

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152641	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 02/28/2013
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE SCOTT COUNTY			STREET ADDRESS, CITY, STATE, ZIP CODE 130 N WESTAVIA BLVD SCOTTSBURG, IN 47170		
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V000000	<p>This was an ESRD federal recertification survey.</p> <p>Survey Dates: 2/25/2013-2/28/2013</p> <p>Facility #: 012200</p> <p>Medicaid Vendor #: 200973080</p> <p>Surveyor: Dawn Snider, RN, PHNS</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN</p> <p>March 7, 2013</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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V000111	<p>494.30 IC-SANITARY ENVIRONMENT The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.</p> <p>Based on facility policy review and observation, the facility failed to ensure supplies used to initiate or discontinue dialysis or to change a central line dressing were protected from potential contamination in 6 of 6 environmental observations (patients #4, 8, 9, 10, 11, and 12) creating the potential for the transmission of disease causing organisms among staff and all of the facility's 34 current patients.</p> <p>The findings include:</p> <p>1. Facility policy titled "Dialysis Precautions" document number FMS-CS-IC-II-155-070A, effective date 1/4/2012, states, "Clean area: An area designated for clean and unused equipment and supplies and medications. Dirty area: An area where there is a potential for contamination with blood or body fluids and where contaminated or "used" supplies, equipment, blood supplies or biohazard containers are stored or handled. "</p>	V000111	<p><u>V 111 494.30 IC-SANITARY ENVIRONMENT</u></p> <p>On February 28, 2013, the Director of Operations met with the Clinical Manager to review the citations from the February 28, 2013, survey and to reinforce the Clinical Manager's responsibilities to monitor staff for compliance. As a result and to further ensure compliance, on March 20, 2013, the Clinical Manager will complete the following:</p> <p>On March 20, 2013 will conduct a staff meeting with the facility personnel to reinforce expectations of compliance to the following: Non-disposable items such as blood pressure cuffs, IV poles, TVs, TV remotes, portable phones etc., as well as clip boards or plastic hemostat clamps placed on the machine used or unused, should be disinfected with 1:100 bleach solution after each treatment Use of Blue Pads: Place the blue pad (under pad) under the catheter limbs or access limb to provide fluid barrier to protect the work area and clothing.</p>	03/21/2013			

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	<p>2. Facility policy titled "Changing the Catheter Dressing" document number FMS-CS-IC-I-105-032C, effective date 1/4/2012, states, "Prepare Dressing Supplies ... Step 2 Tear open on (1) chorhexidine swabstick package and on the underpad surface. Keep swab stick in package until use. 3 Peel back dressing and gauze packages and place on underpad surface."</p> <p>3. Observation number 1: On 2/25/13 at 10:55 AM, employee E, a patient care technician (PCT), was observed to discontinue the dialysis treatment on patient number 8 at station number 3. The PCT placed the supplies to be used on the table attached to the dialysis chair without using a barrier to protect the supplies from possible contamination.</p> <p>4. Observation number 2: On 2/25/13 at 11:05 AM, employee B, a registered nurse (RN), was observed to discontinue the dialysis treatment for patient number 4 at station number 6. The employee placed the supplies to be used on the table attached to the dialysis chair without using a barrier to protect the supplies from possible contamination.</p> <p>5. Observation number 3: On 2/25/13 at 11:45 AM, employee D, a PCT, was observed to initiate the dialysis treatment</p>		<p>Supplies taken to the station must not be opened until ready for use. If supplies are opened, the contents must be maintained in the hand of the user or placed upon the under pad until ready for use.</p> <p>To ensure that all staff understands the importance to comply with facility policies, the Clinical Manager contacted the educational department and arranged for the formal reeducation of all patient care staff to be completed no later than March 20, 2013. This reeducation is inclusive of but not limited to the following:</p> <ul style="list-style-type: none"> · Cleaning and Disinfecting (FMS-CS-IC-155-110A) Exhibit A · Work Surface Cleaning and Disinfection without Visible Blood Using Bleach Solutions (FMS-CS-IC-II-155-110) Exhibit B · Changing the Catheter Dressing (FMS-CS-IC-I-105-032C) Exhibit C <p>The Clinical Manager or assigned designee is responsible to monitor staff for compliance to policy by observation. Additionally, the Clinical manager monitors documentation by daily review of the patient treatment record. Any identified non-compliance will be addressed</p>				

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	<p>on patient number 9 at station number 10. The PCT placed the supplies to be used on the table attached to the dialysis chair without using a barrier to protect the supplies from possible contamination.</p> <p>6. Observation number 4: On 2/26/13 at 12:00 PM, employee B, a RN, was observed to initiate a central line dressing change on patient number 10 at station number 3. The RN placed the supplies to be used on the table attached to the dialysis chair without using a barrier to protect the supplies from possible contamination.</p> <p>7. Observation number 5: On 2/27/13 at 10:30 AM, employee C, a RN, was observed to discontinue the dialysis treatment on patient number 11 at station number 10. The RN placed the supplies to be used on the table attached to the dialysis chair without using a barrier to protect the supplies from possible contamination</p> <p>8. Observation number 6: On 2/27/13 at 10:50 AM, employee C, a RN, was observed to initiate a central line dressing change on patient number 12 at station number 7. The RN placed the supplies to be used on the table attached to the dialysis chair without using a barrier to protect the supplies from possible</p>		<p>immediately and directly with the responsible staff member with progressive disciplinary action.</p> <p>The Clinical Manager will bring the results of the reviews and status of the applied interventions to the monthly QAI meeting for review by the QAI committee. Any identified deviation from compliance will result in a plan of action being developed, implemented, and followed through to resolution.</p> <p>Documentation of this review and/or plan of action will be found in the QAI meeting minutes, available for review at the facility.</p> <p>The Clinical Manager is responsible and the QAI committee monitors for compliance.</p>	

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	contamination. 9. On 2/27/13 at 5:45 PM, employee A, the clinical manager, indicated it is not the practice of the agency to place supplies on a barrier on the table attached to the dialysis chair.			

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V000126	<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.</p> <p>Based on personnel file review and staff interview, the facility failed to ensure all patient care staff had evidence of being vaccinated for Hepatitis B and or the serologic immune status in 1 (file G) of 7 personnel files reviewed of employees providing patient care with the potential to affect all of the facility's staff and 34 current In-center patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Personnel file G, the Medical Director, failed to evidence documentation of being vaccinated for Hepatitis B or an immune status. On 2/28/13 at 1:45 PM, the clinical manager, employee A, indicated the medical director did not have any evidence of serologic testing or vaccination. 	V000126	<p>V 126 494.30(a)(1)(i) <u>IC-HBV-VACCINATE</u> <u>PTS/STAFF</u></p> <p>On March 12, 2013, the Clinic Manager obtained a vaccination declination from the Medical Director. Further, on March 19, 2013 the Governing Body will meet to discuss the need for Medical Directors to know their antibody status and to complete either a consent or declination for the administration of the Hepatitis B Vaccination.</p> <p>On March 20, 2013, the Clinic Manager will complete reeducation with all Direct Patient Care staff on the following Clinical Services Policy: -Employee Testing & Vaccination Hepatitis B (FMS-CS-IC-II-155-143A) Exhibit D</p> <p>As noted in the policy above, focus will include but not be limited to, "A vaccine declination needs to be signed when: ¿ Pre-assignment blood work reveals that the employee has antibodies 10mIU/ml or ¿ Employees indicate they have already received the complete vaccination series but have not converted to immune status and the records are not obtainable, or</p>	03/21/2013	

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			<p>¿Employee has received the vaccination series and has antibodies or</p> <p>¿Employee declines vaccination. To prevent reoccurrence, the Clinic Manager, or assigned supervising nurse, will perform semiannual Medical Staff file audits per the QAI calendar. If documentation is lacking, the Clinic Manager or assigned supervising nurse, will obtain the required documents from the physician or physician's office. The Clinic Manager will summarize the medical staff file audit findings to the QAI Committee on March 27, 2013, then again on April 24, 2013, and semiannual thereafter.</p>		

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V000274	<p>494.40(c) H2O TEST-DEVIATIONS REQUIRE RESPONSE Water testing results including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards must be addressed with a corrective action plan that ensures patient safety.</p> <p>Based on policy review, facility document review, and interview, the facility failed to ensure repeat microbiological testing of water used for dialysis was completed when identified when initial test results were above action level with the potential to affect all 54 patients.</p> <p>Findings:</p> <p>1. Facility policy titled "Interpretation of Test Results" document number FMS-TS-IC-I-500-000A 153-510-010-1 RCG-27-WT-2.01, 2.27, 2.28 effective date 7/31/2009 states, "In the event test results are above the action level: Promptly (within 48 hours) notify the Medical director, Clinical Manager, and Regional Technical Manager / Technical Operations Manager ... Repeat testing must be completed on any post disinfection samples that are above action level."</p> <p>2. A lab document from Spectra laboratories with a report date of 05/04/12</p>	V000274	<p><u>V 274 494.40(c) H2O TEST-DEVIATIONS REQUIRE RESPONSE</u></p> <p>- On March 20, 2013, the Clinic Manager will complete reeducation with all Direct Patient Care staff on the following Technical Services Policy: •Microbiological Monitoring (FMS-TS-IC-I-500-000A) Exhibit E As noted in the policy above, focus will include but not be limited to, "In the event test results are above the action level: - Promptly (within 48 hours) notify the Medical Director, Clinical Manager, and Regional Technical Manager / Technical Operations Manager) of microbiology test results above action levels. In the event test results are above the action levels a second determination will promptly follow (within 48 hours) to assess if the results exceed the allowable limits." To prevent reoccurrence, the Clinic Manager or assigned supervising nurse will review all</p>	03/21/2013	

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	<p>states"Colony count, water Inoculation Date / Time: 05/03/12 13:42 24 hr [hour] Colony Count [greater than] 200.0 AH CFU/ml"</p> <p>A. The lab document was signed by the medical director on 5/8/12.</p> <p>B. The lab document had a hand written notation that stated, "Will redraw 5-10-12 to check" initialed by LS.</p> <p>3. A lab document from Spectra laboratories with a collection date of 5/17/12 indicates the colony count was less than 2.0 at 24 and 48 hours.</p> <p>4. On 2/26/13 at 11:15 AM employee A, the clinical manager, indicated she made the notation to redraw on 5/10/12 and and the water culture tests should have been conducted as indicated on 5/10/12.</p>		<p>water culture results immediately upon receipt and schedule redraws to be completed within 48 hours if necessary. If levels are above action level, the Clinic Manager or assigned supervising nurse will make all appropriate notifications per policy. The Clinic Manager or assigned supervising nurse will follow up to assure all redraws, if necessary, are completed as scheduled.</p> <p>In the event a staff member is found to not follow the facility's microbiological monitoring policy, the Clinic Manager is responsible to immediately address the findings with the identified staff member.</p> <p>The Clinic Manager's action will be structured to reinforce by way of further education following through as necessary with the application of progressive disciplinary action.</p> <p>The Clinic Manager will continue to summarize the water culture results to the QAI Committee with the next meeting being March 27, 2013 and monthly thereafter.</p>		

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V000546	<p>494.90(a)(3) POC-MANAGE MINERAL METABOLISM Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease.</p> <p>Based on medical record review and interview, the facility failed to ensure the correct dose of Zemplar was administered in 1 of 5 (#2) medical records reviewed with the potential to affect all the facility's 34 current patients. Findings include:</p> <p>1. Clinical record #2 evidenced a physician's order dated 2/1/2013 for the patient to receive 2 milligrams (mg) Zemplar three times a week. Employee C, the registered nurse, documented the patient was given 4 mg of Zemplar 2/1/2013 on the hemodialysis treatment sheet.</p> <p>2. On 2/27/13 at 2:48 PM, employee A, the clinical manager, indicated the patient should have received 2 mg of Zemplar and not 4 mg as documented by the registered nurse.</p>	V000546	<p><u>V 546 494.90(a)(3)</u> <u>POC-MANAGE MINERAL METABOLISM</u></p> <p>- On March 20, 2013, the Clinic Manager will complete reeducation with all Direct Patient Care staff on the following Clinical Services Policies:</p> <p>-Medication Administration and Preparation (FMS-CS-IC-I-120-040A) Exhibit F</p> <p>-Special Considerations: Zemplar Multi-dose Vials (FMS-CS-IC-I-120-051A) Exhibit G</p> <p>As noted in the policies above, focus will include but not be limited to, "Follow the "6 Rs" of medication administration when drawing up and giving medications:</p> <ul style="list-style-type: none"> • Right Drug • Right Dose • Right Route • Right Time • Right Patient • Right Documentation <p>As well as, All Zemplar orders must be in whole integers."</p> <p>To prevent reoccurrence, the Clinic Manager or Education Coordinator will perform semiannual medication administration audits on all</p>	03/21/2013	

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			<p>Registered Nurses. Also, the Clinic Manager or Medical Records Manager will perform monthly medical records audits per policy.</p> <p>In the event a staff member is found to not follow the facility's medication administration and preparation policy, the Clinic Manager is responsible to immediately address the findings with the identified staff member.</p> <p>The Clinic Manager's action will be structured to reinforce by way of further education following through as necessary with the application of progressive disciplinary action.</p> <p>The Clinic Manager will summarize the medication administration audit findings to the QAI Committee on March 27, 2013, then again on April 24, 2013, and semiannual thereafter. The Clinic Manager will continue to summarize the medical records audit results to the QAI Committee monthly, with the next meeting being March 27, 2013.</p>		