

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152588	X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	X3) DATE SURVEY COMPLETED  07/29/2015
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NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE IRVINGTON	STREET ADDRESS, CITY, STATE, ZIP CODE 1740 INDUSTRY DRIVE INDIANAPOLIS, IN 46219
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V 0000  Bldg. 00	This was a Federal ESRD recertification survey.  Survey Dates: 7-28-15 & 7-29-15  Facility #: 003639  Medicaid Vendor #: 200467560	V 0000		
V 0122  Bldg. 00	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. Based on observation, interview, and review of facility policy, the facility failed to ensure equipment used for the care of patients had been cleaned and disinfected after use in 2 (#s 3 and 4) of 4 infection control observations completed.  The findings include:  1. Employee H, a registered nurse (RN), was observed to provide care to patient number 2 during a clinic visit on 7-28-15	V 0122	On 9/18/2015, the Governing Body will meet to review the statement of deficiencies and to make certain that all identified deficiencies are being addressed both immediately and with long term resolution.  The Clinic Manager is responsible to ensure that all staff members follow the policy, "Cleaning and Disinfection" to ensure a safe treatment environment that prevents cross contamination of patients and equipment.	08/27/2015

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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	<p>at 2:25 PM. The RN was observed to place a blood pressure cuff on the patient's left arm and found the cuff to be too large. After removing the cuff from the patient's arm, the RN was observed to replace the cuff into a drawer under the clean countertop without cleaning the cuff.</p> <p>A. The RN retrieved a smaller blood pressure cuff and placed it onto the patient's arm. This cuff was found to be too small. The RN was observed to place the smaller cuff on the clean countertop without cleaning the cuff.</p> <p>B. The RN then obtained the patient's blood pressure using a manual blood pressure cuff. The RN replaced this cuff into a drawer under the clean countertop without cleaning and disinfecting the cuff.</p> <p>C. The RN was observed to obtain the patient's temperature using a tympanic thermometer. The RN placed the thermometer onto the clean countertop without cleaning it.</p> <p>2. Employee I, an RN, was observed to provide care to patient number 4 on 7-29-15 at 8:25 AM. The RN was observed to obtain the patient's blood pressure. The RN placed the blood</p>		<p>TheClinic Manager held a staff in service on August 25th and 26th,2015, at the facility to re-educate all staff members on the following policies“Cleaning and Disinfection” FMS-CS-IC-II-155-110A and “Work Surface Cleaningand Disinfection without Visible Blood using Bleach Solution” FMS-CS-IC-II-155-110C1. This procedure in step 3, describes how to clean/disinfect blood pressure cuffsafter use in the patient care area. Attendance sheet is available in thefacility for review.</p> <p>ClinicManager held a counseling session for Employee H and I on 7/29/2015 to discusspolicy violations on 7/28 and 7/29/2015 as noted in the SOD. Emphasis in this counseling session was on theclean and dirty areas in treatment room and reviewing correct cleaning anddisinfecting of all non- disposable supplies. Expectation is that both nurseswill demonstrate in practice, compliance with following policy and procedure.</p> <p>Clinic Manager will ensure that infection controlaudits utilizing the Home Infection Control audit tool (enclosed) are done monthly for 6 months and then asdetermined by the QAI committee. Anydeficiencies noted during the audits will be referred immediately to the ClinicManager who is responsible to</p>	

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V 0545 Bldg. 00	<p>pressure cuff onto the clean countertop and was not observed to clean and disinfect the cuff.</p> <p>3. The clinic manager, employee L, indicated, on 7-29-15 at 12:20 PM, the employees had not followed facility policy regarding the cleaning and disinfection of equipment after use on patients.</p> <p>4. The facility's 1-28-15 "Cleaning and Disinfection" policy number FMS-CS-IC-II-155-110A states, "Non-disposable items such as blood pressure cuffs, . . . should be disinfected with 1:100 bleach solution after each treatment."</p> <p>494.90(a)(2) POC-EFFECTIVE NUTRITIONAL STATUS The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate. Based on clinical record and facility policy review and interview, the facility failed to ensure the interdisciplinary team (IDT) had provided the necessary care and services to maintain the patients'</p>	V 0545	<p>address the issue with each employee including corrective action as appropriate</p> <p>The Clinic Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the QAI committee as noted above.</p> <p>On August 25 and 26th, 2015, the Clinic Manager reviewed the "Comprehensive Interdisciplinary Assessment and Plan of Care" policy with the Dietitian, Social Worker and Nursing Staff in reference to</p>	09/30/2015			

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	<p>albumin levels in 2 (#s 2 and 3) of 2 records reviewed for nutritional status.</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>Clinical record number 2 failed to evidence the IDT had provided the necessary care and services to maintain the patient's albumin level at 4.0 (or greater) grams per deciliter (g/dL) as specified by the Centers for Medicare and Medicaid Services (CMS) Measures Assessment Tool (MAT). <ul style="list-style-type: none"> <li>A. Laboratory results dated 1-13-15 evidenced the albumin level was 2.8 g/dL.</li> <li>B. Laboratory results dated 2-3-15 evidenced the albumin level was 2.6 g/dL.</li> <li>C. Laboratory results dated 3-16-15 and 4-8-15 evidenced the albumin level was 2.9 g/dL.</li> <li>D. Laboratory results dated 5-7-15 evidenced the albumin level was 2.8 g/dL.</li> <li>E. Laboratory results dated 6-8-15 evidenced the albumin level was 2.6 g/dL.</li> </ul> </li> </ol>		<p>"provide the necessary care and counseling services to achieve and sustain an effective nutritional status". The Clinic Manager completed a 100% chart audit of all patients' albumin levels on 8/21/2015 to monitor all patients nutritional status. All patient's with albumins &lt; 4.0 had review of medical record, focusing on specific interventions for nutrition. Any patient medical record/Plan of Care found missing specific interventions, will be presented at the Interdisciplinary Team meeting conducted on 9/22/2015, including patient's # 2, 3,. Patient specific issues as identified will be included in the patient's specific Plan of Care. Of note: in review with RD: monthly dietary notes with hypoalbuminemia and the RD plan were found in the computer system after the survey for patient's # 2, 3. Monthly notes available at clinic. The Clinic Manager will ensure compliance by auditing 25% of all medical records of patients with albumins &lt; 4.0 monthly for a period of 3 months focusing on the patient's nutrition status and interventions. Frequency of ongoing monitoring will be determined by the QAI Committee based on resolution of the issues. The Clinic Manager is responsible to analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to</p>	

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	<p>2. Clinical record number 3 failed to evidence the IDT had provided the necessary care and services to maintain the patient's albumin level at 4.0 (or greater) grams per deciliter (g/dL) as specified by the Centers for Medicare and Medicaid Services (CMS) Measures Assessment Tool (MAT).</p> <p>A. Laboratory results dated 1-13-15 and 2-3-15 evidenced the albumin level was 2.8 g/dL.</p> <p>B. Laboratory results dated 3-11-15 evidenced the albumin level was 3.3 g/dL.</p> <p>C. Laboratory results dated 4-14-15 and 5-14-15 evidenced the albumin level was 3.1 g/dL.</p> <p>D. Laboratory results dated 6-2-15 and 7-9-15 evidenced the albumin level was 3.3 g/dL.</p> <p>3. The clinic manager, employee L, was unable to provide any additional documentation and/or information when asked on 7-28-15 at 2:30 PM regarding the albumin levels for patients numbered 2 and 3.</p> <p>4. The facility's 7-4-12 "Comprehensive Interdisciplinary Assessment and Plan of</p>		<p>presenting the monthly data to the QAI Committee for oversight and review. 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. 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>	

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V 0559 Bldg. 00	<p>Care" policy number FMS-CS-IC-I-110-125A states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: Note: The Measures Assessment Tool (MAT) will be used as a guideline for quality outcome areas listed below . . . Nutritional Status. Provide the necessary care and counseling services to achieve and sustain an effective nutritional status."</p> <p>494.90(b)(3) POC-OUTCOME NOT ACHIEVED-ADJUST POC If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must-</p> <p>(i) Adjust the plan of care to reflect the patient's current condition; (ii) Document in the record the reasons why the patient was unable to achieve the goals; and (iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure the interdisciplinary team (IDT) had identified reasons why desired goals had not been achieved and had</p>	V 0559	On August 25 and 26th, the Clinic Manager reviewed the "Comprehensive Interdisciplinary Assessment and Plan of Care" policy with the Dietitian, Social Worker and Nursing Staff emphasizing the	09/30/2015

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	<p>adjusted the plans of care to address any identified reasons in 2 (#s 2 and 3) of 4 records reviewed.</p> <p>The findings include:</p> <p>1. Clinical record number 2 failed to evidence the IDT had identified any reasons for the patient's inability to achieve an albumin level at 4.0 (or greater) grams per deciliter (g/dL) as specified by the Centers for Medicare and Medicaid Services (CMS) Measures Assessment Tool (MAT). The record failed to evidence the IDT had implemented any changes to the plan of care to address any identified reasons.</p> <p>A. Laboratory results dated 1-13-15 evidenced the albumin level was 2.8 g/dL.</p> <p>B. Laboratory results dated 2-3-15 evidenced the albumin level was 2.6 g/dL.</p> <p>C. Laboratory results dated 3-16-15 and 4-8-15 evidenced the albumin level was 2.9 g/dL.</p> <p>D. Laboratory results dated 5-7-15 evidenced the albumin level was 2.8 g/dL.</p>		<p>requirement that when a patient is unable to achieve an outcome, the team must: 1) adjust the plan of care to reflect the patient's current condition or 2) document in the record the reasons why the patient was unable to achieve the goal and 3) implement plan of care to address issues. Team does well at identifying when not meeting goal, need to document what plans and then follow towards achieving goal.</p> <p>The Clinic Manager will complete 100% chart audit of all patients with albumins &lt; 4 and Plans of Care by 9/30/2015 to review for update on not meeting goal and plan to meet goal. Any patient's medical record /Plan of Care found missing interventions for adjusting POC to achieve goal for albumin, will be presented at the Interdisciplinary Team Meeting conducted on 9/22/2015.</p> <p>The Clinic Manager will ensure compliance by auditing 25% of all medical records with albumin &lt; 4 monthly for a period of 3 months focusing on the nutrition status and interventions. Frequency of ongoing monitoring will be determined by the QAI Committee based on resolution of the issues.</p> <p>The Clinic Manager 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</p>	

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	<p>E. Laboratory results dated 6-8-15 evidenced the albumin level was 2.6 g/dL.</p> <p>2. Clinical record number 2 failed to evidence the IDT had identified any reasons for the patient's inability to achieve an albumin level at 4.0 (or greater) grams per deciliter (g/dL) as specified by the Centers for Medicare and Medicaid Services (CMS) Measures Assessment Tool (MAT). The record failed to evidence the IDT had implemented any changes to the plan of care to address any identified reasons.</p> <p>A. Laboratory results dated 1-13-15 and 2-3-15 evidenced the albumin level was 2.8 g/dL.</p> <p>B. Laboratory results dated 3-11-15 evidenced the albumin level was 3.3 g/dL.</p> <p>C. Laboratory results dated 4-14-15 and 5-14-15 evidenced the albumin level was 3.1 g/dL.</p> <p>D. Laboratory results dated 6-2-15 and 7-9-15 evidenced the albumin level was 3.3 g/dL.</p> <p>3. The clinic manager, employee L, was unable to provide any additional</p>		<p>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>	

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V 0587 Bldg. 00	<p>documentation and/or information when asked on 7-28-15 at 2:30 PM regarding the albumin levels for patients numbered 2 and 3.</p> <p>4. The facility's 7-4-12 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "If the patient is unable to achieve the desired outcomes, the team must adjust the Plan of Care to reflect the patient's current condition and Document in the medical record the reason(s) why the patient is unable to achieve the goal. Implement the Plan of Care changes to address the identified issues."</p> <p>494.100(b)(2),(3) H-FAC RECEIVE/REVIEW PT RECORDS Q 2 MONTHS The dialysis facility must - (2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and (3) Maintain this information in the patient ' s medical record. Based on clinical record and facility policy review and interview, the facility failed to ensure self-monitoring home records had been reviewed in 1 (# 4) of 4 records reviewed of patients on home dialysis.</p>	V 0587	TheClinic Manager during the staff in service on August 25 and 26th,2015 reviewed with the RN staff-Conditions for Coverage: FAC Receive/Review PTRecords Q 2 Months and detailed in FMS policy FMS-CT-HT-200-010A "Patient HomeRecord Keeping", to ensure	08/26/2015

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	<p>The findings include:</p> <p>1. Clinical record number 4 evidenced the patient received home hemodialysis treatments 5 to 6 times per week. The record included physician orders dated 6-3-15 that identifies the patient self-administers Epogen (a medication used to increase production of red blood cells to raise the hemoglobin level) 15,000 units 3 times per week.</p> <p>A. The record included physician, nursing, and medical social services notes dated 7-22-15 that evidenced the patient had been assessed by the disciplines during a clinic visit on this date.</p> <p>B. The record included "Home Therapies - Patient Anemia Medication Administration Records" with entries for entries for 6-24-15 through 7-28-15. The record failed to evidence the patient had self-administered any Epogen during this timeframe.</p> <p>1.). The record included "Home Therapies - Patient Anemia Medication Administration Records" with entries for 7-1-15 through 8-4-15. The record evidenced the patient had self-administered the Epogen only 2 times the week of 7-5-15.</p>		<p>that every home patients home record sheets will bereviewed at least every two months with documentation showing the review wascompleted. This is to include completeness of all forms, correct prescriptionfor dialysis and medications and notations of all trends and actions andeducation provided documented in medical record.</p> <p>TheClinic Manager will complete 100% chart audit of all patient's monthly visitsheets by 9/22/2015 to ensure that all patients have documentation showing thattheir home record sheets have been reviewed at a minimum of every twomonths. Any patient found out ofcompliance, including patient's # 4 will be reviewed at the next monthly clinic..Education will be provided to patients as required to complete home records perpolicy. Patient # 4 educated per Clinic Manager on 8/26/2015 at his clinicappointment.</p> <p>TheClinic Manager is responsible to report a summary of findings monthly utilizingthe medical record audit tool to the QAI committee. The QAI Committee is responsible to analyzethe results and determine a root cause analysis and new Plan of Action ifresolution is not occurring. Ongoing compliance will be monitored by the QAIcommittee.</p>	

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	<p>2.) The record included a nursing note, dated 7-22-15, that identified the nurse had reviewed the Epogen self-administration records but failed to evidence the nurse had noted the patient had not self-administered the Epogen per the physician's orders, had addressed it with the patient, or had notified the physician.</p> <p>C. The record included home hemodialysis treatment flow sheets dated 6-25-15 through 7-19-15. The flow sheets failed to evidence the nurse had completed a review of the flow sheets.</p> <p>1.). The flow sheet dated 6-25-15 had a sticky note attached that had been signed by employee E, a registered nurse (RN), on 7-22-15. The note states, [Employee H, an RN] please review." The RN, employee H, stated, on 7-29-15 at 10:15 AM that she was the patient's primary nurse but that she "was on vacation when the patient came in on 7-22-15." The RN indicated she had not yet reviewed the treatment sheets.</p> <p>2.). The treatment flow sheets identified when the test for chloramines had been completed. The Director of Operations, employee M, indicated, on 7-29-15 at 12:10 PM, the test was to be</p>			

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	<p>completed with each "new batch." The record failed to evidence the nurse had reviewed the flow sheets and noted the flow sheets were incomplete.</p> <p>3.) Flow sheets dated 6-27-15, 7-2-15, 7-13-15, and 7-17-15 failed to evidence if there was a "New Pureflow SL Batch" and whether or not a total chloramine check had been completed.</p> <p>2. The clinic manager, employee L, indicated, on 7-29-15 at 10:00 AM, the record did not evidence the nurse had checked the home records to identify the Epogen had not been administered as ordered and that the chloramine checks had not been documented.</p> <p>3. The facility's 3-7-12 "Patient Home Record Keeping" procedure number FMS-CS-HT-I-200-010C states, "Document review of log in progress note as part of monthly clinic visit."</p> <p>The facility's 3-7-12 "Patient Home Record Keeping" policy number FMS-CS-HT-I-200-010A states, "Home records will be reviewed by Home Program nursing staff during patient monthly clinic visits to identify trends or omissions."</p>			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152588	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 07/29/2015
NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE IRVINGTON			STREET ADDRESS, CITY, STATE, ZIP CODE 1740 INDUSTRY DRIVE INDIANAPOLIS, IN 46219		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	