

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152531	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 07/25/2013
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS WEST	STREET ADDRESS, CITY, STATE, ZIP CODE 805 BEACHWAY DR STE 100 INDIANAPOLIS, IN 46224
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V000000	<p>This was a federal ESRD recertification survey.</p> <p>Survey Dates: 7-22-13, 7-23-13, 7-24-13, and 7-25-13</p> <p>Facility #: 007941</p> <p>Medicaid Vendor #: 260016390</p> <p>Surveyor: Vicki Harmon, RN, PHNS</p> <p>FMC Indianapolis West was found to be out of compliance with Conditions for Coverage 42 CFR 494.90 Patient Plan of Care and 42 CFR 494.110 Quality Assessment and Performance Improvement.</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN July 31, 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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V000113	<p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.</p> <p>Based on observation, facility policy review, and interview, the facility failed to ensure staff members followed the Centers for Disease Control (CDC) recommendations and facility infection control policies during the initiation of dialysis treatments in 2 (observations # 1 and 2) of 2 observations of access of arteriovenous fistula (AVF) for initiation of dialysis creating the potential to affect all dialysis patients with AVFs.</p> <p>The findings include:</p> <p>1. The facility's 1-4-12 "Infection Control Overview" policy number FMS-CS-IC-II-155-060A states, "All infection control policies are consistent with recommendation of the Centers for Disease Control (CDC). All infection control policies will adhere to CMS and OSHA rules and regulation . . . Mandatory Components of Program: Adherence to standard and dialysis precautions . . . Infection control training and education, including maintenance of training records . . . Infection Control Policies: . . . Hand Hygiene, Dialysis unit</p>	V000113	<p>On August 7, 2013 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 Clinical Manager is responsible to ensure that all staff members follow "Hand Hygiene, Personal Protective Equipment and Infection Control Overview" policies to ensure a safe treatment environment that prevents cross contamination of patients and equipment.</p> <p>The Clinical Manager met with the facility Education Coordinator to arrange and schedule staff in-services to re-educate all staff members on the following policies "Hand Hygiene" FMS-CS-IC-II-155-090A and "Personal Protective Equipment" FMS-CS-IC-II-155-080A with emphasis placed on appropriate glove changes and hand hygiene using hand sanitizer after locating and palpating access and before cleansing the patient's access. Training will be completed by August 13 th 2013 and an in-service attendance sheet is</p>	08/13/2013	

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	<p>precautions (including the use of personal protective equipment) . . . Rinsing, cleaning, disinfection, preparation, and storage of reused items conforming to CMS requirement for use."</p> <p>A. The facility's 1-4-12 "Hand Hygiene" policy number FMS-CS-IC-II-155-090A policy states, "Hands will be . . . Decontaminated using alcohol based hand rub or by washing hands with antimicrobial soap and water before and after direct patient contact . . . Immediately after removing gloves, After contact with body fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly soiled, After contact with inanimate objects near the patient, When moving from a contaminated body site to a clean body site of the same patient."</p> <p>B. The facility's 1-4-12 "Personal Protective Equipment" policy number FMS-CS-IC-II-155-080A policy states, "Change gloves and practice hand hygiene between each patient contact and/or station to prevent cross-contamination. Remove gloves and wash hands after each patient contact . . . Avoid touching surfaces with gloves hands that will be touched with ungloved hands (for ex. patient charts and computers)."</p>		<p>available in the facility for review in addition an audit with skills checks will be completed by August 13 th 2013</p> <p>The Clinical Manager will ensure that infection control audits utilizing the QAI Infection Control audit tool are done weekly for 4 weeks, monthly for 6 months and then as determined by the QAI calendar. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager who is responsible to address the issue with each employee including corrective action as appropriate</p> <p>The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.</p>		

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	<p>2. The CDC Morbidity and Mortality Weekly Report (MMWR) October 25, 2002, Volume 51 No. RR-16 "Guideline for Hand Hygiene in Health-Care Setting" states, "Recommendations: Indications for handwashing and hand antisepsis . . . Decontaminate hands before having direct contact with patients . . . Decontaminate hands after contact with a patient's intact skin . . . Decontaminate hands if moving from a contaminated body site to a clean body site during patient care. Decontaminate hands after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient. Decontaminate hands after removing gloves."</p> <p>3. The facility's 7-4-12 "Assessment and Preparation of Internal Access for Needle Placement" procedure number FMS-CS-IC-I-115-006C states, "Ask your patient to wash access area with liquid soap for one minute, rinsing well. Dry with clean paper towel."</p> <p>4. Employee R, a patient care technician (PCT), was observed to initiate the dialysis treatment for patient number 6 on 7-23-13 at 9:50 AM. The employee failed to wash the skin over the access site with soap and water or an antibacterial scrub prior to preparing the site for the initiation of the dialysis treatment. The patient</p>			

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	<p>indicated the patient had not washed the skin over the access site upon entering the facility.</p> <p>Employee R failed to change her gloves and cleanse her hands after locating and palpating the access site with her gloved finger in preparation for cannulation of the sites.</p> <p>5. Employee I, a PCT, was observed to initiate the dialysis treatment for patient number 2 on 7-23-13 at 11:10 AM. The employee failed to change her gloves and cleanse her hands after locating and palpating the access site with her gloved finger in preparation for cannulation of the sites.</p> <p>6. The clinic manager, employee D, and the Director of Operations, employee S, indicated, on 7-23-13 at 2:10 PM, they were unaware of the requirement to change gloves and cleanse hands after locating and palpating the skin over the access site prior to cannulation of the site. The Director indicated this step was not a part of facility policy and procedure.</p>				

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V000403	<p>494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. Based on preventative maintenance (PM) record and facility policy review and interview, the facility failed to ensure equipment used to perform preventative maintenance on the dialysis machines had been maintained in accordance with facility practice in 1 (# 2) of 2 PM records reviewed of equipment used to perform PM on dialysis machines creating the potential to affect all of the facility's 44 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The facility's PM records for the equipment used to perform conductivity, temperature, and pressure monitoring of the dialysis machines failed to evidence the pressure module had been calibrated since 12-12-11. 2. The technical supervisor, employee M, stated, on 7-24-13 at 1:20 PM, "The piece of equipment used to monitor conductivity, temperature, and pressure on the dialysis machines is the 90XL. It 	V000403	<p>On August 7, 2013 the Regional Quality Manager met with the Technical Operations Manager and the Technical Supervisor to review the deficiency related to the 90 XL meter.</p> <p>As a result of the citation on July 25, 2013, the facility reviewed the manufacturer's directions for use and identified that the meter is required to be calibrated prior to each use.</p> <p>Prior to each use, the meter will be calibrated following the manufacturer's directions by the technical staff and documented on the ER-1.</p> <p>An in-service for all technical staff will be conducted by August 9, 2013 to review the calibration and documentation requirements of the 90XL meter. The Technical Supervisor or his designee is responsible to review the ER-1 log monthly ensuring calibrations have been completed and to present the data monthly in QAI.</p> <p>The Director of Operations is</p>	08/16/2013	

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	<p>has 2 modules, one for conductivity and temperature and 1 for pressure. The individual modules are sent out for calibration. It appears the pressure module did not get sent out in 2012. Our usual practice is to have them calibrated annually."</p> <p>3. The facility's 7-15-94 "Preventive Maintenance" policy number 153-060-010 states, "The Preventive Maintenance Program for Medical Equipment, Water Treatment Equipment and Reuse Equipment will be in accordance with the equipment manufacturer printed recommendations. The frequency of performing PM on the above types of equipment will be as recommended by the equipment and manufacturers literature."</p> <p>The "90XL Meter User's Guide" states, "Verify sensor module calibration before use or whenever inaccurate readings are suspected. Calibrate when needed."</p>		<p>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 monitor compliance</p>		

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V000456	<p>494.70(a)(5) PR-PARTICIPATE IN CARE;DISC/REFUSE TX The patient has the right to-</p> <p>(5) Be informed about and participate, if desired, in all aspects of his or her care, and be informed of the right to refuse treatment, to discontinue treatment, and to refuse to participate in experimental research; Based on clinical record review and interview, the facility failed to ensure the patient had been informed of changes in the dialysis prescription before the changes were made in 1 (# 1) of 5 records reviewed.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. During an interview with patient number 1, on 7-24-13 at 11:30 AM, the patient stated, "They changed the size of my dialyzer and I would like to have more information on that. They just did it." 2. Clinical record number 1 evidenced physician orders dated 6-21-13 that identified the dialyzer had been changed to a 180 NRE Optiflux dialyzer. The record failed to evidence the patient had been informed of the change in the dialyzer and had been educated regarding why the dialyzer had been changed. 3. The Director of Operations, employee S, stated, on 7-25-13 at 10:40 AM, "The 	V000456	<p>The Director of Operations met with the facility's Nurses on August 7 th 2013 to review their requirements as stated in the "Patient Rights and Responsibilities Policy" FMS-CS-IC-I-103-005A. This policy provides patients the right to be information about all aspects of their care.</p> <p>Effective immediately, the nursing staff will begin writing a nursing note/plan of care update monthly on each patient and will include discussions with patients if a prescription change has been done.</p> <p>The Clinical Manager will perform a 100% medical record audit by August 20 th 2013 Any patient found to have a recent prescription change done without discussion with the patient will have a plan of care update completed and reviewed at the next plan of care meeting on August 20 th an 28 th 2013 including patient #1.</p> <p>The Clinical Manager will utilize</p>	08/28/2013	

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	doctor changed to bigger dialyzers for some patients that had continued high phosphorous levels." The director was unable to provide any additional documentation and/or information regarding how and when the patient had been informed and educated regarding the change in dialyzer.		<p>the QAI tool for Medical Record Auditing of all patients monthly times 2, then ongoing as determined by the QAI calendar to ensure the timely completion of all plan of care updates.</p> <p>The Clinical Manager is responsible to report a summary of findings monthly utilizing the tracking tool as noted above. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.</p>		

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V000540	<p>494.90 CFC-PATIENT PLAN OF CARE</p> <p>Based on clinical record and facility policy review, interview, and observation, it was determined the facility failed to maintain compliance with this condition by failing to ensure it had managed the patients' volume status by addressing those patients that had not attained their physician ordered estimated dry weights in 4 of 5 records reviewed creating the potential to affect all of the facility's 44 current patients (See V 543); by failing to ensure blood flow rates had been maintained as ordered in 2 of 5 records reviewed creating the potential to affect all of the facility's 44 current patients (See V 544); by failing to ensure albumin levels had been drawn monthly in 1 of 5 records reviewed creating the potential to affect all of the facility's 44 current patients (See V 545); by failing to provide appropriate anemia management to maintain patient's hemoglobin at the desired level in 5 of 5 records reviewed creating the potential to affect all of the facility's 44 current patients (See V 547); and by failing to ensure all patients had been seen by a physician or the nurse practitioner at least monthly in 1 of 5 records reviewed creating the potential to affect all of the facility's 44 current patients (See V 560).</p>	V000540	<p>The Governing Body of this facility acknowledges its responsibility to ensure that all patients' Plans of Care are complete and include the participation of all members of the IDT including the patient in the development and implementation of the Plan; that the Plan provides for blood pressure and fluid monitoring, adequacy monitoring to include ordered blood flow rates, ensuring all labs are monitored monthly and that they are seen by a medical practitioner monthly. The Governing Body reviewed the SOD and determined the immediate corrections required and the following action steps were agreed upon and implemented:</p> <ul style="list-style-type: none"> Effective immediately: <ul style="list-style-type: none"> · The Governing Body will meet weekly to review the status of the Plan of Correction specific to this Statement of Deficiencies. · The Clinical Manager will continue to analyze and trend all data and monitoring/audit results as related to this Plan of Correction focusing on the specifics that were recently identified in the Statement of Deficiency prior to presenting the monthly data to the QAI Committee for oversight and review. · The Director of Operations will present an update on the Plan of Correction and all other actions taken toward the resolution of the deficiencies at 	08/20/2013
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	The cumulative effect of these systemic problems resulted in the facility being found out of compliance with this condition, 42 CFR 494.90 Patient Plan of Care.		each Governing Body meeting through to the resolution. · The processes as noted in this POC will be reviewed by the Governing Body at each meeting. These meetings will ensure ongoing progress towards resolution of noted deficiencies is being provided. · Minutes of the Governing Body and QAI meetings, as well as monitoring forms, educational documentation will provide evidence of these actions, the Governing Body's direction and monitoring of facility activities. These will be available for review at the facility. The response provided for V 543 describes, in detail, the processes and monitoring steps taken to ensure that all members of the interdisciplinary team had addressed the patients' volume status with monthly updates being done as needed. The response provided for V 544 describes, in detail, the processes and monitoring steps taken to ensure that all blood flow rates are maintained including interventions to sustain the blood flow rates with monthly updates being done on the Plan of Care. The response provided for V 545 describes, in detail, the processes and monitoring steps taken to ensure that all patients have a monthly albumin drawn or have documentation as to why one was not done. The response provided for V 547 describes, in detail, the processes and monitoring steps		

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			taken to ensure that all patients' hemoglobin's are at the desired level including interventions to sustain the hemoglobin level with monthly updates being done on the Plan of Care. The response provided for V 560 describes, in detail, the processes and monitoring steps taken to ensure that all patients are seen monthly by a medical practitioner.	

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V000543	<p>494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; Based on clinical record and facility policy review and interview, the facility failed to ensure it had managed the patients' volume status by addressing those patients that had not attained their physician ordered estimated dry weights in 4 (#s 1, 2, 4, and 5) of 5 records reviewed creating the potential to affect all of the facility's 44 current patients.</p> <p>The findings include:</p> <p>1. Clinical record number 1 included physician orders dated 6-21-13 that identified the desired estimated dry weight (EDW) was 71.5 kilograms (kg). (The EDW is the desired weight at the end of the dialysis treatment.)</p> <p>A. A post treatment flow sheet dated 6-24-13 evidenced the dry weight was 72.5 kg at the end of the treatment.</p> <p>B. A post treatment flow sheet dated 7-1-13 evidenced the dry weight was 73.8 at the end of the treatment.</p>	V000543	<p>To specifically address inclusion of the patient's volume status to manage blood pressure in the patient care plan, the following has occurred:</p> <ul style="list-style-type: none"> · Reeducation of the IDT and attending physicians on policy FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care on August 13 h 2013 · Review of 100% of the patient records by August 20 th 2013 · Any patient found out of compliance including patients #1, 2, 4 and 5 will have a plan of care completed and reviewed at the Plan of Care meeting on August 20 th and 28 th 2013 · Implemented a weekly monitoring process of running the hemodialysis treatment report and presenting to the physician any weight variance of +/- 1.0 kg. <p>The Clinical Manager is responsible to report a summary of findings monthly to the QAI. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring.</p>	08/28/2013			

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	<p>C. A post treatment flow sheet dated 7-5-13 evidenced the dry weight was 74.6 at the end of the treatment.</p> <p>D. A post treatment flow sheet dated 7-8-13 evidenced the dry weight was 75 at the end of the treatment.</p> <p>E. A post treatment flow sheet dated 7-10-13 evidenced the dry weight was 73.45 at the end of the treatment.</p> <p>F. A post treatment flow sheet dated 7-12-13 evidenced the dry weight was 72.4 at the end of the treatment.</p> <p>G. A post treatment flow sheet dated 7-17-13 evidenced the dry weight was 74 at the end of the treatment.</p> <p>H. A post treatment flow sheet dated 7-22-13 evidenced the dry weight was 72 at the end of the treatment.</p> <p>I. The record failed to evidence the facility had addressed the issue of the patient not attaining the physician ordered estimated dry weight.</p> <p>2. Clinical record number 2 included physician orders dated 6-1-13 that identified the desired EDW was 69.3 kg.</p> <p>A. A post treatment flow sheet dated</p>		<p>Ongoing compliance will be monitored by the QAI committee.</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>6-27-13 evidenced the dry weight was 70.2 as the end of the treatment.</p> <p>B. A post treatment flow sheet dated 6-29-13 evidenced the dry weight was 70.4 at the end of the treatment.</p> <p>C. A post treatment flow sheet dated 7-2-13 evidenced the dry weight was 70.8 at the end of the treatment.</p> <p>D. A post treatment flow sheet dated 7-4-13 evidenced the dry weight was 70.5 at the end of the treatment.</p> <p>E. A post treatment flow sheet dated 7-9-13 evidenced the dry weight was 71.1 at the end of the treatment.</p> <p>F. A post treatment flow sheet dated 7-11-13 evidenced the dry weight was 70.3 at the end of the treatment.</p> <p>G. A post treatment flow sheet dated 7-13-13 evidenced the dry weight was 70.5 at the end of the treatment.</p> <p>H. A post treatment flow sheet dated 7-16-13 evidenced the dry weight was 70.1 at the end of the treatment.</p> <p>I. A post treatment flow sheet dated 7-18-13 evidenced the dry weight was 70.3 at the end of the treatment.</p>			

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	<p>J. A post treatment flow sheet dated 7-20-13 evidenced the dry weight was 70.1 at the end of the treatment.</p> <p>K. During an interview with patient number 2, on 7-23-13 at 11:20 AM, the patient stated, "Lately I have not been reaching my target weight. My blood pressure drops about 1 1/2 hours into the treatment and they shut me off [the ultrafiltration]. I don't think the machine is reading the blood pressure right. They say it is very low and I feel fine. They readjust the cuff multiple times but they still get low readings. I asked if they had another way to measure it [the blood pressure] and they said they don't. So I don't reach my target weight."</p> <p>L. The record failed to evidence the facility had addressed the issue of the patient not attaining the physician ordered estimated dry weight.</p> <p>3. Clinical record number 4 included physician orders dated 11-28-12 that identified the desired EDW was 56 kg.</p> <p>A. A post treatment flow sheet dated 6-24-13 evidenced the dry weight was 57.2 at the end of the treatment.</p> <p>B. A post treatment flow sheet dated</p>				

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	<p>6-26-13 evidenced the dry weight was 57.8 at the end of the treatment.</p> <p>C. A post treatment flow sheet dated 7-1-13 evidenced the dry weight was 69.5 at the end of the treatment.</p> <p>D. A post treatment flow sheet dated 7-3-13 evidenced the dry weight was 59.1 at the end of the treatment.</p> <p>E. A post treatment flow sheet dated 7-5-13 evidenced the dry weight was 59.2 at the end of the treatment.</p> <p>F. A post treatment flow sheet dated 7-8-13 evidenced the dry weight was 65 at the end of the treatment.</p> <p>G. A post treatment flow sheet dated 7-10-13 evidenced the dry weight was 64 at the end of the treatment.</p> <p>H. A post treatment flow sheet dated 7-12-13 evidenced the dry weight was 58.3 at the end of the treatment.</p> <p>I. A post treatment flow sheet dated 7-19-13 evidenced the dry weight was 60.1 at the end of the treatment.</p> <p>J. The record failed to evidence the facility had addressed the issue of the patient not attaining the physician ordered</p>				

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	<p>estimated dry weight.</p> <p>4. Clinical record number 5 included physician orders dated 4-12-13 that identified the desired EDW was 112.5 kg.</p> <p>A. Post treatment flow sheets dated 6-24-13 and 6-26-13 evidenced the dry weight was 116.8 at the end of the treatment.</p> <p>B. A post treatment flow sheet dated 6-28-13 evidenced the dry weight was 115.4 at the end of the treatment.</p> <p>C. A post treatment flow sheet dated 7-1-13 evidenced the dry weight was 116.5 at the end of the treatment.</p> <p>D. A post treatment flow sheet dated 7-3-13 evidenced the dry weight was 116.6 at the end of the treatment.</p> <p>E. A post treatment flow sheet dated 7-5-13 evidenced the dry weight was 117.4 at the end of the treatment.</p> <p>F. A post treatment flow sheet dated 7-10-13 evidenced the dry weight was 117.7 at the end of the treatment.</p> <p>G. A post treatment flow sheet dated 7-12-13 evidenced the dry weight was 115.6 at the end of the treatment.</p>				

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	<p>H. A post treatment flow sheet dated 7-15-13 evidenced the dry weight was 117.8 at the end of the treatment.</p> <p>I. A post treatment flow sheet dated 7-17-13 evidenced the dry weight was 115.8 at the end of the treatment.</p> <p>J. A post treatment flow sheet dated 7-19-13 evidenced the dry weight was 115.2 at the end of the treatment.</p> <p>K. A post treatment flow sheet dated 7-22-13 evidenced the dry weight was 116.9 at the end of the treatment.</p> <p>L. The record failed to evidence the facility had addressed the issue of the patient not attaining the physician ordered estimated dry weight.</p> <p>5. The Director of Operations, employee S, stated, on 7-25-13 at 12 PM, "It is our usual practice to address the EDW and possibly change after 3 treatments. They physician needs to be notified."</p> <p>6. The facility's 7-4-12 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The patient's individualized comprehensive Plan of Care must include, but is not</p>						

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	limited to the following: . . . Dose of Dialysis . . . Provide necessary care and services to manage the patient's volume status."			

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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. Based on clinical record and facility policy review, observation, and interview, the facility failed to ensure blood flow rates had been maintained as ordered in 2 (#s 4 and 5) of 5 records reviewed creating the potential to affect all of the facility's 44 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 4 included physician orders dated 11-28-12 that identified the blood flow rate (BFR) was 400 milliliters per minute. <ul style="list-style-type: none"> A. A post dialysis treatment flow sheet dated 6-24-13 evidenced the BFR ranged from 338-341 during the treatment. B. A post dialysis treatment flow sheet dated 6-28-13 evidenced the BFR ranged from 317-354. C. A post dialysis treatment flow sheet dated 7-3-13 evidenced the BFR had run at 350 during the treatment. 	V000544	<p>A mandatory in-service is scheduled for all members of the IDT on August 13 th 2013 to review policy "Comprehensive Interdisciplinary Assessment and Plan of Care" FMS-CS-IC-I-110-125A. Special emphasis was placed on ensuring that the patient's prescribed blood flow rate is delivered according to the physician's prescription. Additional education was provided to all direct patient care staff on how and what to document when BFR is not able to be reached and when the physician should be notified on August 13 th 2013</p> <p>This will be monitored daily by the Charge Nurse using the Rounding Tool. Frequency of 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</p>	08/13/2013			

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	<p>D. A post dialysis treatment flow sheet dated 7-5-13 evidenced the BFR had run at 375.</p> <p>E. A post dialysis treatment flow sheet dated 7-15-13 had ranged from 305 to 315 during the treatment.</p> <p>F. Post dialysis treatment flow sheets, dated 7-17-13 and 7-19-13, evidenced the BFR had run at 350 during the treatments.</p> <p>2. On 7-23-13 at 12:50 PM, observation noted the BFR for patient number 5 was 400. Clinical record number 5 included physician orders dated 4-12-13 and 7-24-13 that evidenced the BFR was to run at 500 milliliters per minutes.</p> <p>A. A post dialysis treatment flow sheet dated 6-24-13 evidenced the BFR had run at 450 during the treatment.</p> <p>B. A post treatment flow sheet dated 6-26-13 evidenced the BFR had ranged from 395 to 450 during the treatment.</p> <p>C. A post treatment flow sheet dated 6-28-13 evidenced the BFR had ranged from 415 to 455.</p> <p>D. Post treatment flow sheets, dated 7-1-13, 7-3-13, 7-5-13, 7-10-13, 7-12-13,</p>		<p>the results of the Rounding Tool audits weekly for 4 weeks, monthly for 2 months 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>7-15-13, 7-17-13, 7-19-13, and 7-22-13 evidenced the BFR had run at 450 during the treatment.</p> <p>E. A post treatment flow sheet dated 7-8-13 evidenced the BFR had run at 405 during the treatment.</p> <p>2. The Regional Quality Manager, employee T, and the Director of Operations, employee S, were unable to provide any additional documentation and/or information when asked on 7-25-13 at 10:40 AM.</p> <p>3. The facility's 7-4-12 "Comprehensive Interdisciplinary Assessment and Plan of 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: . . . Dose of Dialysis Sustain the prescribed dose of dialysis to meet FMS target HD eKdrt/V of 1.2 . . . Provide necessary care and services to manage the patient's volume status."</p>			

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V000545	<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 albumin levels had been drawn monthly in 1 (# 3) of 5 records reviewed creating the potential to affect all of the facility's 44 current patients.</p> <p>The findings include:</p> <p>1. Clinical record number 3 included a physician order dated 10-1-12 that identified a monthly albumin level was to be drawn. The record failed to evidence an albumin level had been obtained for the month of June 2013.</p> <p>The record included laboratory results that evidenced an albumin level of 3.8 grams per deciliter on 5-6-13 and that the albumin level had decreased to 3.5 on 7-1-13. According to the Centers for Medicare and Medicaid Services Measures Assessment Tool, the desired albumin level is 4.0 or greater grams per deciliter</p>	V000545	<p>To specifically address inclusion of monitoring albumin level no less often than monthly as part of the patient care plan, the following has occurred:</p> <ul style="list-style-type: none"> · Reeducation of the IDT and attending physicians to policy FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care" on August 13 th 2013 · Review of 100% of the patient records by August 20 th 2013 · Scheduled a care plan meeting for August 20 th and 28 th 2013 to review any plan of care including patient #3. · Implemented a weekly monitoring process of running the lab ordered status report and rescheduling labs when needed · If unable to obtain an albumin level, a plan of care update will be completed with the reason why one was not obtained <p>The Clinical Manager is responsible to report a summary of findings monthly to the QAI. The QAI Committee is responsible to analyze the results</p>	08/28/2013			

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	<p>2. The Director of Operations, employee S, and the Regional Quality Manager, employee T, stated, on 7-25-13 at 10:00 AM, "We did not draw one [in June]."</p> <p>3. The facility's 3-20-13 "Laboratory Testing" policy number FMS-CS-IC-II-135-010A states, "The dialysis facility must provide, or make available, laboratory testing (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient."</p>		<p>and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.</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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V000547	<p>494.90(a)(4) POC-MANAGE ANEMIA/H/H MEASURED Q MO</p> <p>The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level.</p> <p>The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs. Based on clinical record and facility policy review and interview, the facility failed to provide appropriate anemia management to maintain patient's hemoglobin at the desired level in 5 (#s 1, 2, 3, 4, and 5) of 5 records reviewed creating the potential to affect all of the facility's 44 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Clinical record number 1 included physician orders dated 1-1-13 that identified Epogen (a medication used to treat anemia) was to be administered in accordance with the "Corporate MAB Recommended Anemia Algorithm." <p>A. The record evidenced Epogen 17,000 units had been administered 3 times per week starting on 4-19-13. The record included laboratory results that evidenced the patient's hemoglobin level was 11.5 g/dL (grams per deciliter) on</p>	V000547	<p>To specifically address inclusion of managing anemia and monitoring hemoglobin/hematocrit monthly as part of the developed patient care plan, the following has occurred:</p> <ul style="list-style-type: none"> Reeducation of the IDT and attending physicians to policy FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care on August 13 th 2013 Review of 100% of the patient records by August 20 th 2013 Any records found out of compliance will have a plan of care completed and discussed at the care plan meeting on August 20 th and 28 th 2013 including patients #1, 2, 3, 4 and 5 The facility was started on the anemia case management program on July 24, 2013 which is a remote monitoring program. Communication is provided daily to the facility by the anemia case manager 	08/28/2013			

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	<p>5-27-13 and that the Epogen had been held effective 5-30-13. The facility failed to follow the algorithm by holding the Epogen dose at 11.5. The algorithm states, "Hgb [hemoglobin] greater than 11.5 g/dL Hold and re-evaluate with weekly hemoglobin checks."</p> <p>B. The record included laboratory results that evidenced the patient's hemoglobin level was 10.6 on 6-17-13. The record failed to evidence the Epogen had been re-started per the algorithm.</p> <p>C. The record included laboratory results that evidenced the patient's hemoglobin level was 9.3 on 6-24-13 and that the Epogen had been re-started at 12,600 units 3 times per week. The algorithm indicated the Epogen should have been re-started at 13,000 units.</p> <p>D. The Regional Quality Manager, employee T, indicated, on 7-25-13 at 9:00 AM, the Epogen should have been re-started at 13,000 units 3 times per week.</p> <p>2. Clinical record number 2 included physician orders dated 6-22-13 and 7-20-13 that evidenced Epogen 3400 units was to be administered 3 times per week.</p> <p>A. Post treatment flow sheets, dated</p>		<p>The Clinical Manager is responsible to report a summary of findings monthly to the QAI. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.</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>6-27-13, 6-29-13, 7-2-13, 7-4-13, 7-6-13, 7-9-13, 7-11-13, 7-16-13, and 7-18-13, failed to evidence any Epogen had been administered as ordered.</p> <p>B. The record included laboratory results that evidenced the patient's hemoglobin levels were 11.5 on 6-25-13, 11.3 on 7-2-13, 10.8 on 7-9-13, and 10.1 on 7-16-13.</p> <p>C. The clinic manager, employee D, and the Regional Quality Manager, employee T, were asked to provide any additional documentation and/or information on 7-23-13 at 1:25 PM. The Regional Quality Manager stated, at 2:25 PM, "A nurse at another facility was doing the anemia management for this facility. She failed to follow the algorithm. She held the Epogen too soon and did not re-start it soon enough."</p> <p>3. Clinical record number 3 included physician orders dated 1-1-13 that identified Epogen was to be administered in accordance with the "Corporate MAB Recommended Anemia Algorithm."</p> <p>A. The record evidenced the most recent dose of Epogen 1000 units 2 times per week had been administered in February 2013. The record evidenced the patient was out of the facility from</p>				

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	<p>5-27-13 to 6-17-13 and that a hemoglobin level was drawn on 6-17-13 when the patient returned. The patient's hemoglobin level was 10.8 on 6-17-13. The record failed to evidence any Epogen had been re-initiated per the algorithm.</p> <p>B. The algorithm states, "No open EPOGEN order in last 3 months If no open EPOGEN order in the last 3 months, when Hgb is less than or equal to 11.1 g/dL contact physician to obtain a re-start dose." The record failed to evidence the physician had been contacted for the re-start dose.</p> <p>C. The record evidenced Epogen 1000 units 2 times per week had been re-started on 7-12-13. The Regional Quality Manager, employee T, stated, on 7-25-13 at 9:30 AM, "The physician should have been called after the 6-12 lab according to the protocol. It appears the nurse just re-started the previous dose from February."</p> <p>4. Clinical record number 4 included physician orders dated 1-1-13 that identified Epogen was to be administered in accordance with the "Corporate MAB Recommended Anemia Algorithm."</p> <p>A. The record included a physician order dated 6-21-13 that evidenced</p>			

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	<p>12,600 units of Epogen was to be administered 3 times per week. The record included orders dated 7-12-13 and 7-19-13 that evidenced 10,600 units were to be administered 3 times per week.</p> <p>B. The record included an order dated 7-4-13 to discontinue the Epogen. The Regional Quality Manager, employee T, stated, on 7-25-13 at 10 AM, "The order to discontinue the Epogen should have been to decrease the dose to 9800 units according to the protocol."</p> <p>C. The record included laboratory results that evidenced the patient's hemoglobin had decreased from 11.1 on 7-8-13 to 9.6 on 7-22-13.</p> <p>5. Clinical record number 5 included physician orders dated 1-1-13 that identified Epogen was to be administered in accordance with the "Corporate MAB Recommended Anemia Algorithm."</p> <p>A. The hemoglobin laboratory values and Epogen dosage changes were reviewed by the Regional Quality Manager, employee T, on 7-25-13 at 10:00 AM. On 5-13-13, the patient's hemoglobin was 8.6 and the Epogen dosage was correctly increased to 5200 units 3 times per week.</p>				

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	<p>B. The patient's hemoglobin level was 10.2 on 6-3-13. According to the algorithm, a "Hgb [hemoglobin] greater than or equal to 10 and increases by more than 1.0 g/dL over past 2 weeks, Decrease dose by using Column 5 of the Maintenance Dose Chart." The manager indicated that since the 6-3 value was an increase of more than 1.0, the dose should have been decreased to 4,000 units 3 times per week. The record failed to evidence any dose change had been completed.</p> <p>C. The patient's hemoglobin was 11.0 on 6-17-13. According to the algorithm, the Epogen should have been decreased to 4600. The record evidenced the dose had been decreased to 4400.</p> <p>D. On 7-1-13, the patient's hemoglobin was 10.9 and on 7-4-13 the record evidenced the Epogen dose had been decreased to 3600 units 3 times per week. According to the algorithm, the dosage should have been 4000.</p> <p>6. The facility's 7-4-12 "Comprehensive Interdisciplinary Assessment and Plan of 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: . . . Anemia</p>						

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	Provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin level."			

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V000560	<p>494.90(b)(4) POC-PTS SEEN BY MED STAFF 1X/MO The dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist or physician's assistant providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while the hemodialysis patient is receiving in-facility dialysis. Based on clinical record and facility policy review and interview, the facility failed to ensure all patients had been seen by a physician or the nurse practitioner at least monthly in 1 (# 3) of 5 records reviewed creating the potential to affect all of the facility's 44 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 3 failed to evidence a physician, or the nurse practitioner, had seen the patient during the month of June 2013. The record evidenced the physician saw the patient on 5-3-13 and not again until 7-8-13. 2. Employee P, a registered nurse, stated, on 7-25-13 at 10:35 AM, "There was no physician visit in June." 3. The facility's 7-4-12 Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The dialysis facility must ensure that all 	V000560	<p>The Director of Operations met with the Medical Director on August 7 th 2013 to review the requirement as noted in the Conditions for Coverage that all in-center patient's are seen by a medical practitioner (i.e. physician, NP or PA) at least monthly to include quarterly visits while the patient is receiving dialysis as determined by policy FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care" The Medical Director reviewed this with all physicians on August 7 th 2013</p> <p>Physician visits will be documented within the medical record and monitored by the Clinical Manager.</p> <p>The Clinical Manager will run the Absence/Hospitalization report weekly and review with the physician or nurse practitioner any patients that were not seen the prior week. If a patient is unable to be seen, a plan of care update will be done to discuss why a visit was not done.</p>	08/28/2013			

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	in-center patients are seen by a medical practitioner (i.e., physician, advanced practice registered nurse, or physician's assistant) providing ESRD care at least monthly."		<p>The Clinical Manager is responsible to present issues of non-compliance to the QAI Committee and Governing Body.</p> <p>The Director of Operations and Medical Director are responsible to provide further intervention with physicians as appropriate to ensure compliance.</p> <p>The Clinical Manager is responsible to present issues of non-compliance to the QAI Committee and Governing Body and the Director of Operations and Medical Director are responsible to provide further intervention with physicians as appropriate to ensure compliance. Documentation will be provided within QAI and GB minutes</p>		

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V000625	494.110 CFC-QAPI Based on quality assurance and performance improvement document and facility policy review and interview, it was determined the facility failed to maintain compliance with this condition by failing to ensure its QAPI program included monitoring of fluid and blood pressure management and a review and evaluation of all patient deaths in 5 of 5 months reviewed creating the potential to affect all of the facility's 44 current patients (See V 628); by failing to ensure calcium outcomes had been reviewed and evaluated as a part of their mineral metabolism and renal bone disease review in 5 of 5 months reviewed creating the potential to affect all of the facility's 44 current patients (See V 631); by failing to investigate root causes of low hemoglobin values in 5 of 5 months reviewed creating the potential to affect all of the facility's 44 current patients (See V 632); by failing to ensure the QAPI program included a review and evaluation of adverse events in 5 of 5 months reviewed creating the potential to affect all of the facility's 44 current patient (See V 634); and by failing to ensure its infection surveillance included monitoring of antibiotic susceptibility in 5 of 5 months reviewed creating the potential to affect all of the facility's 44	V000625	V 625 The Governing Body acknowledges its responsibility to ensure that Fresenius Medical Care Indianapolis West has an effective, data driven Comprehensive Quality Assessment and Performance Improvement program that reviews patient deaths, patient outcomes with root cause analysis when not meeting goal, patient adverse events, patient infections to include antibiotic susceptibility and implements a process to review fluid and blood pressure management. The Governing Body, on August 7, 2013 reviewed the SOD and developed the following Plan of Correction ensuring that the deficiencies are addressed, both immediately and with long term resolution. The following action steps were implemented The Governing Body will meet weekly to monitor the progress of the Plan of Correction until the Condition level deficiencies are lifted, then monthly for an additional three months to ensure that the corrective actions have resulted in resolution of the cited issues. Once this is determined, the Governing Body will return to quarterly or as needed meetings. Effective immediately: · The Clinical Manager (CM) will analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to	08/20/2013			

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	<p>current patients (See V 637).</p> <p>The cumulative effect of these systemic problems resulted in the facility being found out of compliance with this condition, 42 CFR 494.110 Quality Assessment and Performance Improvement.</p>		<p>presenting the monthly data to the QAI Committee. · A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda. · The QAI Committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution. · The Director of Operations (DO) will present a report on the Plan of Correction data and all actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. · The Governing Body, at its meeting of August 7, 2013, designated the Regional Quality Manager to serve as Plan of Correction Monitor and provide additional oversight. She will actively participate in each QAI and Governing Body meeting - either personally or via conference call - and submit a status report at each of the referenced Governing Body meetings with a copy to the RVP. This additional oversight is to ensure the ongoing correction of deficiencies - as cited in the Statement of Deficiency - through to resolution as well as ensure the Governance of the facility is presented current and complete data to enhance their governance oversight role · The Regional Quality Manager will provide</p>	

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			<p>education on the "Quality Assessment and Performance Improvement Program" FMS-CS-IC-II-101-001A to the QAI committee on August 20 th 2013 on how to conduct a QAI meeting · Minutes of the Governing Body and QAI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's direction and oversight and the QAI Committee's ongoing monitoring of facility activities. These are available for review at the facility.</p> <p>· The responses provided for V 628, V 631, V 632, V 634 and V 637 describe, in detail, the processes and monitoring steps taken to ensure that all deficiencies as cited within this Condition are corrected to ensure ongoing compliance</p>		

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V000628	<p>494.110(a)(2) QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS</p> <p>The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves.</p> <p>Based on quality assurance performance improvement (QAPI) document and facility policy review and interview, the facility failed to ensure its QAPI program included monitoring of fluid and blood pressure management and a review and evaluation of all patient deaths in 5 (February through June 2013) of 5 months reviewed creating the potential to affect all of the facility's 44 current patients.</p> <p>The findings include:</p> <p>1. The facility's QAPI meeting minutes, dated 2-28-13, 4-3-13, 4-18-13, 5-17-13, and 6-20-13, failed to evidence the facility had monitored fluid and blood pressure management by the review and evaluation of the percentage of intradialytic weight loss, blood pressure variances pre and post dialysis, and intradialytic symptoms of depletion.</p> <p>The Regional Quality Manager, employee T, stated, on 7-25-13 at 1:50</p>	V000628	<p>On August 20 th 2013 the Regional Quality Manager scheduled a meeting with all participants of the QAI committee for the purpose of reeducation on the "Quality Assessment and Performance Improvement Program" FMS-CS-IC-II-101-001A. This education included but was not limited to the following:</p> <ul style="list-style-type: none"> ·QAI Processes ·Including tools with all minutes monthly ·Mortality analysis and trending ·Blood pressure and fluid management monitoring and trending <p>The Clinical Manager will review the Mortality summary log and trending tool. Reports will be evaluated to determine if any patient death was a result of the care provided by the facility. Any items identified as not meeting an outcome will have an action plan developed and followed monthly.</p> <p>The Clinical Manager is responsible to report a summary</p>	08/20/2013			

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	<p>PM, "We do not track that [fluid and blood pressure management]."</p> <p>2. The facility's QAPI meeting minutes, dated 2-28-13, 4-3-13, 4-18-13, 5-17-13, and 6-20-13, failed to evidenced the facility had reviewed and evaluated all patient deaths and had analyzed trends in causes of patient deaths.</p> <p>A. The University of Michigan 2012 Dialysis Facility Report evidenced the facility's standardized mortality ratio was 1.05 for 2008-2011 with the U.S. average being 1.00.</p> <p>B. The Regional Quality Manager, employee T, indicated, on 7-25-13 at 2:00 PM, the QAPI meeting minutes do not evidence documentation all patient deaths had been analyzed for trends in causes of patient deaths.</p> <p>3. The facility's 4-4-12 "Quality Assessment and Performance Improvement (QAPI) policy number FMS-CS-IC-I-101-001A states, "The Quality Assessment Performance Improvement (QAI) Program encompasses all aspects of patient care, including in-center, home hemodialysis, home peritoneal dialysis and self care, as well as support services to provide that care . . . Elements to be reviewed in the</p>		<p>of findings monthly. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.</p>				

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	QAI meeting include: Patient Care Outcomes."			

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V000631	<p>494.110(a)(2)(iii) QAPI-INDICATOR-CKD-MBD The program must include, but not be limited to, the following: (iii) Mineral metabolism and renal bone disease.</p> <p>Based on quality assurance performance improvement (QAPI) document and facility policy review and interview, the facility failed to ensure calcium outcomes had been reviewed and evaluated as a part of their mineral metabolism and renal bone disease review in 5 (February 2013 through June 2013) of 5 months reviewed creating the potential to affect all of the facility's 44 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> The facility's 2-28-13 and 4-3-13 QAPI meeting minutes failed to evidence any review and evaluation of calcium outcomes as a part of the mineral metabolism and renal bone disease review. The facility's 4-18-13, 5-17-13, and 6-20-13 meeting minutes included statistics regarding the number of patients with calcium values out of range, but failed to evidence an analysis and review of trends and root causes. The Regional Quality Manager, employee T, indicated, on 7-25-13 at 2:50 	V000631	<p>On August 20 th 2013 the Regional Quality Manager scheduled a meeting with all participants of the QAI committee for the purpose of reeducation on the "Quality Assessment and Performance Improvement Program" FMS-CS-IC-II-101-001A. This education included but was not limited to the following:</p> <ul style="list-style-type: none"> ·QAI Processes ·Including tools with all minutes monthly ·Calcium monitoring and trending and performing a root cause analysis when outcomes are not met <p>The Clinical Manager along with the dietitian will review all patients' calcium outcomes. A root cause analysis will be conducted for those patients not meeting goal. Any items identified as not meeting an outcome will have an action plan developed and followed monthly.</p> <p>The Clinical Manager is responsible to report a summary of findings monthly. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not</p>	08/20/2013			

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	<p>PM, the QAPI meeting minutes did not evidence a review and evaluation of patient outcomes related to calcium.</p> <p>4. The facility's 4-4-12 "Quality Assessment and Performance Improvement Program (QAPI)" policy number FMS-CS-IC-I-101-001A states, "Elements to be reviewed in the QAI meeting include: Patient Outcomes."</p>		<p>occurring. Ongoing compliance will be monitored by the QAI committee.</p>	

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V000632	<p>494.110(a)(2)(iv) QAPI-INDICATOR-ANEMIA MANAGEMENT The program must include, but not be limited to, the following: (iv) Anemia management. Based on quality assurance performance improvement (QAPI) document and facility policy review and interview, the facility failed to investigate root causes of low hemoglobin values in 5 (February 2013 through June 2013) of 5 months reviewed creating the potential to affect all of the facility's 44 current patients.</p> <p>The findings include:</p> <p>1. The facility's 5-17-13 QAPI meeting minutes evidenced a "Decrease of 19.4% from last month for patients meeting hgb adequacies. External employee is managing anemia protocol for west clinic at present . . . 17 patients were less than 10." The 6-20-13 meeting minutes states, "[Employee U] continues to manage anemia off site at this time with an increase of 15%. 28.6 % of pts [patients] [patients] [patients] [patients] [patients] are less than 10 g/gl [sic] . . . MD still questioning how with this % meeting target, how 70% of the company can be doing better."</p> <p>2. The meeting minutes failed to evidence the facility had reviewed and</p>	V000632	<p>On August 20 th 2013 the Regional Quality Manager scheduled a meeting with all participants of the QAI committee for the purpose of reeducation on the "Quality Assessment and Performance Improvement Program" FMS-CS-IC-II-101-001A. This education included but was not limited to the following:</p> <ul style="list-style-type: none"> ·QAI Processes ·Including tools with all minutes monthly ·Anemia monitoring and trending and performing a root cause analysis when outcomes are not met <p>The Clinical Manager along with the anemia manager will review all patients' anemia outcomes. A root cause analysis will be conducted for those patients not meeting goal. Any items identified as not meeting an outcome will have an action plan developed and followed monthly.</p> <p>The Clinical Manager is responsible to report a summary of findings monthly. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not</p>	08/20/2013
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	<p>evaluated the anemia management program. Five of 5 records reviewed failed to evidence the facility had provided the appropriate anemia management to maintain patient's hemoglobin at the desired level. (See G 547).</p> <p>3. The Regional Quality Manager, employee T, indicated, on 7-25-13 at 2:45 PM, the QAI committee had not monitored the anemia management program to the "extent that was needed. We thought we had an expert anemia manager in place but she was not following protocol." The manager indicated the facility had recognized there was an anemia problem in the facility but had not investigated the "root causes" of the problem.</p> <p>4. The facility's 4-4-12 "Quality Assessment and Performance Improvement Program (QAPI)" policy number FMS-CS-IC-I-101-001A states, "Elements to be reviewed in the QAI meeting include: Patient Outcomes."</p>		<p>occurring. Ongoing compliance will be monitored by the QAI committee.</p>		

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V000634	<p>494.110(a)(2)(vi) QAPI-INDICATOR-MEDICAL INJURIES/ERRORS</p> <p>The program must include, but not be limited to, the following: (vi) Medical injuries and medical errors identification.</p> <p>Based on quality assurance performance improvement (QAPI) document and facility policy review and interview, the facility failed to ensure the QAPI program included a review and evaluation of adverse events in 5 (February 2013 through June 2013) of 5 months reviewed creating the potential to affect all of the facility's 44 current patient.</p> <p>The findings include:</p> <ol style="list-style-type: none"> The facility's "QAI Adverse Event Report Log/Plan" evidenced 6 infections and 2 patient falls. QAPI meeting minutes, dated 2-28-13, 4-3-13, 4-18-13, 5-17-13, and 6-20-13, failed to evidence the facility had investigated the occurrences to determine root causes and to formulate a plan to address any identified reasons and prevent future occurrences. The Regional Quality Manager, employee T, indicated, on 7-25-13 at 2:15 PM, the meeting minutes did not evidence discussion of the adverse events. 	V000634	<p>V 634</p> <p>On August 20 th 2013, the Regional Quality Manager scheduled a meeting with all participants of the QAI committee for the purpose of reeducation on the Quality Assessment and Performance Improvement Program. This education included but was not limited to the following:</p> <ul style="list-style-type: none"> ·QAI processes including monthly analysis and trending of adverse events ·Adverse Event reporting as defined with the AE policy, analysis and trending ·Reviewing requirements within the QAI Meeting Minute Template <p>On August 20 th 2013 the Regional Quality Manager met with the Clinical Manager to review and reinforce the Clinical Manager's responsibility to utilize the QAI Minute Template to report, analyze, trend and develop action plans as necessary for all indicators defined within QAI. Additionally to utilize the Minutes to document all QAI Committee activities with emphasis placed on adverse</p>	08/20/2013			

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	3. The facility's 4-4-12 "Quality Assessment and Performance Improvement Program" policy number FMS-CS-IC-I-101-001A states, "All Adverse Events will be reviewed by the QAI committee to ensure appropriate intervention. Root cause analysis will be completed as appropriate."		<p>events as defined within the Adverse Event policy.</p> <p>The Clinical Manager or her designee will review treatment sheets daily for 2 weeks, weekly until the Condition is lifted, monthly times 2, then quarterly to ensure that all details of an adverse event or other incident as required with the QAI Meeting Template are reported and documented. Any areas of non-compliance will be addressed immediately including corrective action as appropriate and added to the QAI documentation for that date.</p> <p>The Governing Body, through its ongoing monitoring of the QAI committee, will ensure the immediate and on going identification of potential and actual problems to patient care and take appropriate steps to identify the root causes of problems and to develop, implement and track corrective actions through to resolution of those problems. Any issues/problems will be addressed via the above-specified process, documented in the QAI Minutes, and formally reported to the Governing Body by the Minutes. Minutes of both QAI Committee and Governing Body meetings will be available for review at the facility.</p>	

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V000637	<p>494.110(a)(2)(ix) QAPI-INDICATOR-INF CONT-TREND/PLAN/ACT The program must include, but not be limited to, the following: (ix) Infection control; with respect to this component the facility must-</p> <p>(A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence; (B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and (C) Take actions to reduce future incidents. Based on quality assurance performance improvement (QAPI) document and facility policy review and interview, the facility failed to ensure its infection surveillance included monitoring of antibiotic susceptibility in 5 (February through June 2013) of 5 months reviewed creating the potential to affect all of the facility's 44 current patients.</p> <p>The findings include:</p> <p>1. The facility's QAPI meeting minutes, dated 2-28-13, 4-3-13, 4-18-13, 5-17-13, and 6-20-13, failed to evidence the facility had reviewed and evaluated antibiotic susceptibility in reported infections.</p> <p>The facility's "2013 Infection Reporting Tool" evidenced the facility had 3 central venous catheter related infections, 1 blood infection, 1 positive</p>	V000637	<p>V 637 On August 20 th 2013 the Regional Quality Manager scheduled a meeting with all participants of the QAI committee for the purpose of reeducation on the QAI process. This education included but was not limited to the following:</p> <ul style="list-style-type: none"> ·QAI Processes ·Infection control reporting, analysis and trending <p>The Clinical Manager will review all infections and review the antibiotic susceptibility when cultures are obtained. Reports will be analyzed and any identified as not meeting an outcome will have an action plan developed and followed monthly.</p> <p>The Clinical Manager is responsible to report a summary of findings monthly. The QAI Committee is responsible to</p>	08/20/2013			

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	<p>wound culture, and 1 urine infection. The tool failed to evidence the facility had monitored the susceptibility of the antibiotic used to treat the infection in relation to the identified causative organism.</p> <p>2. The Regional Quality Manager, employee T, stated, on 7-25-13 at 2:15 PM, "There is no documentation [antibiotic susceptibility] is being tracked."</p> <p>3. The facility's 4-4-12 "Quality Assessment and Performance Improvement Program (QAPI)" policy number FMS-CS-IC-I-101-001A states, "Elements to be reviewed in the QAI meeting include: . . . Infection Surveillance."</p>		analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.		