

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152569	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 09/11/2014
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NAME OF PROVIDER OR SUPPLIER EAST EVANSVILLE DIALYSIS PD	STREET ADDRESS, CITY, STATE, ZIP CODE 1312 PROFESSIONAL BLVD EVANSVILLE, IN 47714
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V000000	<p>This was a Federal ESRD [CORE] recertification survey.</p> <p>Survey Dates: 9-8-14, 9-9-14, 9-10-14, and 9-11-14</p> <p>Facility #: 002562</p> <p>Medicaid Vendor #: 200071340A</p> <p>Surveyor: Vicki Harmon, RN, PHNS</p> <p>East Evansville Dialysis was found to be out of compliance with Condition for Coverage 42 CFR 494.60 Physical Environment and with 42 CFR 494.110 Quality Assessment and Performance Improvement.</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN September 17, 2014</p>	V000000		
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, interview, and review of facility policy, the facility failed to ensure staff had cleansed their hands and changed gloves appropriately</p>	V000113	<p>Facility Administrator (FA) held mandatory in-service for all clinical Teammates (TMs) on 9/24/2014. In-service included but was not limited to: review of Policy &</p>	10/11/2014

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	<p>in accordance with facility policy in 2 (#s 5 and 15) of 15 infection control observations completed creating the potential to affect all of the facility's 165 current patients. (Employees B and AA)</p> <p>The findings include:</p> <p>1. Employee B, a registered nurse (RN), was observed to initiate the dialysis treatment on patient number 13 on 9-8-14 at 11:10 AM. The RN was observed to insert the needles into the access and prepare to administer the bolus dose of heparin. The RN gathered empty packages into her left hand, removed the glove with the trash in it and disposed of the trash in the waste can. The RN then cleansed her left finger tips with an alcohol cleanser and donned a clean glove.</p> <p>A. The RN connected the syringe with the heparin bolus to the venous line. The RN removed the glove from her right hand and touched the data entry station. The RN then cleansed her right finger tips with an alcohol cleanser and donned a clean glove to the right hand. The RN completed the administration of the heparin bolus.</p> <p>B. The facility administrator, employee F, indicated, on 9-11-14 at 7:45</p>		<p><i>Procedure # 1-05-01: Infection Control for Dialysis Facilities and Policy & Procedure #7-03-02B: Use of Alcohol Based Hand Rubs. TMs instructed on proper hand hygiene technique including need to apply alcohol based disinfectant to hand and rub both hands together cleaning all surfaces of the hand after removing gloves, prior to touching keyboards, and prior to donning new gloves.</i></p> <p>Home Services FA held mandatory in-service for all home modality TMs on 9/24/2014 reviewing Home Hemodialysis Policy & Procedure #12-07-01: Infection Control for Dialysis Facilities. TMs instructed to perform hand hygiene upon entering the facility, prior to gloving, after removal of gloves, after contamination with infectious material, after patient and dialysis delivery system contact, between patients even if the contact is casual, before touching clean areas such as supplies and before leaving the patient care area.</p> <p>Verification of in-services will be evidenced by TM signature on in-service sheet.</p> <p>Home Services FA/designee will conduct infection control audit for compliance daily x 2 weeks then weekly x 2 weeks then monthly. FA will report findings to Medical Director during monthly Facility Health Meetings (FHM, minutes will</p>				

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	<p>AM, the RN had not changed her gloves and cleansed her hands appropriately in accordance with facility policy.</p> <p>2. Employee AA, an RN, was observed to administer Venofer (iron) intravenously to patient number 8 on 9-11-14 at 9:05 AM. The employee washed his hands and retrieved supplies to administer the medication from 3 different cabinets and a drawer. The RN removed the cap from the Venofer vial and placed an alcohol pad on top of the vial. The RN then donned clean gloves without cleansing his hands. The RN drew up the Venofer into 2 syringes. The RN then removed his gloves and was not observed to cleanse his hands.</p> <p>A. The RN then took the patient's blood pressure, both sitting and standing, removed the blood pressure cuff, and documented the results. The RN washed his hands and donned clean gloves. The RN then placed the Chux under the patient's arm, applied a tourniquet and palpated the site. The RN cleansed the needle insertion site with alcohol and Betadine, retrieved a laboratory tube from a plastic bag, and prepared tape for application to the insertion site. Without changing gloves and cleansing his hands, the RN then inserted the intravenous needle into the patient's antecubital space,</p>		<p>reflect.</p> <p>FA and Medical Director are responsible for compliance with this plan of correction</p>	

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	<p>drew blood into the laboratory tube and administered the Venofer.</p> <p>B. The home program manager, employee BB, indicated, on 9-11-14 at 2:30 PM, the RN had not changed his gloves and cleansed his hands appropriately in accordance with facility policy.</p> <p>3. The facility's March 2014 incenter "Infection Control For Dialysis Facilities" policy number 1-05-01 states, "Hand hygiene is to be performed upon entering the patient treatment area, prior to gloving, after removal of gloves, after contamination with blood or other infectious material, after patient and dialysis delivery system contact, between patients even if the contact is casual, before touching clean areas such as supplies and on exiting patient treatment area."</p> <p>4. The facility's September 2013 home hemodialysis "Infection Control for Dialysis Facilities" policy number 12-07-01 states, "Hand hygiene is to be performed upon entering the facility, prior to gloving, after removal of gloves, after contamination with blood or other infectious material, after patient and dialysis delivery system contact, between patients even if the contact is casual,</p>			

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V000119	<p>before touching clean areas such as supplies and before leaving the patient care area."</p> <p>494.30(a)(1)(i) IC-SUPPLY CART DISTANT/NO SUPPLIES IN POCKETS If a common supply cart is used to store clean supplies in the patient treatment area, this cart should remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood. Such carts should not be moved between stations to distribute supplies.</p> <p>Do not carry medication vials, syringes, alcohol swabs or supplies in pockets. Based on observation, interview, and review of facility policy, the facility failed to ensure staff had not carried supplies in pockets in 2 (#s 7 & 9) of 15 infection control observations completed creating the potential to affect all of the facility's 165 current patients. (Employee J)</p> <p>The findings include:</p> <p>1. Employee J, a patient care technician (PCT), was observed to perform central venous catheter exit site care to patient number 14 on 9-9-14 at 12:00 PM. The PCT was observed to reach into her pocket and retrieve a pen. The PCT used the pen to document the date on the tape</p>	V000119	<p>FA held mandatory in-service for all clinical TMs on 9/24/2014. In-service included but was not limited to: review of <i>Policy & Procedure # 1-05-01: Infection Control for Dialysis Facilities</i>. TMs informed that supplies including pens must not be carried in pockets to prevent cross contamination. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet. FA/designee will conduct infection control audit for compliance daily x 2 weeks then weekly x 2 weeks then monthly. FA will report findings to Medical Director during monthly FHM, minutes will reflect. FA and Medical Director are responsible for compliance with this plan of correction</p>	10/11/2014	

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V000147	<p>used to secure the clean dressing. The PCT then replaced the pen into her pocket.</p> <p>2. Employee J, a PCT, was observed to initiate the dialysis treatment on patient number 14 on 9-9-14 at 12:15 PM. The employee was observed to reach into her pocket 3 different times to retrieve and replace a pen used to document information during the initiation of the treatment.</p> <p>3. The facility administrator, employee F, indicated, on 9-11-14 at 7:45 AM, facility staff are not to carry supplies in their pockets.</p> <p>4. The facility's March 2014 "Infection Control For Dialysis Facilities" policy number 1-05-01 states, "Medication vials, syringes, tape, alcohol swabs, gloves or other supplies will not be carried in pockets."</p> <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</p>			

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	<p>the ... appropriate infection control measures to prevent intravascular catheter-related infections.</p> <p>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].</p> <p>Based on observation, interview, and review of facility policy, the facility failed to ensure staff had provided central venous catheter (CVC) care in accordance with facility policy in 4 (#s 1, 2, 3, and 4) of 4 CVC observation completed creating the potential to affect all of the facility's current patients with CVCs. (Employees J and L)</p> <p>The findings include:</p> <p>1. Employee J, a patient care technician (PCT), was observed to provide CVC</p>	V000147	<p>FA held mandatory in-service for all clinical TMs on 9/24/2014.</p> <p>In-service included but was not limited to: review of <i>Policy & Procedure #1-04-02A: Central Venous Catheter (CVC) Procedure</i> emphasizing importance of instructing patient to keep head turned to opposite side of CVC exit to decrease risk of site contamination and prevent infection during CVC care. TMs must keep the field around the patient's exit site clean to prevent cross contamination of the field.</p> <p>Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p>	10/11/2014	

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	<p>exit site care to patient number 14 on 9-9-14 at 12:00 PM. The PCT was not observed to ask the patient to turn the patient's head to the opposite side of the CVC exit site prior to performing the dressing change.</p> <p>2. Employee L, a PCT, was observed to provided CVC exit site care to patient number 15 on 9-9-14 at 12:35 PM. The PCT was not observed to ask the patient to turn the patient's head to the opposite side of the CVC exit site prior to performing the dressing change.</p> <p>3. Employee J, a PCT, was observed to initiate the dialysis treatment on patient number 14 on 9-9-14 at 12:15 PM. The PCT was not observed to ask the patient to turn the patient's head to the opposite side of the CVC exit site prior to accessing the CVC. The patient was observed to be wearing a surgical mask and was observed to cough directly onto the CVC exit site.</p> <p>4. Employee L, a PCT, was observed to initiate the dialysis treatment on patient number 15 on 9-9-14 at 12:40 PM. The PCT was not observed to ask the patient to turn the patient's head to the opposite side of the CVC exit site prior to accessing the CVC.</p>		<p>FA/designee will conduct infection control audit for compliance daily x 2 weeks then weekly x 2 weeks then monthly. FA will report findings to Medical Director during monthly FHM, minutes will reflect.</p> <p>FA and Medical Director are responsible for compliance with this plan of correction</p>				

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V000188	<p>5. The facility administrator, employee F, indicated, on 9-11-14 at 7:45 AM, the PCTs should asked the patients to turn their head to the opposite side of the CVC exit site.</p> <p>6. The facility's March 2014 "Central Venous Catheter (CVC) Cleaning and Dressing Change" procedure number 12-06-02C states, "Instruct patient to turn head to opposite side of CVC exit site. Decreases the risk of aerosolized bacteria contaminating site."</p> <p>7. The facility's March 2014 "Central Venous Catheter (CVC) Procedure" procedure number 1-04-02A states, "Instruct patient to turn head to opposite side of CVC exit site. Decreases the risk of aerosolized bacteria contaminating site."</p> <p>494.40(a) SEDIMENT FILTERS-CONFIG & MONITORING 5.2.2 Sediment filters: config and monitoring [Refer to RD62:2001, 4.3.8 Sediment filters:] Sediment filters shall have an opaque housing or other means to inhibit proliferation of algae.</p>						

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	<p>5.2.2 Sediment filters: Bed filters should be fitted with gauges to measure the hydrostatic pressure at the filters' inlet and outlet.</p> <p>6.2.2 Sediment filters: Sediment filters should be monitored on a periodic basis ... [for a] pressure drop (delta pressure) across the filter [that] can be used to determine when the filter is retaining particulate matter to the point that the filter will no longer allow the required water flow without an excessive reduction in pressure at the outlet of the filter. A backwash cycle is used to remove particulate matter from the sediment filter. The frequency of backwashing should follow the manufacturer's recommendations. Sediment filter monitoring should include daily verification that the timer used to initiate backwashing cycles is set to the correct time of day. A log sheet should be developed to record the pressure drop measurements and timer verifications.</p> <p>Based on water log and facility policy review and interview, the facility failed to ensure staff had notified the biomedical technician of pressure readings outside of desired limits on 2 (7-10-14 and 8-26-14) of 60 days reviewed creating the potential to affect all of the facility's 90 current incenter hemodialysis patients</p> <p>The findings include:</p> <p>1. The facility's "Daily Water Treatment Log" evidenced the pretreatment feed water pressure on 7-10-14 was 54 with the desired limit being 60 to 75 psi</p>	V000188	FA held mandatory in-service for all TMs responsible for water treatment monitoring on 9/24/2014 reviewing <i>Policy & Procedure #2-04-02: Daily Water Treatment System Monitoring, and Policy & Procedure #2-04-02A: Daily Water Treatment Log</i> . TMs instructed to verify that all test results are within the specified limits on the "Daily Water Treatment Log", and if any test results are not within specified limits to notify the FA and Biomedical Technician (BMT) assigned to the facility at the time it is noted out of range. TMs instructed to document time BMT notified in appropriate area on the "Daily Water Treatment	10/11/2014			

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V000228	<p>(pounds per square inch). The log failed to evidence the biomedical technician had been notified of the less than desired pressure reading.</p> <p>2. The facility's "Daily Water Treatment Log" evidenced the pretreatment feed water pressure on 8-26-14 was 56 with the desired limit being 60 to 75 psi. The log failed to evidence the biomedical technician had been notified of the less than desired pressure reading.</p> <p>3. The biomedical technician, employee T, stated, on 9-10-14 at 9:25 AM, "I don't recall being notified of the out of range water pressure readings."</p> <p>4. The facility's March 2014 "Daily Water Treatment System Monitoring" policy number 2-04-02 states, "All observations and test results will be within the limits specified on the 'Daily Water Treatment Log' . . . In addition to following the log form instructions, the teammate completing the log will notify the Facility Administrator/designee and Biomed teammate assigned to the facility of any observation or test result found outside the limit specified on the 'Daily Water Treatment Log.'"</p> <p>494.40(a) MIXING SYSTEMS-LABELING</p>		<p>Log". BMT or designee must take appropriate action and documentation must support actions taken and any necessary follow-up. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA/designee to conduct Daily Water Treatment Log audits to monitor compliance daily x 2 weeks, then weekly x 2 weeks then monthly. FA will report findings to Medical Director during monthly FHM, minutes will reflect.</p> <p>FA and Medical Director are responsible for compliance with thisplan of correction</p>				

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	<p>5.4.4.1 Mixing systems: labeling Labeling strategies should permit positive identification by anyone using the contents of mixing tanks, bulk storage/dispensing tanks, and small containers intended for use with a single hemodialysis machine.</p> <p>Mixing tanks: Prior to batch preparation, a label should be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. This labeling should remain on the mixing tank until the tank has been emptied.</p> <p>Bulk storage/dispensing tanks: These tanks should be permanently labeled to identify the chemical composition or formulation of their contents.</p> <p>Concentrate jugs: At a minimum, concentrate jugs should be labeled with sufficient information to differentiate the contents from other concentrate formulations used at the facility.</p> <p>Based on observation, interview, and facility policy review, the facility failed to ensure dialysate jugs had been labeled appropriately in 2 (#s 1 & 2) of 2 use of concentrate jugs observations completed creating the potential to affect all of the facility's 90 current incenter patients.</p> <p>The findings include:</p> <p>1. On 9-9-14 at 11:55 AM, observation noted a concentrate jug attached to the dialysis machine at station number 7. Employee E, a registered nurse (RN),</p>	V000228	<p>FA held mandatory in-service for all clinical TMs on 9/24/2014 reviewing <i>Policy & Procedure #2-07-05: Acid Concentrate System, Incoming, Acid Concentrate and Supply Log and use of Acid Gallon Concentrate Containers</i>. TM instructed that all concentrate containers must be labeled with the exact concentrate type and formulation. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA/designee to conduct observational audit to monitor compliance daily x 2 weeks, then</p>	10/11/2014	

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	<p>stated, "There are problems with the machine conductivity. I had to switch from the wall [centralized solution delivery system] to the jug. There is a problem with the loop. [The biomedical technician] is working on it." The jug was observed to be labeled "regular."</p> <p>The RN was observed to bring patient number 16 to the dialysis chair at station number 7 to prepare for the treatment. The patient was heard to voice discontent with having to wait "55 minutes" to begin the treatment. The RN stated, "Well, we had to get your machine ready."</p> <p>2. On 9-10-14 at 1:05 PM, jugs were observed to be in use at stations numbered 5, 13, 15, 19, 20, 21, 22, 10, 11, and 12. The jugs attached to the dialysis machines at stations numbered 5, 13, 15, 19, 20, 21, and 22 were labeled "regular." The labels failed to identify the exact content of the jugs.</p> <p>3. The facility administrator, employee F, indicated, on 9-10-14 at 1:10 PM, the jugs should be labeled with the exact content.</p> <p>4. Employee I, a patient care technician (PCT) stated, on 9-10-14 at 1:55 PM, "We are supposed to write 2K 2.5 Ca++ [2 potassium and 2 calcium] on the jugs.</p>		<p>weekly x 2 weeks then monthly. FA will report findings to Medical Director during monthly FHM, minutes will reflect.</p> <p>FA and Medical Director are responsible for compliance with this plan of correction</p>				

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V000356	<p>Sometimes we get in a hurry and forget to."</p> <p>5. The facility's September 2013 "Acid Concentrate System, Incoming, Acid Concentrate and Supply Log and Use of Acid Gallon Concentrate Containers" policy number 2-07-05 states, "All dialysate deliver systems, all concentrate ports, i.e., outlet boxes, storage tanks and piping will be labeled and color coded (red) according to their concentrate type and formulation."</p> <p>494.50(b)(1) RECORD ADV EVENTS/DIALYZER C/O LOG 13.2.3 Recording: adverse events dialyzer complaint log Any significant events such as the occurrence of symptoms listed in [AAMI] 13.2.1 and 13.2.2 should be recorded on an incident report form which would include the results of any evaluations conducted by the physician and others, and the event should be considered for reporting to the manufacturer(s) in accordance with the FDA's Medical Device User Reporting procedures. The resolution of actual or suspected problems caused by reprocessed dialyzers should be indicated. This form should be kept in the complaint investigation record file (see [AAMI] 4.5).</p> <p>4 Records 4.5 Complaint investigation record Records shall be kept of all complaints by patients and staff members about failures of</p>			

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	<p>preprocessed and reprocessed dialyzers or possible adverse reactions to any dialyzers; the results of a comprehensive investigation of these alleged problems; and, if appropriate, the corrective actions taken. The records shall be reviewed periodically for trends of adverse reactions. Compliance with the FDA's Medical Device User Reporting procedures shall be demonstrated.</p> <p>Based on reuse complaint log and facility policy review and interview, the facility failed to ensure complaint investigation records had been completed for all required instances of reprocessed dialyzer failures in 4 (March, May, July, and August 2014) of 6 months reviewed creating the potential to affect all of the facility's current patients that participate in the reuse program.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The facility's dialyzer failure log for March 2014 evidenced a failed dialyzer for patient number 17 on 3-29-14 due to "not reprocessable." The complaint investigation log failed to evidence an investigation had been completed. 2. The facility's dialyzer failure log for May 2014 evidenced a failed dialyzer for patient number 18 on 5-8-14 due to "pressure" and patient number 19 on 5-27-14 due to "pressure". The complaint investigation log failed to 	V000356	<p>FA held mandatory in-service for all Reuse TMs by 9/19/2014 reviewing <i>Policy & Procedure #6-01-13: Complaint Investigation Record</i>. TMs instructed on importance of completing Complaint Investigation Record, Complaint Investigation Record must be completed for dialyzer failures and process for completing record. Complaint Investigation and Reuse Communication Log must be reviewed monthly during FHM. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet</p> <p>FA/designee will audit complaint investigation record and reuse communication log weekly x 2 2 months, then monthly. Result of audits, Complaint Investigation Records and Reuse Communication Log will be reviewed monthly with Medical Director during FHM, minutes will reflect.</p> <p>FA and Medical Director are responsible for compliance with this plan of correction</p>	10/11/2014			

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V000400	<p>evidence an investigation had been completed for either instance of dialyzer failure.</p> <p>3. The facility's dialyzer failure log for July 2014 evidenced a failed dialyzer for patient number 20 on 7-9-14 due to "improper storage." The complaint investigation log failed to evidence an investigation had been completed.</p> <p>4. The facility's dialyzer failure log for August 2014 evidenced a failed dialyzer for patient number 21 on 8-25-14 due to "visual inspection." The complaint investigation log failed to evidence an investigation had been completed.</p> <p>5. The facility administrator, employee F, was unable to provide any additional documentation and/or information when asked on 9-11-14 at 11:30 AM.</p> <p>6. The facility's September 2013 "Complaint Investigation Record" policy number 6-01-13 states, "A Complaint Investigation Record is completed for the following: . . . Improper Storage . . . Not Reprocessable, Pressure Failure, Visual Inspection."</p> <p>494.60 CFC-PHYSICAL ENVIRONMENT Based on observation, review of</p>	V000400	DaVita East Evansville Dialysis	10/11/2014			

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	<p>administrative record and facility policy, and interview, it was determined the facility failed to maintain compliance with this condition by failing to maintain a safe environment on the treatment floor creating the potential to affect all of the facility's 90 current incenter patients (See V 401) and by failing to ensure treatment room floors and the central solution delivery system had been maintained creating the potential to affect all of the facility's 90 current incenter patients (See V 402).</p> <p>The cumulative effect of these systemic problems resulted in the facility being found out of compliance with this condition, 42 CFR 494.60 Physical Environment.</p>		<p>takes the conditions of coverage very seriously, immediate steps were taken to ensure facility has provided and maintained a safe environment on the treatment floor. These actions are outlined in depth in the Plan of Correction (POC) for V401, and V402. Governing Body (GB) meeting was held on 9/18/2014 to review the deficiencies received as a result of a survey concluded on 9/11/2014. Members of the GB including the Medical Director, FA, and Regional Operations Director (ROD) have agreed to meet weekly to monitor the facility's ongoing progress towards compliance providing clean and safe environment including but not limited to: 1) Immediate removal of electrical cords up off floor and securing, keeping walkways unobstructed; 2) Immediate repair of any identified leaks; 3) Immediate cleaning, stripping, waxing, buffing of floors to eliminate stains; 4) Replacement of Regulators and documentation to support; 5) Repair of countertops to allow for appropriate disinfection; 6) Concentrate jugs labeled with exact content in jug; 7) Inside chase cabinets cleaned of any debris, crystalline or powdery substance; 8) Auditing in place to maintain safe, sanitary environment for all identified areas; 9) Obtaining bid and approval to replace countertops and chase cabinets. GB will</p>		

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V000401	<p>494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment. Based on observation, interview, and review of administrative record and facility policy, the facility failed to maintain a safe environment on the treatment floor creating the potential to affect all of the facility's 90 current incenter patients.</p> <p>The findings include:</p> <p>1. On 9-8-14 at 10:35 AM, observation noted the treatment area to be a long rectangular room with the short sides being on the north and south ends of the room and long sides being on the east and west sides of the room. Dialysis stations</p>	V000401	<p>review FHM minutes to ensure minutes reflect, action plans are evaluated for effectiveness, new plans developed as applicable. Once compliance is achieved, POC will be monitored during GB at a minimum of quarterly. This POC will also be reviewed during FHM and the FA will report progress, as well as any barriers to maintaining compliance, with supporting documentation included in the meeting minutes</p> <p>Following immediate actions were taken by facility to ensure safe environment on treatment floor: 1) Equipment cords secured off floor by end of day 9/8/2014; 2) All walkways cleared and items placed in designated areas out of walkway; 3) Identified spills cleaned. Governing Body was held on 9/8/2014 to discuss environment clutter and actions for securing equipment and electrical cords out of pathway and keeping walkways free of obstacles, including wheelchairs/scooters, trash containers, linen containers, and chair-side snappy carts.</p> <p>FA immediately in-serviced clinical TMs on 9/8/2014 reviewing <i>Policy</i></p>	10/11/2014

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	<p>lined the perimeter of the room and 6 stations were located in the center (3 back to back). A nurses' station was located in the center of each end of the treatment floor with half walls delineating the area.</p> <p>Observation noted 3 to 4 long electrical cords on the floor at each of the 24 stations located around the perimeter and in the center of the treatment room. The cords were plugged into power strips dangling from carts that held the computers and keyboards. The carts were observed to be pulled out away from the perimeter walls and were sitting perpendicular to the hemodialysis machines, partially blocking the walkway in front of the dialysis stations. Laundry carts, hazardous trash cans, regular trash cans, and wheelchairs were observed to also be partially blocking the pathways in front of the dialysis stations.</p> <p>2. On 9-9-14 at 9:00 AM, observation noted 3 to 4 long electrical cords on the floor at each of the 24 stations located around the perimeter and in the center of the treatment room. The cords were plugged into power strips dangling from carts that held the computers and keyboards. The carts were observed to be pulled out away from the perimeter walls and were sitting perpendicular to the</p>		<p><i>& Procedure #8-04-01 Physical Environment and Policy & Procedure #4-13-01 Patient Fall Prevention Policy and Program.</i> FA also conducted mandatory in-service on 9/18/2014 reviewing <i>Policy & Procedure # 8-04-01 Physical Environment and Policy & Procedure #4-13-01 Patient Fall Prevention Policy and Program.</i> Education emphasized all TMs are responsible for providing a sanitary and safe environment in the treatment area, and throughout facility. 1) Facility must remain clean, uncluttered, and organized; 2) TMs must immediately clean up any spills; 3) Facility floors must remain clean and free of debris or trash; 4) Facility walkways must remain clear at all times, free of obstacles, electrical cords must remain secure out of walkways, equipment/supplies including but not limited to trash containers, linen containers, and chair-side snappy carts must be maintained in designated areas out of walkways; 5) Wheelchairs, scooters must be stored in designated area out of walkway. TMs instructed that verifying these safety procedures are followed will assist facility in maintaining a safe environment for TMs and patients. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet</p> <p>FA/designee to conduct observational audit to monitor compliance daily x 2 weeks, then</p>		

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	<p>hemodialysis machines, partially blocking the walkway in front of the dialysis stations. Laundry carts, hazardous trash cans, regular trash cans, and wheelchairs were observed to also be partially blocking the walkways in front of the dialysis stations.</p> <p>A. On the north end of the treatment floor, observation noted at 9:05 AM, a patient's scooter was sitting in the walkway in front of stations numbered 16, 17, 18, and 19 in addition to the laundry carts, trash cans, and wheelchairs.</p> <p>B. At 10:00 AM on 9-9-14 patient number 24 was observed to ambulate from station number 19 past stations numbered 20, 21, 22, 10, 11, and 12 towards the exit from the treatment room. The patient was pushing a wheelchair and employee M, a patient care technician (PCT), was walking in front of the patient moving obstacles (trash cans, other wheelchairs, etc.) out of the way so the patient could get through.</p> <p>C. At 10:30 AM, the facility administrator, employee F, was observed to bring patient number 25 to the treatment room in a wheelchair. The patient was complaining of chest pain. The patient was transferred to the first</p>		<p>weekly x 2 weeks then monthly. FA will report findings to Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA and Medical Director are responsible for compliance with this plan of correction</p>	

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	<p>dialysis chair (station number 1) at the entrance to the treatment room on the south end of the treatment floor. Employee A, a registered nurse, was observed to administer a nitroglycerin tablet to the patient and Emergency Medical Services (EMS) was called. EMS arrived at 10:35 AM and placed their gurney in the entrance to the treatment room next to the dialysis chair at station number 1. A dialysis machine, trash cans, and the computer cart had to be moved around to make room for the gurney and further obstructed the west side of the treatment room. The gurney blocked the entrance to the treatment room. Multiple patient treatments were completed at this time and other patients were waiting to be placed on the machines (change of shift).</p> <p>D. The emergency crash cart was located half way down the walkway between the dialysis stations and the nurses' stations on the east side of the treatment room. The walkway was partially obstructed with trash cans, laundry carts, supply carts, and other patient belongings.</p> <p>E. While EMS was providing care to patient number 25, patient number 11 had completed the treatment and had to be escorted out of the treatment area. The</p>						

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	<p>patient was observed to fold the walker and the patient's arm was being held by employee J, a PCT, to assist the patient to walk from station number 3 to the exit next to station number 1. The patient and the PCT had to maneuver among people and equipment to get out of the treatment room creating a fall risk to the patient.</p> <p>F. Also while EMS was providing care to patient number 25, patient number 26 was receiving treatment at station number 11 next to the alcove where the crash cart was located. The patient was observed to be vomiting and the patient's adult child was at the patient's chair side. The computer cart was observed to be pulled out away from the wall and was sitting perpendicular to the dialysis machine partially blocking the walkway in front of the dialysis station.</p> <p>G. On 9-9-14 at 5:05 PM, observation noted a large amount of clear fluid on the floor 1 to 2 inches away from the electrical cords under the cart that held the computer and keyboard.</p> <p>3. On 9-9-14 at 10:55 AM, observation noted the walkway at the north end of the treatment floor was completely blocked by 2 patient scooters, trash cans, laundry carts, and supply carts.</p>						

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	<p>4. On 9-9-14 at 11:30 AM, the facility administrator, employee F, and the clinical services specialist, employee HH, indicated the partially blocked walkways between the dialysis stations and the half walls of the nurses' stations created a hazard and the potential for falls or other injuries.</p> <p>5. The facility's administrative records included "Monthly OSHA and Safety Checklists" dated 3-28-14, 4-28-14, 5-28-14, 7-4-14, 7-29-14, and 8-29-14. The 4-28-14 checklist states, "Biohazard containers moved out of pt [patient] walkways on tx [treatment] floor. Homeroom done to review keeping walkways free of hazards." The issue was not identified again after 4-28-14.</p> <p>The registered nurse that completed the checklists, employee B, stated, on 9-10-14 at 1:25 PM, "I did not notice any more problems with blocked walkways."</p> <p>6. The facility's December 2012 "Physical Environment" policy number 8-04-01 states, "The dialysis facility will be designed, constructed, equipped, and maintained to provide dialysis patients, teammates, and the public a safe, functional, and comfortable treatment environment . . . The space for treating each patient will be sufficient to provide</p>			

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V000402	<p>needed care and services, prevent cross contamination, and to accommodate medical emergency equipment and teammates."</p> <p>The facility's March 2012 "Patient Fall Prevention Policy and Program" policy number 4-13-01 states, "Environmental Clutter: . . . Secure equipment and cords out of pathway . . . Keep hallways free of boxes, supplies, or obstacles, keep all patient wheelchairs in a separate location, away from the main traffic areas."</p> <p>494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public. Based on observation, interview, and review of facility policy, the facility failed to ensure treatment room floors and the central solution delivery system had been maintained creating the potential to affect all of the facility's 90 current incenter patients.</p> <p>The findings include:</p> <p>1. On 9-8-14 at 3:05 PM, observation noted black areas on the floor tiles in the areas between the tiles. There were 10 tiles at station 8 with black areas. At</p>	V000402	<p>On 9/18/2014 floors stripped, cleaned and waxed removing identified black areas on floor tiles and between floor tiles. The yellow stains were unable to be removed; FA has obtained consultation from outside contractor to conduct maintenance on specific floor tiles that will include procedures to remove possible moisture from floor, estimated 2 weeks to complete then, strip, wax, buff floors to assure stains are removed. Identified scuffed, and cracked countertops on chase cabinets covered with</p>	10/11/2014

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	<p>station 9, there were yellow stains on 2 of the tiles.</p> <p>The facility administrator, employee F, stated, "We have had a leak. [The biomedical technician] is aware and has addressed. Housekeeping is working on getting the stains up."</p> <p>2. On 9-9-14 at 5:05 PM, observation noted that chase cabinets lined the perimeter of the dialysis treatment floor and were also observed in the center of the treatment floor. The cabinets housed the central solution delivery system and had countertops with doors that could be lifted to view the inside of the cabinets. The outside of the cabinets were inset with piping that delivered 3 types of acid concentrate.</p> <p>A. Observation noted the counter tops on the chase cabinets at each of the 24 stations were scuffed, cracked, pocked, and had black stains. The metal framework that held the cabinets was rusted at each of the stations.</p> <p>B. The concrete floor was wet on the inside of the cabinet at station number 11. A white, powdery substance was observed on the floor.</p> <p>C. At station number 10, 2 test strips</p>		<p>protective material to assure intact surface that be appropriately disinfected. BMT will clean the inside of cabinet housing for the central solution delivery system by 10/11/2014, removing debris including test strips and residual substances on floor or piping. FA will obtain bid to replace cabinets housing for the central solution delivery system and counter tops and submit for approval by 10/11/2014; once bid approved construction will be scheduled. Specialized cabinets will take estimated 6 weeks to make the cabinets, and then full installation will be scheduled. Buckled baseboard identified at station 5 and 6 will be repaired/replaced by 10/11/2014. BMT will replace all remaining regulators in central solution delivery system by 10/11/2014 and log details of what regulator was changed and date of replacement. Log will be maintained and used to track which regulators are replaced and date of replacement. FA held mandatory in-service for clinical TMs on 9/24/2014. In-service included but was not limited to: 1) Instructing TMs to shut off all concentrate valves at the end of the day to prevent possible slow leaking; any identified leaks must be immediately reported to FA and BMT for repair; 2) Review of <i>Policy & Procedure #2-07-05 Acid Concentrate System, Incoming Acid Concentrate and Supply Log</i></p>	

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	<p>were observed on the floor inside the cabinet. There was a dried, white, powdery substance on the floor.</p> <p>D. At station number 22, a test strip was observed on the floor inside the cabinet.</p> <p>E. At stations numbered 19 and 20, 3 test strips were observed on the floor inside the cabinet.</p> <p>F. At stations numbered 15 and 17, a crystalline substance was observed on the piping in the inset box where the acid concentrates were dispensed.</p> <p>G. At stations numbered 5 and 6 the black baseboard was observed to be buckled and out of place.</p> <p>2. On 9-9-14 at 5:20 PM, the facility administrator, employee F, stated, "We need all new cabinetry. It all needs to be replaced."</p> <p>3. The biomedical technician, employee T, indicated, on 9-10-14 at 8:25 AM, the fluid noted on the floor and inside the cabinets was bicarbonate or acid solution. The technician stated, "There are a couple of reasons there are leaks. One is that the ports are being eaten by the acid. There is stainless steel inside the colored,</p>		<p><i>and Use of Acid Gallon Concentrate Container</i> with emphasis that all concentrate containers must be labeled with exact contents in container. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet FA/designee to conduct observational audit to monitor compliance daily x 2 weeks, then weekly x 2 weeks then monthly. BMT will conduct monthly observational physical plant audits to ensure facility is in good repair, along with ensuring facility maintains safe environment for patients and TMs. FA will review results of all audits with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance. FA and Medical Director are responsible for compliance with this plan of correction</p>				

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	<p>plastic adaptors. We started using a new acid about 1 1/2 years ago. The leaks started about 3 months ago. We discussed it in the quality meetings. The second reason is because the regulators are old and are not supported by the company anymore so we need to replace them. I have replaced 10 to 12 of them. If I can get enough money and the help, we could have them all replaced in one weekend. The girls leave the valves in the on position and there is a slow leak. At another clinic we have them make sure all the valves are in the off position every night."</p> <p>4. The medical director stated, on 9-10-14 at 1:00 PM, "I have been the medical director for about 1 month. I was aware they were replacing the regulators and that there was a problem."</p> <p>5. On 9-9-14 at 11:55 AM, observation noted a concentrate jug attached to the dialysis machine at station number 7. Employee E, a registered nurse (RN), stated, "There are problems with the machine conductivity. I had to switch from the wall [centralized solution deliver system] to the jug. There is a problem with the loop. [The biomedical technician] is working on it." The jug was observed to be labeled "regular."</p>			

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	<p>A. The RN was observed to bring patient number 16 to the dialysis chair at station number 7 to prepare for the treatment. The patient was heard to voice discontent with having to wait "55 minutes" to begin the treatment. The RN stated, "Well, we had to get your machine ready."</p> <p>B. On 9-10-14 at 1:05 PM, jugs were observed to be in use at stations numbered 5, 13, 15, 19, 20, 21, 22, 10, 11, and 12. The jugs attached to the dialysis machines at stations numbered 5, 13, 15, 19, 20, 21, and 22 were labeled "regular." The labels failed to identify the exact content of the jugs.</p> <p>6. Employee M, a patient care technician, stated, on 9-11-14 at 11:40 AM, "Sometime we have to get high calcium from the tanks in the back." The PCT indicated this was because of problems with machine conductivity and the central solution delivery system.</p> <p>7. The biomedical technician, employee T, stated, on 9-10-14 at 9:20 AM, "The conductivity problems with the machines are due to the regulator problems on the loop. The regulators are either bad and won't let the solution in at all or the regulators won't adjust. Using the jugs showed the regulator is the problem, not</p>			

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V000544	<p>the dialysis machine. We use jugs at least 10 per day especially the last 5 stations at the end of the loop. About 1/3 of the regulators need to be replaced, there are 4 per station. I have done 8 to 10 of them and have 10 more to do. I have the parts ordered to do 8 of them. I do not keep a log to tell which ones have been done."</p> <p>The technician indicated he covers at least 9 different dialysis clinics. He stated, "It is all I can do to get the routine things done. If something special comes up it is hard to find the time to fix things. I am supposed to be getting some help."</p> <p>8. The facility's December 2012 "Physical Environment" policy number 8-04-01 states, "The building in which dialysis services are furnished will be constructed and maintained for the safety of the patients, the teammates, and the public."</p> <p>494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.</p>			
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	<p>Based on clinical record review and interview, the facility failed to ensure the prescribed dose of dialysis had been maintained by failing to ensure heparin had been administered as ordered in 1 (# 1) of 7 incenter records reviewed and by failing to ensure the correct dialyzer had been utilized in 1 (# 3) of 6 observations completed creating the potential to affect all of the facility's 90 current incenter patients.</p> <p>The findings include:</p> <p>1. Clinical record number 1 included physician orders, dated 7-23-14, that evidenced 4000 units of bolus heparin were to be administered each dialysis treatment. A hemodialysis treatment flow sheet dated 8-23-14 evidenced the heparin was "not given. pt [patient] had a fall yesterday, infusion canceled for today."</p> <p>A. The record included a "Progress and POC [plan of care] Follow-up Notes Report" with an entry by employee E, a registered nurse, dated 8-23-14. The note identified the physician was notified of the fall. The note states, "Notified doctor and instructed pt that should go to ER to get head scanned. Pt agreed that would if still had a headache post tx [treatment]." The record failed to evidence an order</p>	V000544	<p>Immediately on 9/8/2014 2 TMs verified the assigned dialyzer with physician order for each specific patient.</p> <p>FA held mandatory in-service team on 9/22/2014 reviewing <i>Policy & Procedure #1-03-02 Reprocessed Dialyzer Prescription Verification and Safety Checks</i> emphasizing TMs must verify dialysis prescription, prescribed dose of dialysis, and perform safety checks prior to each treatment initiation. Nurses are responsible for ensuring patients are achieving prescribed dose of dialysis and physician orders are followed. Prior to patient treatment initiation 2 clinical TMs must verify name on label and verify dialyzer type/model with physician order for specific patient. Verification of attendance at in-service will be evidenced by teammate's signature on in-service sheet.</p> <p>FA held mandatory in-service for clinical TMs on 9/24/2014 reviewing <i>Policy & Procedure #1-06-01: Medication Policy</i>. TMs instructed that Medications must be administered as prescribed and documented in the patient's medical record. Physician order must be obtained and entered into the patient medical record for any change in medication regimen. Verification of attendance at in-service will be evidenced by teammate's signature on in-service sheet.</p>	10/11/2014			

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V000550	<p>from the physician to hold the heparin on 8-23-14.</p> <p>B. The facility administrator, employee F, stated, on 9-8-14 at 5:20 PM, "It is not our usual practice to get an order when we hold heparin."</p> <p>2. On 9-8-14 at 2:55 PM, observation noted a 21R dialyzer in use at station number 16 on patient number 12. The clinical record included physician orders, dated 7-25-14, that evidenced a 24R dialyzer had been ordered by the physician.</p> <p>The facility administrator, employee F, stated, on 9-8-14 at 3:20 PM, "The orders do say a 24R should be used."</p> <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>FA/designee will conduct observational audit for compliance daily x 2 weeks then weekly x 2 weeks then monthly. FA/designee will audit 10% daily flow sheets x 2 weeks then weekly x 2 weeks then monthly to ensure prescribed dose of dialysis. FA will review results of all audits with Medical Director during monthly FHM, minutes will reflect. FA and Medical Director are responsible for compliance with this plan of correction</p> <p>FA and Medical Director are responsible for compliance with this plan of correction</p>	

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	<p>Based on observation, interview, and review of facility policy, the facility failed to ensure post treatment access care had been provided per the facility's own policy in 2 (#s 1 and 2) of 2 post fistula/graft access care observations completed creating the potential to affect all of the facility's current patients with a fistula or graft. (Employees J and M)</p> <p>The findings include:</p> <ol style="list-style-type: none"> Employee M, a patient care technician (PCT), was observed to discontinue the dialysis treatment on patient number 22 on 9-8-14 at 11:45 AM. The PCT was observed to remove both needles and place a Band-Aid and then gauze taped into place over the insertion sites. After the patient had stopped bleeding, the PCT removed the soiled gauze but failed to change the Band-Aid. Employee J, a PCT, was observed to discontinue the dialysis treatment on patient number 23 on 9-9-14 at 9:30 AM. The PCT was observed to remove both needles and place a Band-Aid and then gauze taped into place over the insertion sites. After the patient had stopped bleeding, the PCT removed the soiled gauze but failed to change the Band-Aid. The facility administrator, employee 	V000550	<p>FA held mandatory in-service for all clinical TMs on 9/24/2014 reviewing <i>Policy & Procedure #7-04-03B Post Dialysis Vascular Access Care: Fistula/Graft Using Safety Fistula Needles</i>. TMs instructed once bleeding has stopped, discard gauze or Band-Aid used to hold site, inspect site for any trauma and for hemostasis, and apply clean Band-Aid type or sterile dressing over cannulation site. Verification of attendance at in-service will be evidenced by teammate's signature on in-service sheet. FA/designee will conduct infection control audit for compliance daily x 2 weeks then weekly x 2 weeks then monthly. FA will report findings to Medical Director during monthly FHM, minutes will reflect. FA and Medical Director are responsible for compliance with this plan of correction</p>	10/11/2014			

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V000625	<p>F, indicated, on 9-11-14 at 7:45 AM, the PCTs should have changed the Band-Aid once the patients had stopped bleeding before the patients left the treatment floor.</p> <p>4. The facility's March 2014 "Post Dialysis Vascular Access Care: Fistula/Graft Using Safety Fistula Needles" procedure number 1-04-01B states, "Hold site for at least 5-10 minutes before checking to see if bleeding has stopped. Once bleeding has stopped, discard gauze or band-aid used to hold site. Inspect site for any trauma and hemostasis. Apply band-aid type of sterile dressing over cannulation site."</p> <p>494.110 CFC-QAPI</p> <p>Based on quality assessment and performance improvement (QAPI) meeting minute and facility policy review and interview, it was determined the facility failed to maintain compliance with this condition by failing to ensure maintenance of components of the water and dialysate systems had been tracked and analyzed in 3 (June, July, and August 2014) of 3 months reviewed (See V 628) and by failing to ensure performance improvement projects addressed identified areas and had been updated to</p>	V000625	<p>DaVita East Evansville Dialysis takes the conditions of coverage very seriously, immediate steps were taken to ensure facilities QAPI Program has oversight to verify safe provision and monitoring of ESRD services to its patients. These actions are outlined in depth in the Plan of Correction (POC) for V628, and V638. Governing Body (GB) meeting was held on 9/18/2014 to review the deficiencies received as a result of a survey concluded on 9/11/2014. Members of the GB including the Medical</p>	10/11/2014	

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V000628	<p>reflect improvement in 10 of 10 months reviewed creating the potential to affect all of the facility's 90 current incenter patients (See V 638).</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>494.110(a)(2) QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or</p>		<p>Director, FA, and ROD have agreed to meet weekly to monitor the facility's ongoing progress towards compliance including but not limited to: 1) QAPI program verifies maintenance of components of the water and dialysate systems are tracked and analyzed; 2) QAPI program ensures performance improvement projects address identified areas and those areas are updated monthly in FHM to reflect improvement in identified areas; 3) QAPI program addresses, monitors, and trends issues that occur in the facility developing plans of action, intervention, and those plans are re-evaluated for effectiveness with new interventions initiated as needed. GB will review FHM minutes to ensure minutes reflect, action plans are evaluated for effectiveness, new plans developed as applicable. Once compliance is achieved, POC will be monitored during GB meetings at a minimum of quarterly. This POC will also be reviewed during FHM and the FA will report progress, as well as any barriers to maintaining compliance, with supporting documentation included in the meeting minutes</p>		

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	<p>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 assessment and performance improvement (QAPI) documentation and facility policy review and interview, the facility failed to ensure maintenance of components of the water and dialysate systems had been tracked and analyzed in 3 (June, July, and August 2014) of 3 months reviewed.</p> <p>The findings include:</p> <ol style="list-style-type: none"> The facility's QAPI meeting minutes, dated 11-27-13, 12-18-13, 1-29-14, 2-26-14, 3-26-14, 4-21-14, 5-22-14, 6-25-14, 7-30-14 and 8-27-14, evidenced physical plant was monitored and tracked as a quality indicator. <p>The meeting minutes failed to evidence the condition of the facility's central solution delivery system had been addressed.</p> <ol style="list-style-type: none"> On 9-8-14 at 3:05 PM, observation noted black areas on the floor tiles in the areas between the tiles. There were 10 tiles at station 8 with black areas. At station 9, there were yellow stains on 2 of the tiles. 	V000628	<p>Clinical Service Specialist (CSS) will conduct in-service for Facility Health Team by 10/11/2014. In-service will include but not be limited to: Review of <i>Policy & Procedure 1-14-06: Continuous Quality Improvement Program</i> with emphasis that team must ensure facility monitoring and identification of problems by analyzing data collected including facility internal audits, identifying root causes for underperformance, develop recommendations and priority action plans to ensure patient safety. Team must set measurable goals, timelines, conduct ongoing monitoring/evaluation, and initiate interventions for maintenance of components of the water and dialysate systems. FA or designee is responsible for reviewing all communications, TM education and results of internal quality improvement audits for review with Medical Director during FHM. Team must review any identified underperformance and analyze to identify root causes and have action plan identified that will include a timeline and result in performance improvement, and track change in performance over time to ensure improvements are</p>	10/11/2014			

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	<p>The facility administrator, employee F, stated, "We have had a leak. [The biomedical technician] is aware and has addressed. Housekeeping is working on getting the stains up."</p> <p>3. On 9-9-14 at 5:05 PM, observation noted the concrete floor was wet on the inside of the cabinet at station number 11. A white, powdery substance was observed on the floor.</p> <p>A. At station number 10, 2 test strips were observed on the floor inside the cabinet. There was a dried, white, powdery substance on the floor.</p> <p>B. At station number 22, a test strip was observed on the floor inside the cabinet.</p> <p>C. At stations numbered 19 and 20, 3 test strips were observed on the floor inside the cabinet.</p> <p>D. At stations numbered 15 and 17, a crystalline substance was observed on the piping in the inset box where the acid concentrates were dispensed.</p> <p>E. At stations numbered 5 and 6 the black baseboard was observed to be buckled and out of place.</p>		<p>sustained. FHM minutes must reflect discussion, actions and evaluation by team. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet. BMT will be responsible to present at FHM and report on identified physical plant issues including those related to facility maintenance and results from monthly physical plant audits (BAUDIT). FA will be responsible to be present at FHM and report on identified trends/concerns from facility monthly internal audits including but not limited to OSHA and Infection Control. CSS will attend FHM or review meeting minutes for the next 3 months to ensure compliance, minutes are comprehensive, and reflective of actions taken. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance. The FA and Medical Director are responsible for compliance with this plan of correction</p>				

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	<p>4. The biomedical technician, employee T, indicated, on 9-10-14 at 8:25 AM, the fluid noted on the floor and inside the cabinets was bicarbonate or acid solution. The technician stated, "There are a couple of reasons there are leaks. One is that the ports are being eaten by the acid. There is stainless steel inside the colored, plastic adaptors. We started using a new acid about 1 1/2 years ago. The leaks started about 3 months ago. We discussed it in the quality meetings. The second reason is because the regulators are old and are not supported by the company anymore so we need to replace them. I have replaced 10 to 12 of them. If I can get enough money and the help, we could have them all replaced in one weekend. The girls leave the valves in the on position and there is a slow leak. At another clinic we have them make sure all the valves are in the off position every night."</p> <p>5. The medical director stated, on 9-10-14 at 1:00 PM, "I have been the medical director for about 1 month. I was aware they were replacing the regulators and that there was a problem."</p> <p>6. On 9-9-14 at 11:55 AM, observation noted a concentrate jug attached to the dialysis machine at station number 7. Employee E, a registered nurse (RN),</p>			

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	<p>stated, "There are problems with the machine conductivity. I had to switch from the wall [centralized solution deliver system] to the jug. There is a problem with the loop. [The biomedical technician] is working on it." The jug was observed to be labeled "regular."</p> <p>A. The RN was observed to bring patient number 16 to the dialysis chair at station number 7 to prepare for the treatment. The patient was heard to voice discontent with having to wait "55 minutes" to begin the treatment. The RN stated, "Well, we had to get your machine ready."</p> <p>B. On 9-10-14 at 1:05 PM, jugs were observed to be in use at stations numbered 5, 13, 15, 19, 20, 21, 22, 10, 11, and 12. The jugs attached to the dialysis machines at stations numbered 5, 13, 15, 19, 20, 21, and 22 were labeled "regular." The labels failed to identify the exact content of the jugs.</p> <p>7. Employee M, a patient care technician, stated, on 9-11-14 at 11:40 AM, "Sometime we have to get high calcium from the tanks in the back." The PCT indicated this was because of problems with machine conductivity and the central solution delivery system.</p>			

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	<p>8. The biomedical technician, employee T, stated, on 9-10-14 at 9:20 AM, "The conductivity problems with the machines are due to the regulator problems on the loop. The regulators are either bad and won't let the solution in at all or the regulators won't adjust. Using the jugs showed the regulator is the problem, not the dialysis machine. We use jugs at least 10 per day especially the last 5 stations at the end of the loop. About 1/3 of the regulators need to be replaced, there are 4 per station. I have done 8 to 10 of them and have 10 more to do. I have the parts ordered to do 8 of them. I do not keep a log to tell which ones have been done."</p> <p>The technician indicated he covers at least 9 different dialysis clinics. He stated, "It is all I can do to get the routine things done. If something special comes up it is hard to find the time to fix things. I am supposed to be getting some help."</p> <p>9. The facility's September 2013 "Continuous Quality Improvement Program" policy number 1-14-06 states, "The facility will measure, analyze, and track quality indicators or other aspects of performance . . . Continuous monitoring of the above indicators will be reflected in the meeting minutes. Any area identified as underperforming will</p>			

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V000638	<p>be reviewed to identify root causes for underperformance, will have an action plan identified that will result in performance improvement, and will track this change in performance over time to verify improvements are sustained."</p> <p>494.110(b) QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time. Based on quality assessment and performance improvement (QAPI) program review and interview, the facility failed to ensure performance improvement projects addressed identified areas and had been updated to reflect improvement in 10 (November 2013 through August 2014) of 10 months reviewed creating the potential to affect all of the facility's 90 current incenter patients.</p> <p>The findings include:</p> <p>1. The facility's 11-27-13 QAPI meeting minutes identify a physical plant issue</p>	V000638	<p>CSS will conduct in-service for Facility Health Team by 10/11/2014. In-service will include but not be limited to: Review of <i>Policy & Procedure 1-14-06: Continuous Quality Improvement Program</i> emphasizing team must develop, implement, maintain, and evaluate an effective, data-driven quality assessment and performance improvement program with participation by all members of team. Facility Health Team must measure, analyze and track quality indicators or other aspects of performance that reflect processes of care and facility operations. Importance of having an ongoing and comprehensive FHM process that includes tracking,</p>	10/11/2014

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	<p>with the chase cabinets in the treatment room. The minutes state, "Chase cabinets in treatment area have warping with visual issue only. Quote has been obtained. At this time we will continue to evaluate monthly and report and evaluate need for replacement if worsens."</p> <p>2. The facility's 12-18-13 QAPI meeting minutes state, "Treatment room chase cabinets have areas of warping at baseboards and areas under [unreadable] inside cabinet are warped . . . GOV [governing] body is aware and will continue to evaluate monthly and report in FHM [QAPI meetings]. If status deteriorates [sic] will replace cabinets."</p> <p>3. The facility's 1-29-14 QAPI meeting minutes state, "Treatment room chase cabinets have areas of warping at baseboards and areas under [unreadable] inside cabinet are warped . . . GOV body is aware and will continue to evaluate monthly for deterioration . . . Continue to monitor both areas for deterioration monthly and report in FHM. If status deteriorates [sic] will replace cabinets."</p> <p>4. The facility's 2-26-14 QAPI meeting minutes state, "Treatment room chase cabinets have areas of warping at baseboards and areas under [unreadable]</p>		<p>trending, data analysis, action plan development and effective implementation dates related for facility indicators. Specific emphasis was placed on 1) Analyzing data collected, 2) Set measurable goals and continuously evaluate, track and trend indicators not meeting facility goals, 3) Identifying root causes for underperformance, 4) Developing action plans and timelines, 5) Reviewing current action plans in place, evaluating their effectiveness, and initiating new plans as needed to meet goals. 6) Tracking performance over time to ensure improvements are sustained, 7) Ensuring meeting minutes reflect discussion, actions and evaluation by team. Team is responsible to ensure that all areas of the FHM are completed for effective QAPI program. . Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>CSS will attend FHM or review meeting minutes for the next 3 monthsto ensure compliance, minutes are comprehensive, and reflective of actions taken. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>The FA and Medical Director are responsible for compliance with this plan of correction</p>		

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	<p>inside cabinet are warped . . . GOV body is aware and will continue to evaluate monthly for deterioration . . . Continue to monitor both areas for deterioration monthly and report in FHM. If status deteriorates [sic] will replace cabinets."</p> <p>5. The facility's 3-26-14 QAPI meeting minutes state, "Treatment room chase cabinets have areas of warping at baseboards and areas under [unreadable] inside cabinet are warped . . . GOV body is aware and will continue to evaluate monthly for deterioration . . . Continue to monitor both areas for deterioration monthly and report in FHM. If status deteriorates [sic] will replace cabinets."</p> <p>6. The facility's 4-21-14 QAPI meeting minutes state, "Treatment room chase cabinets have areas of warping at baseboards and areas under [unreadable] inside cabinet are warped . . . GOV body is aware and will continue to evaluate monthly for deterioration . . . Continue to monitor both areas for deterioration monthly and report in FHM. If status deteriorates [sic] will replace cabinets."</p> <p>7. The facility's 5-22-14 QAPI meeting minutes state, "Treatment room chase cabinets have areas of warping at baseboards and areas under [unreadable] inside cabinet are warped . . . GOV body</p>			

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	<p>is aware and will continue to evaluate monthly for deterioration . . . Continue to monitor both areas for deterioration monthly and report in FHM. If status deteriorates [sic] will replace cabinets."</p> <p>8. The facility's 6-25-14 QAPI meeting minutes state, "Treatment room chase cabinets have areas of warping at baseboards and areas under inside cabinet warped . . . GOV body is aware and will continue to evaluate monthly for deterioration . . . Continue to monitor both areas for deterioration monthly and report in FHM. If status deteriorates [sic] will replace cabinets. Get estimates for cabinet."</p> <p>9. The facility's 7-30-14 QAPI meeting minutes state, "Treatment room chase cabinets have areas of warping at baseboards and areas under sinks inside cabinets warped . . . GOV body is aware and will continue to evaluate monthly for deterioration . . . Continue to monitor both areas for deterioration monthly and report to FHM. If status deteriorates [sic] will replace cabinets."</p> <p>10. The facility's 8-27-14 QAPI meeting minutes state, "Treatment room chase cabinets have areas of warping at baseboards and areas under sinks inside cabinets warped . . . GOV body is aware</p>			

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V000712	<p>and will continue to evaluate monthly for deterioration . . . Continue to monitor both areas for deterioration monthly and report to FHM. If status deteriorates [sic] will replace cabinets."</p> <p>11. On 9-9-14 at 5:20 PM, the facility administrator, employee F, stated, "We need all new cabinetry. It all needs to be replaced."</p> <p>494.150(a) MD RESP-QAPI PROGRAM Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program. Based on quality assessment and performance improvement (QAPI) committee meeting minutes review and interview, the facility failed to ensure active participation by the medical director in and oversight of the home program QAPI activities in 7 (February through August 2014) of 7 months reviewed creating the potential to affect all of the facility's 75 current home program patients.</p> <p>The findings include:</p> <p>1. Employee BB, the home program</p>	V000712	<p>Immediate steps were taken to ensure the facility QAPI Program is monitored/reviewed by GB including the Medical Director who assumes operational responsibility to ensure QAPI Program analyzes data, develops plans/interventions for improvement of care, and re-evaluates focusing on health outcomes and safety of patients. GB meeting was held on 9/18/2014 to review the deficiencies received as a result of a survey concluded on 9/11/2014. Members of the GB including the Medical Director, FA, and ROD have agreed to meet weekly to monitor the</p>	10/11/2014

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	<p>manager, indicated, on 9-11-14 at 2:30 PM employee GG, a physician, had been the facility's medical director when the February through July 2014 home program QAPI committee meetings had been held.</p> <p>QAPI meeting minutes, dated 2-20-14, 3-19-14, 4-16-14, 5-20-14 and 5-21-14, 6-19-14, and 7-16-14, failed to evidence active participation by the medical director in and oversight of the home program QAPI activities.</p> <p>2. Employee BB, the home program manager, indicated, on 9-11-14 at 2:30 PM, employee S, a physician, was the facility's current medical director and had been for "about a month." The home program QAPI committee meeting minutes dated 8-21-14 failed to evidence active participation by the medical director in and oversight of the home program QAPI activities.</p> <p>3. Employee BB, the home program manager, stated, on 9-11-14 at 2:30 PM, "The medical director does review home program key quality indicators but it is not documented. The medical director does not attend our meetings."</p>		<p>facility's ongoing progress towards compliance including but not limited to: 1) Ensuring all members of the quality improvement committee participate in meetings; 2) Ensuring QAPI program is comprehensive including setting measurable goals, timelines, conducts ongoing monitoring/evaluation, and initiate interventions for indicators; 3) Ensuring plans of action are developed for all indicators not meeting facility goals, and those plans are re-evaluated for effectiveness with new interventions initiated as needed to meet goals; 4) QAPI program tracks performance over time to ensure improvements are sustained; 5) Ensuring meeting minutes reflect discussion, actions and evaluation by team. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance, minutes will reflect. CSS will conduct in-service for Facility Health Team by 10/11/2014. In-service will include but not be limited to: <i>Review of Policy & Procedure 1-14-06: Continuous Quality Improvement Program</i> emphasizing team must develop, implement, maintain, and evaluate an effective, data-driven quality assessment and performance improvement program with participation by all members of team. Members will be notified that if they are unable</p>		

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			to attend monthly FHM in person that they may attend telephonically, or they may report off to a committee member and designate another person from his/her discipline to attend in their absence. FA will send out notification to all members informing them of the scheduled meeting and expectation to attend in person or via teleconference. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet. CSS will attend FHM or review meeting minutes for the next 3 months to ensure compliance, minutes are comprehensive, and reflective of actions taken. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance. The FA and Medical Director are responsible for compliance with this plan of correction		