiated at 3:52 PM and the mid-treatment heparin had been administered at 8:02 PM.</p> <p>C. A post treatment flow sheet dated 5-18-12 evidenced the dialysis treatment had been initiated at 3:44 PM and the mid-treatment heparin had been administered at 7:33 PM.</p> <p>D. A post treatment flow sheet dated 5-21-12 evidenced the dialysis treatment had been initiated at 3:37 PM and the mid-treatment heparin had been administered at 7:38 PM.</p> <p>E. A post treatment flow sheet dated 5-23-12 evidenced the dialysis treatment had been initiated at 3:33 PM and the</p>			

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	<p>mid-treatment heparin had been administered at 7:05 PM.</p> <p>F. A post treatment flow sheet dated 5-28-12 evidenced the dialysis treatment had been initiated at 3:34 PM and the mid-treatment heparin had been administered at 7:43 PM.</p> <p>G. A post treatment flow sheet dated 5-30-12 evidenced the dialysis treatment had been initiated at 3:36 PM and the mid-treatment heparin had been administered at 7:50 PM.</p> <p>H. A post treatment flow sheet dated 6-4-12 evidenced the dialysis treatment had been initiated at 3:40 PM and the mid-treatment heparin had been administered at 8:03 PM.</p> <p>4. The facility administrator, employee C, indicated, on 6-6-12 at 10:20 AM, the records did not evidence the mid-treatment heparin had been administered at the appropriate times.</p>			

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V0551	<p>494.90(a)(5) POC-VA MONITOR/PREVENT FAILURE/STENOSIS The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care provided for the monitoring of patients' accesses in 8 (#s 1, 3, 5, 6, 7, 8, 9, and 10) of 10 records reviewed of patients that had been on service for longer than 30 days creating the potential to affect all of the facility's 111 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 1 included a plan of care (PoC) dated 4-25-12 that identified the patient's access was an "AV Fistula [AVF]." The plan included the goal, "AVF will remain patent & free of infection." The plan failed to evidence interventions to monitor the access and achieve the desired goal. 2. Clinical record number 3 included a PoC dated 2-23-12 that identified the patient's access was a "graft other." The plan failed to evidence interventions to monitor the access. 3. Clinical record number 5 included a 	V0551	<p>On June 19th 2012, the Clinic Manager met with members of the IDT to emphasize the requirements as defined within the Conditions of Coverage and Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care" that all patients must have a Plan of Care that includes vascular access monitoring. Emphasis was placed upon including interventions to monitor and maintain the patient's access.</p> <p>The Clinical Manager will ensure ongoing compliance by auditing medical records monthly via the QAI Calendar. Any Plan of Care found out of compliance will be addressed with the IDT team members. The Clinical Manager (CM) is responsible to analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee for oversight and review.</p> <p>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.</p> <p>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>	06/19/2012			

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	<p>PoC dated 3-15-12 that identified the patient's access was an "AV Fistula." The plan failed to evidence interventions to monitor the access.</p> <p>4. Clinical record number 6 included a PoC dated 4-25-12 that identified the patient's access was a "Catheter, double lumen cuffed." The plan included the goal, "PC will remain free of infection & PC will remain patent." The plan failed to evidence interventions to monitor the access and to achieve the desired goal.</p> <p>5. Clinical record number 7 included a PoC dated 6-1-12 that identified the patient's access was a "Catheter, double lumen cuffed." The plan included the goal, "PC will remain patent & free of infection." The plan failed to evidence interventions to monitor the access and to achieve the desired goal.</p> <p>6. Clinical record number 8 included a PoC dated 2-15-12 that identified the patient's access was a "Catheter, double lumen cuffed." The plan failed to evidence interventions to monitor the patient's access.</p> <p>7. Clinical record number 9 included a PoC dated 5-24-12 that identified the patient's access was an "AV Fistula." The plan included the goal, "AVF will remain</p>			

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	<p>patent & free of infection." The plan failed to evidence interventions to monitor the access and achieve the desired goal.</p> <p>8. Clinical record number 10 included a PoC dated 3-15-12 that identified the patient's access was a "Catheter, Double lumen cuffed." The plan failed to evidence interventions to monitor the patient's access.</p> <p>9. The facility administrator, employee C, was unable to provide any additional documentation and/or information when asked on 6-7-12 at 10:40 AM and just prior to the exit conference on 6-7-12 at 12:30 PM.</p> <p>10. The facility's February 2, 2011 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-138-020-091 states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Provide vascular access monitoring . . . Provide PD Catheter access monitoring for patency, catheter, tunnel, or exit site infection."</p>			