

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152525	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 08/23/2013
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS NORTH	STREET ADDRESS, CITY, STATE, ZIP CODE 1225 W 86TH ST INDIANAPOLIS, IN 46260
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V000000	<p>This was a federal ESRD recertification survey.</p> <p>Survey Dates: 8-20-13, 8-21-13, 8-22-13, and 8-23-13.</p> <p>Facility #: 005139</p> <p>Medicaid Vendor #: 100217180A</p> <p>Surveyor: Vicki Harmon, RN, PHNS</p> <p>FMC Indianapolis North was found to be out of compliance with Condition for Coverage 42 CFR 494.90 Patient Plan of Care.</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN August 28, 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 changed gloves and cleansed hands at the appropriate times during central venous catheter dressing changes in 1 (#2) of 2 central venous catheter exit site care observations completed creating the potential to affect all facility patients with central venous catheters. (Employee L)</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Employee L, a patient care technician (PCT), was observed to change the central venous catheter exit site dressing on patient number 5 on 8-21-13 at 2:25 PM. The PCT was observed to perform hand hygiene and don clean gloves. The PCT removed the old dressing and, without changing her gloves or cleansing her hands, cleansed the exit site and applied a clean dressing. 2. The Regional Quality Manager, employee Y, indicated, on 8-23-13 at 1:00 PM, employee L had not performed the central venous catheter dressing change in 	V000113	<p>On September 5th 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. The Clinical Manager is responsible to ensure that all staff members follow "Hand Hygiene and Changing the Catheter Dressing" policies to ensure a safe treatment environment that prevents cross contamination of patients and equipment. 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 "Changing the Catheter Dressing" FMS-CS-IC-I-105-032C with emphasis placed on appropriate glove changes and hand hygiene when changing the catheter dressing. Training will be completed on September 17th 2013 and an in-service attendance sheet is available in the facility for review in addition an audit with skills checks will be completed by September 17th 2013 The Clinical Manager will</p>	09/20/2013			

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	<p>accordance with facility policy.</p> <p>3. The facility's 4-4-12 "Changing the Catheter Dressing" procedure number FMS-CS-IC-I-105-032C states, "Inspect and remove the old dressing . . . Discard dressing and remove gloves. Perform hand hygiene."</p>		<p>ensure that infection control audits utilizing the QAI Infection Control audit tool are done daily for 2 weeks, weekly for 4 weeks, monthly for 3 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. 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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V000117	<p>494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.</p> <p>When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.</p> <p>Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.</p> <p>Based on observation, interview, and review of facility policy, the facility failed to ensure the registered nurse prepared and administered medications in a manner to prevent cross-contamination in 2 (#s 1 and 2) of 2 parenteral medication preparation and administration observations completed creating the potential to affect all of the facility's 133 current patients. (Employees Q and I)</p> <p>The findings include:</p>	V000117	V 117 The Clinical Manager is responsible to ensure that all the nursing staff follow "Infection Control Overview" and "Medication Preparation and Administration" policies to ensure a safe treatment environment that prevents cross contamination of patients and equipment. The Clinical Manager met with the facility Education Coordinator to arrange and schedule staff in-services to re-educate all nursing staff on the following policies "Infection Control	09/20/2013			

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	<p>1. Employee Q, a registered nurse (RN), was observed to prepare and administer parenteral medications to patients numbered 14, 15, 16, and 4 on 8-21-13 at 1:50 PM. The RN prepared medications for the 4 patients at the medication preparation area. The RN carried all of the medications in her hand to the station where patient number 14 was dialyzing. The RN was observed to place the other 3 patients' medications on a counter-top behind the dialysis machine where patient number 14 was dialyzing and then administered Venofer, Zemplar, and Epogen to patient number 14. The RN then documented the administration of the medications using the keyboard on the computer located between stations 3 and 4.</p> <p>A. The RN retrieved the medications for patients numbered 15, 16, and 4 from the countertop behind the station where patient number 14 was dialyzing. She proceed to patient number 15 and placed the medications for the remaining 2 patients on the counter-top behind the station where patient number 15 was dialyzing. She donned clean gloves without cleansing her hands and administered Epogen to patient number 15. She removed her gloves and cleansed her hands and documented the</p>		<p>Overview” FMS-CS-IC-II-155-060A and “Medication Preparation and Administration” FMS-CS-IC-I-120-040A” with emphasis placed on clean versus contaminated areas and how and where medications are prepared and administered. Training will be completed on September 17th 2013 and an in-service attendance sheet will be available in the facility for review. Clinical Manager will ensure that infection control audits utilizing the QAI Infection Control audit tool are done daily for 2 weeks, weekly for 4 weeks, monthly for 3 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 The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body. 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</p>		

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	<p>administration of the medications to patient number 15 on the keyboard of the computer located between stations 5 and 6.</p> <p>B. The RN retrieved the medications intended for patients number 16 and 4 and dropped one of the syringes onto the floor. She picked it up, placed it in a biohazard trash can, and carried the remaining medications back to the medication preparation area. She placed them on the counter in the medication preparation area and prepared another syringe of Epogen to replace the one she dropped. After preparing the Epogen, she proceeded to the station where patient number 16 was dialyzing.</p> <p>C. Upon arrival at the station where patient number 16 was dialyzing, she placed the medications intended for patient number 4 on the counter-top behind the dialysis station where patient number 16 was dialyzing. She donned clean gloves without cleansing her hands. She was observed to administer Venofer and Epogen to patient number 16. After administering the medication she removed her gloves and cleansed her hands. She documented the administration of the medications on the computer keyboard located between stations 9 and 10.</p>		analysis then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee		

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	<p>D. The RN was observed to proceed to the station where patient number 4 was dialyzing. She donned clean gloves without cleansing her hands and administered the medications to patient number 4.</p> <p>2. Employee I, a RN, was observed to prepare and administer parenteral medications to patients numbered 7 and 17. She prepared the medications at the medication preparation area. She carried both patients' medications with her to the station where patient number 7 was dialyzing. She placed the medications for patient number 17 on the computer keyboard next to patient number 7's station. She donned clean gloves without cleansing her hands and administered the medications to patient number 7. She removed her gloves and cleansed her hands.</p> <p>The RN documented the administration of the medications to patient number 7 on the computer keyboard and retrieved the medications prepared for patient number 17. The RN proceeded to the station where patient number 17 was dialyzing and placed the medications on the chairside table without using a barrier to prevent contamination of the syringes from any pathogens</p>						

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	<p>possibly found on the chairside table. The RN administered administered Venofer, Epogen, and Zemplar to patient number 17. The RN removed her gloves and cleansed her hands.</p> <p>3. The Regional Quality Manager, employee Y, indicated, on 8-23-13 at 1:00 PM, the RNs had not administered the parenteral medications in accordance with facility policy. The employee indicated the RNs should not have taken other patients' medications to the stations.</p> <p>4. The facility's 7-4-2013 "Medication Preparation and Administration" procedure number FMS-CS-IC-I-120-040C states, "Wash hands. Apply full PPE to protect staff and patients from contamination with blood and body fluids. Check the label for the date and time when the medication was prepared. Take the medication to the patient's chair or bedside."</p> <p>The facility's 7-4-12 "Medication Preparation and Administration" policy number FMS-CS-IC-I-120-040A states, "Medications shall be prepared in a clean work area away from dialysis patient stations and delivered separately to each patient."</p> <p>5. The facility's 1-4-12 "Infection Control</p>						

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	<p>Overview" policy number FMS-CS-IC-II-155-060A states, "All infection control policies for patient care are consistent with recommendation of the Centers for Disease Control (CDC) Mandatory Components of Program: Adherence to standard and dialysis precautions."</p> <p>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>			

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V000147	<p>494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE Recommendations for Placement of Intravascular Catheters in Adults and Children</p> <p>I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters.</p> <p>II. Surveillance A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site.</p> <p>Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.</p> <p>VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections]. Based on observation, interview, and review of facility policy, the facility failed to ensure the registered nurse (RN) provided central venous catheter care in accordance with facility policy in 1 (# 1) of 2 initiation of dialysis with central</p>	V000147	The Clinical Manager is responsible to ensure that all staff members follow "Hand Hygiene and Changing the Catheter Dressing" policies to ensure a safe treatment environment that prevents cross contamination of	09/20/2013	

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	<p>venous catheter observations completed (employee I) and central venous catheter exit site care had been documented in accordance with facility policy in 4 (#s 1, 5, 7, and 8) of 4 records reviewed of patients with catheters creating the potential to affect all facility patients with a central venous catheter.</p> <p>The findings include:</p> <p>Re: Central Venous Catheter Dressing Change Timing:</p> <ol style="list-style-type: none"> 1. Employee I, a RN, was observed to initiate the dialysis treatment for patient number 18 on 8-21-13 at 11:40 AM. The RN initiated the dialysis treatment without first changing the exit site dressing. 2. The RN stated, on 8-21-13 at 11:50 AM, "I will start the treatment then do the dressing change." 3. The facility's 4-4-12 "Changing the Catheter Dressing" policy number FMS-CS-IC-I-105-032A states, "Complete the catheter exit site care and dressing replacement before initiation of treatment." <p>Re: Central Venous Catheter Dressing Change Documentation:</p>		<p>patients and equipment. 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 "Changing the Catheter Dressing" FMS-CS-IC-I-105-032C with emphasis placed on changing the catheter dressing prior to initiating treatment and documenting the observation of the exit site, catheter integrity and if any abnormal findings were reported. Training was completed on September 17th 2013 and an in-service attendance sheet is available in the facility for review in addition an audit with skills checks will be completed by September 17th 2013. The Clinical Manager will ensure that infection control audits utilizing the QAI Infection Control audit tool are done daily for 2 weeks, weekly for 4 weeks, monthly for 3 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. 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>1. The facility's 4-4-12 "Changing the Catheter Dressing" procedure number FMS-CS-IC-I-105-032 C states, "Document the dressing change in the patient's medical record. Include any observations of the exit site, catheter integrity, notifications to the team leader/charge nurse of abnormal findings, instructions, interventions made during the dressing change."</p> <p>2. Clinical record number 1 evidenced "catheter care" had been completed on 7-29-13, 7-31-13, and 8-5-13. The record failed to evidence documentation of the any observations of the exit site, catheter integrity, and if any abnormal findings had been reported.</p> <p>3. Clinical record number 5 evidenced "catheter care" had been completed on 7-29-13, 7-31-13, 8-2-13, 8-5-13, 8-7-13, 8-9-13, 8-12-13, 8-14-13, 8-16-13, and 8-19-13. The record failed to evidence documentation of the any observations of the exit site, catheter integrity, and if any abnormal findings had been reported.</p> <p>4. Clinical record number 7 evidenced "catheter care" had been completed on 7-30-13, 8-1-13, 8-3-13, 8-6-13, 8-8-13, and 8-10-13. The record failed to evidence documentation of the any</p>			

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	<p>observations of the exit site, catheter integrity, and if any abnormal findings had been reported.</p> <p>5. Clinical record number 8 evidenced "catheter care" had been completed on 7-30-13, 8-3-13, 8-6-13, 8-8-13, 8-10-13, 8-13-13, 8-15-13, and 8-17-13. The record failed to evidence documentation of any observations of the exit site, catheter integrity, and if any abnormal findings had been reported.</p> <p>6. The Regional Quality Manager, employee Y, indicated, on 8-23-13 at 1 PM, the exit site care had not been documented per the facility's own policy.</p>				

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V000540	<p>494.90 CFC-PATIENT PLAN OF CARE</p> <p>Based on clinical record and facility policy review, observation, and interview, 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 13 records reviewed creating the potential to affect all of the facility's 133 current patients (See V 543), by failing to provide appropriate anemia management to maintain patient's hemoglobin at the desired level in 5 of 13 records reviewed creating the potential to affect all of the facility's 133 current patients (See 547), and facility failed to ensure staff had provided appropriate access care prior to the initiation of the dialysis treatment in 1 of 2 access of arteriovenous fistula (AVF) or graft for initiation of dialysis observations and failed to provide appropriate post access care after discontinuation of dialysis in 2 of 2 discontinuation of dialysis and post dialysis access care for AV fistula and graft observations creating the potential to affect all patients with an AVF or graft (See V 550).</p> <p>The cumulative effect of these systemic problems resulted in the facility being</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 fluid monitoring, appropriate anemia management and access care both pre and post treatment. The Governing Body reviewed the SOD and determined the immediate corrections required and the following action steps were agreed upon and implemented: Effective immediately: 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 each Governing Body meeting through to the resolution. The processes as noted in this POC</p>	09/24/2013			

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	found out of compliance with this condition, 42 CFR 494.90 Patient Plan of Care.		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 547 describes, in detail, the processes and monitoring steps 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 550 describes, in detail, the processes and monitoring steps taken to ensure that all patients are provided with appropriate access care both pre and post treatment.		

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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, 4, 6, & 7) of 13 records reviewed creating the potential to affect all of the facility's 133 current patients.</p> <p>The findings include:</p> <p>1. Clinical record number 1 included physician orders dated 7-8-13 and 8-7-13 that identified the physician ordered estimated dry weight (EDW) as 69 kilograms (kg).</p> <p>A. A post dialysis treatment flow sheet dated 7-29-13 evidenced the patient's post dialysis weight was 73.50 kg.</p> <p>B. A post dialysis treatment flow sheet dated 7-31-3 evidenced the patient's post weight was 71.4 kg.</p>	V000543	<p>V543 To specifically address inclusion of the patient's volume status to manage blood pressure in the patient care plan, the following has occurred: Reeducation of the IDT and attending physicians on policy FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care on September 18th 2013 Review of 100% of the patient records by September 9th 2013 Any patient found out of compliance including patients #1, 2, 4 and 5 will have a plan of care update completed and reviewed at the Plan of Care meeting on September 24th 2013 Implemented a weekly monitoring process of running the hemodialysis treatment report and presenting to the physician any weight variance of +/- 1.0 kg. 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. The Director of Operations is</p>	09/24/2013	

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	<p>C. A post dialysis treatment flow sheet dated 8-2-13 evidenced the patient's post weight was 71.8 kg.</p> <p>D. A post dialysis treatment flow sheet dated 8-5-13 evidenced the patient's post weight was 71 kg.</p> <p>E. A post dialysis treatment flow sheet dated 8-7-13 evidenced the patient's post weight was 70.3 kg.</p> <p>F. A post dialysis treatment flow sheet dated 8-9-13 evidenced the post weight was 71 kg.</p> <p>G. A post dialysis treatment flow sheet dated 8-12-13 evidenced the post weight was 72 kg.</p> <p>H. A post dialysis treatment flow sheet dated 8-14-13 evidenced the post weight was 71.8 kg.</p> <p>2. Clinical record number 4 included physician orders dated 6-24-13 that identified the physician ordered estimated dry weight (EDW) as 64 kilograms (kg).</p> <p>A. A post dialysis treatment flow sheet dated 8-7-13 evidenced the patient's post dialysis weight was 64.8 kg.</p> <p>B. A post dialysis treatment flow</p>		responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body.		

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	<p>sheet dated 8-9-13 evidenced the patient's post dialysis weight was 65.8 kg.</p> <p>C. A post treatment flow sheet dated 8-12-13 evidenced the post weight was 65.9 kg.</p> <p>D. A post treatment flow sheet dated 8-14-13 evidenced the post weight was 65.4 kg.</p> <p>E. A post treatment flow sheet dated 8-16-13 evidenced the post weight was 65.5 kg.</p> <p>F. A post treatment flow sheet dated 8-19-13 evidenced the post weight was 65.4 kg.</p> <p>3. Clinical record number 6 included physician orders dated 7-2-13 that identified the physician ordered EDW as 70 kg.</p> <p>A. A post dialysis treatment flow sheet dated 7-30-13 evidenced the post treatment weight was 81 kg.</p> <p>B. A post dialysis treatment flow sheet dated 8-1-13 evidenced the post treatment weight was 80.9 kg.</p> <p>C. A post dialysis treatment flow sheet dated 8-3-13 evidenced the post</p>						

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	<p>treatment weight was 82.1 kg.</p> <p>D. A post treatment flow sheet dated 8-20-13 evidenced the post weight was 83 kg.</p> <p>E. The Regional Quality Manager, employee Y, stated, on 8-22-13 at 3:55 PM, "This should have been addressed."</p> <p>4. Clinical record number 7 included physician orders dated 7-9-13 and 8-8-13 that identified the physician ordered EDW as 70.5 kg.</p> <p>A. A post dialysis treatment flow sheet dated 7-30-13 evidenced the post treatment weight was 71.1 kg.</p> <p>B. A post treatment flow sheet dated 8-1-13 evidenced the post treatment weight was 72 kg.</p> <p>C. A post treatment flow sheet dated 8-3-13 evidenced the post weight was 71.5 kg.</p> <p>D. A post treatment flow sheet dated 8-10-13 evidenced the post weight was 72 kg.</p> <p>E. A post treatment flow sheet dated 8-15-13 evidenced the post weight was 74 kg.</p>						

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	<p>5. The Director of Operations, employee A, stated, on 8-23-13 at 1 PM, "We address anything above or below 1 kilogram of the estimated dry weight."</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: . . . Dose of Dialysis . . . Provide necessary care and services to manage the patient's volume status."</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 2, 3, 6, 7, and 11) of 13 records reviewed creating the potential to affect all of the facility's 133 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 2 included physician orders dated 1-2-13 that identified Epogen (a medication used to treat anemia) was to be administered in accordance with the "ANEMIA ALGORITHM EPO IV Administration (InCenter Only) Version 12.12." <p>A. The record evidenced Epogen 2,000 units had been administered 3 times per week starting on 7-5-13 per the algorithm. The record included laboratory results that evidenced the</p>	V000547	V547 To specifically address inclusion of managing anemia and monitoring hemoglobin/hematocrit monthly as part of the developed patient care plan, the following has occurred: Reeducation of the IDT and attending physicians to policy FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care on September 18th 2013 Review of 100% of the patient records by September 17th 2013 Any records found out of compliance will have a plan of care update completed and discussed at the care plan meeting on September 24th 2013 including patients #2, 3, 6, 7 and 11 The facility will start on the anemia case management program on September 9th 2013 which is a remote monitoring program. Communication is provided daily to the facility by the anemia case manager The Clinical Manager is responsible to report a summary of findings monthly to the QAI. The QAI Committee is responsible to	09/24/2013	

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	<p>patient's hemoglobin level was 9.0 g/dL (grams per deciliter) on 8-5-13 and that the Epogen had been increased to 2800 units 3 times per week on 8-9-13. The facility failed to follow the algorithm by increasing the Epogen dose to 2800. The algorithm states that if the hemoglobin level is less than 10 g/dL, "Increase EPO by 25% rounded to next lower even unit."</p> <p>B. The Regional Quality Manager, employee Y, stated, on 8-21-13 at 4:15 PM, "The does should have been 2400 units."</p> <p>2. Clinical record number 3 included physician orders dated 1-2-13 that identified Epogen was to be administered in accordance with the "ANEMIA ALGORITHM EPO IV Administration (InCenter Only) Version 12.12."</p> <p>A. The record evidenced Epogen 2400 units 3 times per week had been administered starting on 7-12-13 per the algorithm and that the Epogen had been held on 7-17-13 because the hemoglobin level had increased to 12.1. The algorithm states that for a hemoglobin level 11.8 or greater, "Hold EPO. Restart EPO decreasing does 50% from the last ordered dose rounded down to the next lower even unit 1 week after there Hgb [hemoglobin] falls below 11.3 g/dL."</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. 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.		

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	<p>B. The record evidenced the Hgb level decreased to 10.7 on 8-12-13 and that Epogen 2000 units 3 times per week had been initiated on 8-16-13 per the algorithm.</p> <p>C. The Regional Quality Manager, employee Y, stated, on 8-22-13 at 9:15 AM, "The EPO should have been re-started at 1200 units due to the last ordered dose was 2400 units on 7-12-13.</p> <p>3. Clinical record number 6 included physician orders dated 1-2-13 that identified Epogen was to be administered in accordance with the "ANEMIA ALGORITHM EPO IV Administration (InCenter Only) Version 12.12."</p> <p>A. The record evidenced Epogen 15,600 units had been administered 3 times per week starting 7-4-13 and that the Hgb level had decreased to 9.7 on 8-8-13. The algorithm states that for a hemoglobin level less than 10, "Increase EPO by 25% rounded to next lower even unit."</p> <p>B. The record failed to evidence the Epogen dosage had been increased per the algorithm.</p> <p>C. The Regional Quality Manager,</p>			

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	<p>employee Y, indicated, on 8-22-13 at 3:50 PM, the Epogen dose should have been increased per the algorithm.</p> <p>4. Clinical record number 7 included physician orders dated 1-2-13 that identified Epogen was to be administered in accordance with the "ANEMIA ALGORITHM EPO IV Administration (InCenter Only) Version 12.12."</p> <p>A. The record evidenced Epogen 10,000 units had been administered 3 times per week per the algorithm and that the hemoglobin level was 10.5 g/dL on 8-6-13. The algorithm states that for a hemoglobin level of 10.4 to 10.8, "Maintain current EPO dose."</p> <p>B. The record evidenced the EPO dose had been decreased to 7400 units 3 times per week on 8-10-13.</p> <p>C. The Regional Quality Manager, employee Y, indicated, on 8-22-13 at 4:25 PM, the Epogen dose should have remained at 10,000 units.</p> <p>5. Clinical record number 11 included physician orders dated 5-10-13 that identified Epogen was to be administered in accordance with the "Anemia Management Algorithm Home Therapies."</p>			

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	<p>A. The record evidenced the hemoglobin level was 11.4 on 7-9-13. The algorithm states, "If Hgb 11.1 - 11.4 g/dL Decrease dose by 25% and recheck in 2 weeks." The record failed to evidence any changes to the Epogen dose had been made.</p> <p>B. The home therapies director, employee S, indicated, on 8-23-13 at 12:15 PM, the Epogen dose should have been decreased by 25%.</p> <p>6. The facility's 1-4-12 "Medical Algorithm" procedure number FMS-CS-IC-II-150-010C states, "Staff must follow the Algorithm in all respects. Document in the medical record all steps taken to implement the Algorithm . . . As with all clinical care, the nurse is ultimately responsible for compliance with physician ordered Algorithms, including calculating and implementing dose changes."</p> <p>7. 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. Provide the necessary care and services to</p>			
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	<p>achieve and sustain the clinically appropriate hemoglobin level."</p> <p>8. The medical director, employee AA, stated, on 8-23-13 at 12:39 PM, "I was not aware the algorithm was not being followed. My algorithm is different. There are certain things I don't agree with so it is the way I want to practice medicine. I want to make sure patient anemia is well managed."</p>			

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V000550	<p>494.90(a)(5) POC-VASCULAR ACCESS-MONITOR/REFERRALS The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement.</p> <p>Based on observation, interview, and facility policy review, the facility failed to ensure staff had provided appropriate access care prior to the initiation of the dialysis treatment in 1 (#1) of 2 access of arteriovenous fistula (AVF) or graft for initiation of dialysis observations and failed to provide appropriate post access care after discontinuation of dialysis in 2 (#s 1 and 2) of 2 discontinuation of dialysis and post dialysis access care for AV fistula and graft observations creating the potential to affect all patients with an AVF or graft. (Employees A and M)</p> <p>The findings include:</p> <p>Regarding access for initiation of dialysis</p> <p>1. Employee A, a patient care technician (PCT), was observed to initiate the dialysis treatment on patient number 19 on 8-21-13 at 10:20 AM. The PCT failed</p>	V000550	<p>V 550 To specifically address vascular access monitoring and appropriate, timely referrals/follow-up to achieve and sustain vascular access, the following has occurred: Reeducation of the IDT and attending physicians to facility policy by September 18th 2013 Reeducation of the facility staff on washing a patient's access prior to initiation of their treatment and "Post Treatment Fistula Needle Removal" FMS-CS-IC-I-115-013C by September 18th 2013 Patient education to be provided to each patient on access washing by September 18th 2013 Implemented a monitoring process to be included with the infection control audit that will focus on washing a patient's access and post treatment needle removal. 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>	09/20/2013	

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	<p>to ask the patient to wash the skin over the access site with soap and water or antibacterial scrub.</p> <p>The patient stated, on 8-21-13 at 10:20 AM, "I took a shower this morning. I did not wash my access again when I came here."</p> <p>2. The Regional Quality Manager, employee Y, indicated, on 8-23-13 at 1:00 PM, the PCT had provided care in accordance with facility policy.</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>Regarding discontinuation of dialysis and post access care:</p> <p>1. Employee A, a PCT, was observed to discontinue the dialysis treatment on patient number 7 on 8-20-13 at 2:00 PM. The PCT was observed to remove the needles and place a Band-Aid over the insertion sites. The PCT then folded pieces of gauze into a small squares and secured them with tape over the insertion sites. When the insertion sites had</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. 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>stopped bleeding, the PCT removed the gauze and left the Band-Aid in place.</p> <p>2. Employee M, a registered nurse (RN), was observed to discontinue the dialysis treatment on patient number 20 on 8-21-13 at 9:30 AM. The RN removed the needles and placed a Band-Aid over the insertion sites. The RN then folded pieces of gauze into small squares and secured them with clamps over the insertion sites. The gauze over the 2nd insertion site was observed to be saturated with blood. The RN changed the gauze but did not change the Band-Aid when the bleeding had stopped.</p> <p>3. The Regional Quality Manager, employee Y, was unable to provide any additional documentation and/or information when asked on 8-23-13 at 1:00 PM.</p> <p>4. The facility's 7-4-12 "Post Treatment Fistula Needle Removal" procedure number FMS-CS-IC-I-115-013C states, "Follow the steps below to remove the arterial and venous needle . . . Stabilize the needle and carefully remove any tape . . . Position the gauze over the insertion site but do not apply pressure. Place your, or the patient's middle and index fingers on top of the gauze. Carefully remove the needle . . . Compress the needle exit site</p>			

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	with two fingers following complete removal of the needle . . . Apply pressure continuously . . . Once hemostasis has been achieved, dress the sites with band-aids of clean tape with gauze dressing."			

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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 7 (January through July 2013) of 7 months reviewed creating the potential to affect all of the facility's 133 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> The facility's QAPI meeting minutes, for the months of January 2013 through July 2013, 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>The Regional Quality Manager, employee Y, stated, on 8-23-13 at 3:00</p>	V000628	<p>On September 18th 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: QAI Processes Including tools with all minutes monthly Mortality analysis and trending Blood pressure and fluid management monitoring and trending 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. Fluid and blood pressure management will also be reviewed monthly and discussed in the clinical issues section within the QAI minutes. Any items identified as not meeting an outcome will have an action plan developed and followed monthly. The Clinical Manager is responsible to report</p>	09/20/2013	

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	<p>PM, "We do not track that [fluid and blood pressure management]."</p> <p>2. 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 QAI meeting include: Patient Care Outcomes."</p>		<p>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 occurring. Ongoing compliance will be monitored by the QAI committee.</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.</p> <p>Based on administrative record and facility policy review and interview, the facility failed to ensure its quality assessment performance improvement (QAPI) program addressed identified problems with infection control practices by home program staff in 2 (June and July 2013) of 2 months reviewed creating the potential to affect all of the facility's 41 current home patients.</p> <p>The findings include:</p> <p>1. The facility's QAPI meeting minutes dated 6-19-13 state, "The infection control audit was performed on all staff nurses in HT [home therapy] in May. there [sic] were some noted violations and report is pending and will be discussed in the June meeting."</p> <p>A. The 6-19-13 meeting minutes failed to evidence any discussion of the</p>	V000637	V 637 On September 18th 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: QAI Processes Infection control reporting, analysis and trending The Clinical Manager and Home Therapy Manager will review all infection control audits and discuss the findings at the next QAI meeting. Audits will be analyzed and any identified as not meeting an outcome will have an action plan developed and followed monthly. 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 occurring. Ongoing compliance will be monitored by the QAI committee.	09/20/2013	

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	<p>infection control audit results.</p> <p>B. The 7-17-13 meeting minutes failed to evidence any discussion of the infection control audit results.</p> <p>2. The Home Program Director of Operations, employee BB, was unable to provide any additional documentation and/or information when asked on 8-23-13 at 4 PM.</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>				

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V000715	<p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; Based on clinical record and facility policy review and interview, the medical director failed to ensure the facility policy requiring an initial evaluation by a registered nurse before the initiation of the first treatment had been implemented in 2 (#s 12 and 13) of 6 records reviewed of patients on service for less than 3 months creating the potential to affect all of the facility's new patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> The facility's 7-4-12 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "A registered nurse must evaluate patients NEW to dialysis BEFORE initiation of their first treatment to determine immediate needs." Clinical record number 12 evidenced the first dialysis treatment was 5-17-13. The post treatment flow sheet dated 5-17-13 evidenced the treatment had been 	V000715	<p>The Director of Operations met with the Medical Director on September 9th 2013 to review his requirements as defined in the Condition for Coverage and Medical Staff Bylaws to ensure that all policies and procedures relative to patient admission, patient care, infection control and patient safety are adhered to by all individuals who treat patients in the facility, including attending physicians and non-physician providers emphasizing ensuring that an initial nursing assessment is completed before initiation of a patient's first treatment in order to determine their immediate needs. The Director of Operations also reviewed the Plan of Correction to be instituted to correct this issue. The Medical Director approved and directed the implementation of the plan as noted below. The facility's patient care staff will be in-serviced on the following policies, "Hand Hygiene", "Changing the Catheter Dressing", "Medication Preparation and Administration", "Comprehensive Interdisciplinary Assessment and Plan of Care",</p>	09/20/2013			

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	<p>initiated at 12:15 PM and that the registered nurse had not evaluated the patient until 12:18 PM, after the treatment had been initiated.</p> <p>3. Clinical record number 13 evidenced the first dialysis treatment was 7-8-13. The post treatment flow sheet dated 7-8-13 evidenced the treatment had been initiated at 1:57 PM and that the registered nurse had not evaluated the patient until 2:25 PM, after the treatment had been initiated.</p> <p>4. The Regional Quality Manager, employee Y, indicated, on 8-23-13 at 3:30 PM, the registered nurse had not evaluated patient numbered 12 and 13 before the initiation of the first treatment.</p>		<p>on (date) by education with a record of training reviewed by the QAI committee. The Clinical Manager (CM) is responsible to present all data and monitoring/audit results as related to this Plan of Correction to the Medical Director at the QAI Meeting for oversight and review. The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented to the Medical Director during the monthly QAI Committee Meeting. The Medical Director as Chairperson of the QAI Committee is responsible to analyze the results and direct a root cause analysis with the development of a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee</p>		