

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 10/05/2010
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552592	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 08/05/2010
NAME OF PROVIDER OR SUPPLIER STOCKTON KIDNEY CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 1523 E MARCH LANE STOCKTON, CA 95210	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 000	<p>INITIAL COMMENTS</p> <p>Surveyor: 21174 The following reflects the findings of the California Department of Public Health during a recertification survey from 8/2/10 to 8/5/10.</p> <p>Representing the Department: Nikki Kratt, HFEN and Dorothy Rice, HFEN.</p> <p>The patient census at the facility on 8/2/10 was 79.</p> <p>Acronyms and Abbreviations commonly used in this report:</p> <p>ESRD-end-stage renal disease. Treatment options include hemodialysis [using a manufactured artificial kidney to remove fluid and waste]; peritoneal dialysis [using the patient's peritoneal membrane in their abdominal cavity as a filter to remove fluids and waste]; or kidney transplant.</p> <p>EDW - estimated dry weight. The weight of a person when all excess fluid is removed.</p> <p>Dialyzer - an artificial kidney using a membrane to filter and remove excess fluid and waste from the body.</p> <p>Dialysate - specific mixture of treated water, acidified concentrate with variable ratios of potassium (K) and calcium (Ca), and bicarbonate used in the dialyzer to clean the blood.</p> <p>Dialysis machine - the delivery system for hemodialysis.</p>	V 000		

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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V 000	<p>Continued From page 1</p> <p>Cross-contamination - spread of infection from a patient to another through breaks in infection control practices.</p> <p>Measurements of Dialysis Adequacy: Kt/V = kinetic modeling for dialysis adequacy reflecting clearance, time and volume URR = Urea reduction ratio (percentage of urea reduction)</p> <p>Blood Flow Rate (BFR) -the speed of blood flow from the patient into the lines and dialyzer and back to the patient. BFR is determined by the blood pump on the dialysis machine and the condition of the patient's vascular access. The higher the rate, the more dialysis occurs.</p> <p>Dialysate Flow Rate (DFR)- the speed of dialysate flow to the dialysate side of the dialyzer. The higher the rate, the greater clearance of toxins from the patient's blood</p> <p>Vascular Access - the site on patient's body where blood is removed and returned during dialysis. AVF - arteriovenous fistula-surgically created direct connection between an artery and vein in the patient's body, usually on the lower or upper arm. AVG - arteriovenous graft: a synthetic type material utilized to create a connection between an artery and vein. Catheter- a synthetic tube outside the body that inserted into a large vessel in the circulatory system: a tunneled catheter is tunneled beneath the skin usually through the internal jugular vein or into the subclavian vein.</p>	V 000			

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V 000	Continued From page 2 Hepatitis B - a serious disease affecting the liver caused by Hepatitis B virus. Antigen - a substance that prompts the generation of antibodies and could cause an immune response. Used in Hepatitis B testing to denote a person who has been exposed to Hepatitis B. Antibody - particle generated by the body in response to an antigen. Used in Hepatitis B testing and vaccination to measure the degree of immunity to Hepatitis B. PPE - personal protective equipment QAPI - quality assurance performance improvement Venous Pressure - a measurement of the extracorporeal (outside the body) blood circuit at some point after the dialyzer and before the blood enters the patient's body. A sudden drastic increase in the venous pressure from 50 to 150 mm Hg (mercury) could indicate clotting conditions. MSW-Social worker RN-Registered Nurse CHT-Certified Hemodialysis Technician PCT-hemodialysis technician who has not received national certification RD-Registered Dietitian CDC - Centers for Disease Control mm - millimeter mg. - milligrams mcg. - micrograms	V 000		

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V 000	Continued From page 3 ml. - milliliter cc - cubic centimeter	V 000			
V 113	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. This STANDARD is not met as evidenced by: Surveyor: 21174 Based on observation, interview, and document review, the facility failed to ensure staff followed facility policy to avoid cross-contamination during patient care for one (Patient 5) of six sampled in-center patients. This failure increased the risk of spreading infection. Finding: On 8/3/10 at 1:12 p.m., observation showed CHT M cleaning the dialysis machine at treatment station 2 in preparation for the next patient who would be Patient 5. No one was sitting in the treatment chair, but a blood pressure cuff and personal patient items were observed left on the treatment chair and on the attached tray table. According to CHT M, the patient who had just undergone dialysis was in the bathroom. At 1:25 p.m., observation showed the patient standing by the treatment chair, with the blood pressure cuff wrapped around his arm. CHT M was wearing a pair of gloves. He touched the patient and the blood pressure cuff. He then touched the front of the cleaned dialysis machine to start blood pressure readings wearing the same gloves. He	V 113		9/1/10	

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V 113	Continued From page 4 touched the front of the dialysis machine two additional times for additional blood pressure readings after touching the patient again and the blood pressure cuff. Again, he wore the same gloves. CHT M was interviewed immediately afterward regarding the observation. He stated "My gloves are clean." He was informed he touched both the patient and the blood pressure cuff using the same gloves and then touched the cleaned dialysis machine. He stated "You're right." During an interview on 8/4/10 at 11:12 a.m., the facility administrator stated, "They shouldn't be touching the patients and (patient's) equipment and then touching the cleaned equipment." Review of the facility policy "Infection Control for Dialysis Facilities", dated September 2009, indicated, "Teammates will wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Gloves should be changed when: After (sic) touching one patient or their dialysis delivery system and before arriving to care for another patient or touch another patient's dialysis delivery system." :	V 113			
V 126	494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF Hepatitis B Vaccination Vaccinate all susceptible patients and staff members against hepatitis B. This STANDARD is not met as evidenced by: Surveyor: 21174 Based on interview and record review, the facility failed to vaccinate two (Patients 1 and 7) of eight	V 126		9/1/10	

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V 126	<p>Continued From page 5</p> <p>sampled patients against Hepatitis B, leaving them susceptible to Hepatitis B infection.</p> <p>Findings:</p> <p>1. Record review on 8/4/10 showed Patient 7 was admitted to the facility on 5/21/09 for in-center hemodialysis. Review of the physician orders, dated 7/20/09, showed Patient 7 was to be administered four doses of Engerix (Hepatitis B vaccine) 40 mcg intramuscular, given on a schedule at 0, 1, 2 and 6 months intervals per (facility) P&P (policy and procedure). Review of the patient Vaccination Report showed Patient 7 received only a single Hepatitis B vaccination injection on 8/22/09, not the four injection series in specific time sequence recommended by the manufacturer and facility policy. Her antibody level on 1/5/10 was less than 1 mIU/mL, indicating she was susceptible to Hepatitis B infection.</p> <p>During an interview on 8/4/10 at 10:20 a.m. Clinical Manager reviewed the computer record and stated, "It looks like she got the one shot." According to the Clinical Manager, the patient's nurse was responsible for putting in the order. "If it's not put in (the computerized order set), the order gets missed." He confirmed Patient 7 should have received the four shot series timely.</p> <p>Review of the facility policy "Hepatitis Surveillance, Vaccination and Infection Control Measures", dated December 2008, indicated the purpose was, "To prevent the spread of hepatitis infections in the dialysis setting" and "Hepatitis B vaccination is recommended for all susceptible chronic dialysis patients and should be offered upon admission with physician order."</p>	V 126			

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V 126	Continued From page 6 Surveyor: 05189 2. On 8/3/10, record review showed Patient 1 was admitted to the facility on 7/6/10 with a physician order for hepatitis B vaccine if Patient 1 had HBsAG [Hepatitis B surface Antigen] Negative and HBsAB [Hepatitis B surface Antibody] < 1 [non-immune status]. Review of the "IDT Assessment and Plan of Care Report", printed 8/3/10, and the current "6 Month Cumulative Report" showed Patient 1 had a Negative test result for HBsAg on 7/6/10 and an HBsAb test result < 1 in July 2010. On 8/4/10 at approximately 9:00 a.m., the Clinical Specialist stated that the facility's practice was to offer the vaccine to all patients who were not immune to Hepatitis B infection. Further record review showed no evidence that Patient 1 was offered the vaccine. Clinical Specialist stated Patient 1 "wanted the vaccine", but could not explain why Patient 1 did not receive the vaccination.	V 126			
V 127	494.30(a)(1)(i) IC-HBV-TEST PTS/STAFF POST LAST DOSE Hepatitis B Screening: Patients and Staff Test all vaccines [patients and staff] for anti-HBs 1-2 months after last primary vaccine dose. -- If anti-HBs is <10 mIU/mL, consider patient or staff member susceptible, revaccinate with an additional three doses, and retest for anti-HBs. -- If anti-HBs are =10 mIU/mL, consider immune, and retest patients annually. -- Give booster dose of vaccine to patients if anti-HBs declines to <10 mIU/mL and continue to retest patients annually.	V 127		9/1/10	

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V 127	Continued From page 7 This STANDARD is not met as evidenced by: Surveyor: 21174 Based on staff interview and record review, the facility failed to revaccinate one (Patient 6) of eight sampled patients, considered susceptible to Hepatitis B infection. This failure caused Patient 6 to remain at continued risk for contracting Hepatitis B. Findings: Record review on 8/3/10 showed Patient 6 was admitted to the facility on 3/29/08 for in-center hemodialysis. Patient 6 received Recombivax Hepatitis B vaccine on 5/3/08, 6/28/08, and 9/30/08. She received Engerix Hepatitis B vaccine on 12/9/08. Review of the record showed Patient 6 was not revaccinated with an additional Hepatitis B series despite having a Hepatitis B surface antibody result of less than 1 mIU/mL on 8/4/09 and 1/5/10, indicating Patient 6 had not become immune to Hepatitis B as a result of the initial vaccination series and was still susceptible. On 8/4/10 at 10:05 a.m. the Clinical Manager reviewed Patient 6's Hepatitis surface antibody results and agreed that Patient 6 should have had a second series in 2009. Review of the facility policy "Hepatitis Surveillance, Vaccination and Infection Control Measures", dated December 2008, indicated, "If Hepatitis B surface antibody (HBsAB) is < (less than) 10 mIU/mL, consider the patient susceptible, revaccinate with an additional full series, and retest for HBsAB one to two months after the last dose of the second series."	V 127			
V 142	494.30(b)(1) IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P	V 142		9/1/10	

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V 142	Continued From page 8 The facility must- (1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit; This STANDARD is not met as evidenced by: Surveyor: 21174 Based on interview and record review, the facility failed to ensure that all staff received annual TB (tuberculosis) screening, increasing the potential of TB exposure to patients. Findings: During the review of seven employee files on 8/5/10, three employee files did not contain documentation of current TB evaluations. During an interview on 8/5/10 at 12:40 p.m, the Area Manager confirmed one RN had not received PPD testing since 9/28/08 to confirm non exposure to TB. Two CHTs who did not require yearly PPD testing but were required to complete an annual Tuberculosis Risk Appraisal Questionnaires (TB-RAQ) did not have a current TB-RAQ on file. Review of the facility policy "Tuberculosis Monitoring and Follow-Up", dated September 2009, indicated, "Follow up TB screening using TST (Tuberculin skin test) will occur on an annual basis, from the date of the last TST." For employees who were exempt from baseline and annual TST (employees with a history of a positive PPD and/or received the BCG vaccine) "In lieu of baseline and annual TST, a TB-RAQ will be completed."	V 142			
V 146	494.30(c)(2) IC-CATHETERS:GENERAL	V 146		9/1/10	

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V 146	Continued From page 9 (2) The "Guidelines for the Prevention of Intravascular Catheter-Related Infections" entitled "Recommendations for Placement of Intravascular Catheters in Adults and Children" parts I - IV; and "Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients," Morbidity and Mortality Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection as the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html This STANDARD is not met as evidenced by: Surveyor: 21174 Based on observation, interview, and record review, the facility failed to ensure staff followed facility policy and procedures to avoid cross-contamination during catheter site care for two (Patients 5 and 7) of five sampled patients with catheters. This failure increased the potential for catheter-related infection. Findings: 1. On 8/3/10 at 2:10 p.m., observation showed RN H preparing to perform catheter exit site care	V 146			

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V 146	Continued From page 10 and dressing change for Patient 5. Both Patient 5 and RN H wore face masks; Patient 5's face mask covered her nose and mouth and RN H's face mask covered his mouth only. After removing the dressing covering the catheter exit site, RN H removed his gloves, rubbed his hands with alcohol gel, donned a new pair of gloves, and preceded to cleanse the exit site area with a cleanser-saturated gauze. RN H waited approximately two minutes, then applied a new dressing to the catheter exit site. 2. On 8/3/10 at 2:45 p.m., observation showed RN H preparing to perform catheter exit site care and dressing change for Patient 7. Both Patient 7 and RN H wore face masks; Patient 7's face mask covered her nose and mouth and RN H's face mask covered his mouth only, then slipped so his upper lip was barely covered. After removing the dressing covering the catheter exit site, RN H preceded to cleanse the exit site area with a cleanser-saturated gauze without removing his gloves or performing hand hygiene and donning new gloves. RN H then paused and waited approximately two minutes. Patient 7 started looking around, including in the direction of the catheter on her upper left chest. RN H began to manipulate the catheter limb leads to attach them to the dialysis machine's blood lines while the exit site was still uncovered, now for over four minutes. RN H left Patient 7's side and returned with a clean cover transparent dressing. A total of five minutes had passed with the catheter exit site exposed before RN H placed a sterile gauze dressing followed by the transparent dressing over the site. RN H was interviewed at 2:55 p.m., after Patient 7's dressing change. He was asked why the catheter exit site was left exposed for five minutes. He stated, "The site is supposed to dry	V 146			

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V 146	Continued From page 11 for three to five minutes." He was informed that although he was observed removing his gloves, performing hand hygiene and donning new gloves prior to cleansing the exit site for Patient 5, he did not do so for Patient 7. He stated "I know." Review of the facility policy "Predialysis Central Venous Catheter (CVC) Care", dated June 2008, indicated the cleanser (ExSept Plus) used for access (exit) site cleansing had a two minute air drying time. Review of the facility policy "Central Venous Catheter (CVC) Cleaning and Dressing Change", dated September 2007, indicated, "Both patient and teammate (nurse) will wear face masks covering nose and mouth." The rationale: "These measures are vital to preventing the exposure of the catheter and exit site to nasal droplets and infectious bacteria". Staff should "Ensure patient's face is turned to side opposite CVC exit site." The rationale: "Decreases the risk of aerosolized bacteria contaminating site." Staff was to remove the old dressing covering the exit site and inspect the site for infection. Staff was then to, "Remove gloves and discard. Wash hands and reglove". The rationale: "Hand washing protects patient and teammate from cross contamination." During an interview with the Clinical Manager on 8/5/10 at 10 a.m., the observations of the catheter exit site care were discussed. The Clinical Manager reviewed the two policies and agreed RN H did not follow the policies for catheter care.	V 146			
V 189	494.40(a) CARTRIDGE FILTERS-CONFIG & MONITORING 5.2.3 Cartridge filters: config and monitoring The cartridge is contained within an opaque filter housing with seals to separate the feed and product water streams.	V 189		9/1/10	

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V 189	<p>Continued From page 12</p> <p>When the maximum [pressure drop] ?P recommended by the filter manufacturer is reached, the cartridge should be replaced according to the manufacturer ' s instructions.</p> <p>6.2.3 Cartridge filters Cartridge filters should be monitored on a periodic basis for a [pressure drop] ?P 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 marked decrease in ?P without a corresponding decrease in flow rate may indicate a loss of filter integrity. Follow the manufacturer ' s recommendations concerning when to replace cartridge filters. Replacement of the cartridge will usually be indicated by an increase in ?P to some specified value. A log sheet should be developed to record the pressure drop measurements.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 05189 Based on staff interview and record review, the facility failed to implement the manufacturer's instructions to replace the cartridge filters every three months on fifteen of fifteen dialysis machines in the facility. This failure resulted in thirteen machines alarming and having the staff shorten the treatment of three of eight sampled patients (Patients 1, 2, 4) and six randomly selected patients (Patients 11, 12, 13, 14, 15, 16). This placed patients at risk for fluid volume overload with increased potential for cardiac problems.</p>	V 189			

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V 189	<p>Continued From page 13</p> <p>Findings:</p> <p>On 8/3/10 and 8/4/10 , review of facility records showed that patient treatments were shorted on 7/23/2010, "due to machine problem".</p> <p>During an interview on 8/4/10, Biomed Staff J stated he was notified and aware of the machines' problem. Staff J further stated that the cause of the problem was the fact that Staff K did not replace the machines' filters (Diasafe Plus cartilage filters).</p> <p>Review of the facility policy regarding the maintenance of the filters showed, "The use of a Diasafe Plus filter is not to exceed 90 days".</p> <p>On 8/4/2010, review of the "Last Filter Date" section of the "Dialysis Machine Filter Replacement Schedule #1 " showed that staff replaced the filters on 2/16/2010. The "Next Filter Replacement" section of the schedule indicated the filters were scheduled to be replaced 90 days later, on 5/17/2010. However, under "Filter Status By Date" section of the schedule, it was documented the word, "Overdue".</p> <p>Staff K stated during a telephone interview on 8/4/10 that he was aware that the filters on the back of the machines were to be changed every three months, but he had not changed them as scheduled because he did not have time to do so.</p> <p>a. Review of Patient 2's treatment flowsheet , dated 7/23/10, showed the physician ordered a 180 minutes treatment and a dry weight of 61.5 kg. The treatment was started at 1:04 p.m. and a goal of 2.9 kg fluid to be removed was documented. However, Patient 2's treatment was</p>	V 189		

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V 189	<p>Continued From page 14</p> <p>discontinued at 2:59 p.m. instead of 4:04 p.m., "due to machine problem". There was only a volume of 0.4 kg. removed.</p> <p>Further review of the flowsheet, dated 7/23/10, showed the nurse documented, "Off early D/T [due to] Mach. [machine] Prob [problems]. Adv [Advised] to Watch Fluid Intake."</p> <p>b. Patient 13 received treatment on 7/23/10. Review of the treatment flowsheet showed an order for 180 minutes and a dry weight of 50.0 kg. The treatment was initiated at 1:26 p.m. and 2.5 kg of fluid were to be removed. The treatment was discontinued early at 3:10 p.m. instead of 5:26 p.m. and only 1.7 kg were removed. Patient 13 left the facility without reaching the dry weight.</p> <p>c. Record review on 8/4/10 showed Patient 4 received treatment on 7/23/10. The prescribed treatment duration was 150 minutes and the patient's dry weight was 49 kg. The treatment flowsheet showed that staff started Patient 4's treatment at 1:45 p.m. and that the patient had a pre treatment weight of 51.2 kg. , requiring a 2.2 kg of fluid to be removed. The treatment was discontinued at 3:45 p.m., instead of 5:30 p.m., "due to machine problem". Patient 4 had only 0.2 kg removed and left the facility without reaching the dry weight.</p> <p>d. Review of the treatment flowsheet, dated 7/23/10, showed Patient 13 received treatment, and had a prescription for 180 minutes (three hours) and a dry weight of 50.0 kg. Patient 13's weight on 7/23/10, prior to treatment, was 52.5 kg a gain of 2.5 kg, that needed to be removed). The treatment was initiated at 1:26 p.m. Further review showed the treatment was discontinued</p>	V 189		

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V 189	Continued From page 15 after only 104 minutes, "due to machine problem". Patient 13's weight after treatment was 51.7 kg. e. Patient 15 received treatment on 7/23/10. Review of the treatment flowsheet showed Patient 15 received 141 minutes of treatment instead of the 195 minutes prescribed by the physician. Patient 15's dry weight was 76.5 kg. On 7/23/10, pre-treatment, Patient 15 weigh 78.6 kg and left the facility without reaching his dry weight, having a post-treatment weight of 77.2 kg. f. Review of the flowsheet, dated 7/23/10, showed Patient 1 had a prescription for 210 minutes of treatment, but received only 184 minutes, "due to machine problems". g. Clinical record review showed Patient 11's treatment was discontinued one hour early on 7/23/10, due to machine's "low flow". h. The treatment flowsheet, dated 7/23/10, showed Patient 12's treatment was discontinued more than an hour early, due to "machine problem". i. The review of the flowsheet, dated 7/23/10, showed Patient 14 had a prescription for a treatment duration of 180 minutes (three hours). The patient's treatment was discontinued after only 110 minutes, due to "machine problem". j. Review of the treatment flowsheet, dated 7/23/10, showed Patient 16's treatment was cut short "due to machine problem". Patient 16 received only 130 minutes of treatment instead of 195 minutes prescribed.	V 189			
V 401	494.60	V 401		9/1/10	

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V 401	Continued From page 16 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. This STANDARD is not met as evidenced by: Surveyor: 05189 Based on observation and staff interview, the facility failed to maintain a safe environment that was free from puddles of water on the clinical area floor. This failure increased the risk of falls for patients, staff and public. Findings: On 8/3/10 at approximately 1:10 p.m., while staff and patients were walking through the clinical area, a pool of a moderate amount of clear fluid was observed on the floor on the left side of the treatment chair and the machine at Station 6. At approximately 1:45 p.m. after the interview, the puddle of water was again observed, in the same location. Furthermore, there was another puddle of a moderate amount of clear fluid on the floor to the right side of the chair. Facility Administrator acknowledged the practice and stated that the puddles of "water" needed to cleaned up immediately.	V 401			
V 408	494.60(d) PE-EMERGENCY PREPAREDNESS-PROCEDURES The dialysis facility must implement processes and procedures to manage medical and non medical emergencies that are likely to threaten	V 408		9/1/10	

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V 408	Continued From page 17 the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. This STANDARD is not met as evidenced by: Surveyor: 05189 Based on staff interview and record review, the facility failed to completely develop and implement a facility-specific disaster/emergency plan that included natural disasters in its geographic location and man-made disasters. This failure did not ensure that staff and patients will be knowledgeable of what to do during emergency situations. Findings: On 8/3/10 at 2:15 p.m., during the review of the facility's Emergency/Disaster Program, Clinical Service Specialist stated that the facility had adopted CMS (Center for Medicaid/Medical Service)'s comprehensive "template" disaster program, entitled, "Emergency Preparedness For Dialysis Facilities". The Clinical Service Specialist further stated he was diligently "working" on the plan, but it was not yet facility-specific, adopted by the Governing Body and had not been implemented.	V 408			
V 412	494.60(d)(2) PE-ER PREP-PTS ORIENTED/TRAINED The facility must provide appropriate orientation and training to patients, including the areas specified in paragraphs (d)(1)(i) of this section.	V 412		9/1/10	

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V 412	<p>Continued From page 18</p> <p>This STANDARD is not met as evidenced by: Surveyor: 21174</p> <p>Based on interview and record review, the facility failed to ensure patients had sufficient knowledge of emergency and disaster procedures in and out of the facility. Three (Patients 2, 6, 7) of six sampled incenter patients could not verbalize the procedure to clamp and disconnect themselves from the dialysis machine. Three (Patients 1, 10, 6) of six sampled incenter patients could not verbalize actions they should take for emergencies outside of dialysis. These failures increased the potential for patient harm during emergencies and disasters.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. Patient 6 was interviewed on 8/3/10 at 11:15 a.m. She was asked if she knew what to do if there was a fire or power outage at the facility while she was dialyzing. She stated "I hope I can call (RN H)." She was asked if she knew what to do if she were at her current residence (Patient 6 was currently living in an assisted living establishment while trying to convalesce to return home). She stated "I'd call my husband." 2. Patient 7 was interviewed on 8/3/10 at 3:10 p.m. She was asked if she knew what to do if there were a fire or power outage at the facility while she was dialyzing. She stated "I'm not sure. If I clamp, how do I move with this machine?" With much prompting from CHT O, she finally stated she would then cut the blood lines. She looked around for the emergency clamp and scissor kit and was unable to locate it. Surveyor: 05189 3. On 8/3/10 at approximately 1:10 p.m., Patient 10 stated no-one had explained to him what to do 	V 412			

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V 412	Continued From page 19 during an out of facility emergency situation.	V 412		
V 415	<p>4. On 8/4/10 at 1:50 p.m., Patient 1 stated no-one had given him any information regarding the in center and out of the center emergency procedures.</p> <p>5. On 8/4/10 at approximately 1:55 p.m., Patient 2 stated that the only thing she could remember regarding the in-center Disaster/Emergency procedure was that the staff would clamp and cut the bloodlines. In reference to the External Disaster/Emergency procedure, Patient 2 stared at the surveyor with a quizzical facial expression and stated, "I don't know what to do if an earthquake would struck."</p> <p>During an interview on 8/4/10, the facility director stated staff was in the process of reviewing some aspects of the external emergency procedures with the patients, but had not completed the process with all patients.</p> <p>494.60(d)(4)(ii) PE-ANNUAL EVAL-EMERGENCY/DISASTER PLANS</p> <p>The facility must- Evaluate at least annually the effectiveness of the emergency and disaster plans and update them as necessary;</p> <p>This STANDARD is not met as evidenced by: Surveyor: 05189 Based on staff interview and record review, the facility failed to evaluate its emergency and disaster plan annually. This failure does not ensure that staff will be knowledgeable, educated and skillful to conduct the emergencies.</p>	V 415		9/1/10

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V 415	Continued From page 20 Findings: On 8/3/10 at 2:50 p.m., Clinical Service Specialist and Facility Administrator stated that the facility was "working on" the facility's comprehensive emergency and disaster plan, which had not been evaluated annually.	V 415			
V 416	494.60(d)(4)(iii) PE-CONTACT LOCAL EOC ANNUALLY The facility must- (iii) Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency. This STANDARD is not met as evidenced by: Surveyor: 05189 Based on staff interview and record review, the facility failed to contact its local disaster management agency. This failure does not ensure that the agency was aware of the facility needs during an emergency situation. Findings: On 8/3/10 at 2:50 p.m., Clinical Service Specialist and Facility Administrator stated they were "working on" the facility's comprehensive emergency plan and had not yet contacted the local disaster management agency. Administrative Staff stated the contact would be made once the plan was completed.	V 416		9/1/10	
V 466	494.70(a)(15) PR-INFORMED OF EXTERNAL GRIEVANCE PROCESSES The patient has the right to-	V 466		9/1/10	

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V 466	Continued From page 21 (15) Be informed of external grievance mechanisms and processes, including how to contact the ESRD Network and the State survey agency; This STANDARD is not met as evidenced by: Surveyor: 21174 Based on interview and record review, the facility failed to provide seven (Patients 1, 2, 3, 5, 6, 7, 8) of eight sampled patients with specific contact information for the Network and State survey agency while informing them of the patient grievance procedure. This failure could delay or inhibit the patient's ability to seek external resolution for complaints. Findings: 1. Review of Patients 1, 2, 3, 5, 6, 7, and 8's medical records showed each patient's record contained a form entitled "Patient Grievance Procedure". The form outlined steps the facility should take to resolve a patient's problem with the facility. The form also contained a statement "The use of this procedure is not a requirement to the filing of a grievance with the State Department of Health and Human Services, the ESRD Network or other appropriate state or federal agencies." There was no statement indicating that a patient might choose external agencies to help resolve problems or complaints. There was a large void in the form where contact information for the State Agency or Network could have been included, but was not. Each patient signed the form following two statements: "The Patient Grievance Procedure has been read and fully explained to me" and "I attest that the above	V 466		

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V 466	Continued From page 22 information is correct." <p>The facility administrator was interviewed on 8/3/10 at 10:30 a.m. He was asked why contact information was not provided on a form that was to outline the grievance procedure for incoming patients. He acknowledged the form lacked the obvious contact information and that issue had come up for discussion.</p> <p>Surveyor: 05189</p> <p>2. On 8/3/10 at approximately 1:10 p.m., during an interview in reference to the external grievance procedure, Patient 10 stated no-one had given him any information as to any "outside" resources or persons.</p>	V 466			
V 503	494.80(a)(2) PA-APPROPRIATENESS OF DIALYSIS RX <p>The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>(2) Evaluation of the appropriateness of the dialysis prescription,</p> <p>This STANDARD is not met as evidenced by: Surveyor: 05189 Based on observation, interview and record review, the facility failed to deliver the correct prescription for two of eight sampled patients. (Patients 3 and 4)</p> <p>1. The facility's failure to deliver the prescribed 2.0 potassium dialysate to Patient 2 during treatment created a risk for not maintaining the potassium blood level within therapeutic range which could lead to possible physical complications.</p> <p>2. The facility's failure to utilize the prescribed 180</p>	V 503		9/1/10	

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V 503	<p>Continued From page 23</p> <p>NR Dialyzer during treatment created a risk for potential inadequate clearances of waste products from the body leading to possible physical complications for Patient 3.</p> <p>Findings:</p> <p>On 8/2/10 at 3:30 PM, the Facility Director accompanied the Surveyor during the initial tour of the facility. During the tour, the Facility Director and staff assisted the surveyor in reconciliation of the observed patient treatment delivery prescriptions and the chairside computerized prescription orders.</p> <p>1. At approximately 3:37 PM, the Facility Director and Surveyor observed that Patient 2 was receiving treatment with a 3.0 mEq/L potassium (K) dialysate solution bath while the chairside computer showed a prescription for a 2.0 mEq/L potassium (K) dialysate bath solution. At approximately 4:00 PM, the Medical Director visited the facility and acknowledged the deficient practice.</p> <p>(Potassium is an element that helps to regulate heart contractibility or function. The normal potassium blood level are 3.5 to 5.0 mEq/L. To maintain the potassium blood levels within these parameters, the physician might order different potassium level dialysate solutions. For example, the "Review of Hemodialysis for Nurses and Dialysis Personnel, 2005, 7 th Ed., p. 55", reflected that if the serum potassium level is less than 3.5 mEq, dialyzing the patient on a higher potassium bath will help maintain the serum level...If the serum potassium level is greater that 5.5 mEq/L, dialyzing the patient on a lower dialysate potassium bath will help maintain the</p>	V 503		

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V 503	<p>Continued From page 24 serum level.")</p> <p>The review of the record showed that Patient 2 was admitted to the facility on 7/01/2009. The review of the current summary laboratory blood test results showed normal blood potassium levels (3.5 to 5.0 mEq/L) from March to May, 2010. For example, for March= 4.6, for April= 4.7, for May= 4.6. However for June 2010, the potassium level elevated to 5.7, and remained high for July at 5.6. On 7/12/2010, the dialysis prescription was changed from the admission 3.0 potassium mEq/L dialysis solution bath prescription to a 2.0 potassium solution bath prescription.</p> <p>The review of the flowsheet, dated 8/2/2010 showed that Patient 2's treatment was started at 13:30 (1:30 PM), and that the erroneous 3.0 K dialysate bath was changed to the 2.0 K prescribed dialysate solution bath at 16:00 (4:00 PM).</p> <p>On 8/2/2010 at approximately 4:40 PM, Staff P (caretaker) acknowledged the error. Staff P stated that he had cared for the patient 5-6 months where the patient had a prescription for the 3.0 K dialysate solution bath. Staff P further stated he was not informed of the changed potassium orders.</p> <p>On 8/3/10 at approximately 8:30 am, the Medical Director stated that the incident should have never occurred.</p> <p>The review of the subsequent ordered potassium blood level result for 8/4/10 was 4.5 mEq/L.</p> <p>2. At approximately 3:40 PM, the Facility Director and Surveyor observed that Patient 3 was receiving treatment with a Optiflux 200 NR dialyzer while the chairside computer showed a a</p>	V 503		

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V 503	Continued From page 25 prescription for a Optiflux 180 NR dialyzer. At approximately 3:37 PM, the Facility Director and Surveyor observed that Patient 2 was receiving treatment with a 3.0 mEq/L potassium (K) dialysate solution bath while the chairside computer showed a prescription for a 2.0 mEq/L potassium (K) dialysate bath solution. At this time, the Facility Director stated, "It's [dialyzer's] too big." At approximately 4:00 PM, the Medical Director visited the facility and acknowledged the deficient practice. At 4:45 PM, Staff Q acknowledged the deficient practice and stated that the error occurred when Patient 3 sat in the wrong treatment chair at Station 1 instead of in his assigned treatment chair as Station 4. (Subsequent record review showed that Patient 9 who was assigned to Station 1, but did not come into the facility had orders for an Optiflux 200 NR dialyzer order.) On 8/3/10 at approximately 8:30 am, the Medical Director stated that the incident should have never occurred. On 8/3/10 at approximately 9:10 am, the Facility Director stated and the "Optiflux" dialyzer informational manufacture insert literature indicated that the larger size dialyzer had higher surface creating increased waste product clearances. The Facility Director further stated that it probably would have been different if the situation was vice versa, where if a smaller size dialyzer was used instead of a larger sized dialyzer and the clearance was less.	V 503			
V 715	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	V 715		9/1/10	

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V 715	<p>Continued From page 26</p> <p>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;</p> <p>This STANDARD is not met as evidenced by: Surveyor: 05189 Based on observation, interview and record review, the facility failed to consistently ensure the arterial chambers were 3/4 filled with blood during treatment at nine (Stations 2, 3, 5, 7, 8, 9, 10, 12, 13) of thirteen stations observed throughout the survey. This deficient practice increased the risk for clotting and air entering the circuit system and the patients' bloodstream.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. During the tour on 8/2/10 at approximately 3:30 p.m., while patients were receiving treatment, the following were observed: <ol style="list-style-type: none"> a. At station 2, 7, 8, and 13, the arterial chamber was approximately 1/2 filled with blood. b. At station 5, the arterial chamber was approximately 1/3 filled with blood. 2. On 8/3/10 at 8:00 a.m., at station 12, the arterial chamber was approximately 1/3 filled with blood. 3. On 8/5/10 at approximately 7:40 a.m., the following were observed: <ol style="list-style-type: none"> a. At Station 10, the arterial chamber was almost empty of blood. b. At Station 5 and 12, the arterial chamber was approximately 1/4 filled with blood. c. At Station 3, the arterial chamber was approximately 1/3 filled with blood. 	V 715			

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V 715	Continued From page 27 Clinical Specialist and Facility Administrator stated on 8/2/10 that the facility's practice and policy and procedure was to maintain the arterial chambers at least 3/4 filled with blood. Review of the the facility Policy titled, "Priming A Reprocessed Dialyzer Free of Peracetic Acid.." showed the following: "When the arterial drip chamber is approximately 3/4 full [of blood] or at the manufacturer's fill line indicator, tighten the cap and re-clamp line." Clinical Specialist further stated that once the 3/4 blood-filled level was achieved as indicated in the policy and procedure, staff was to maintain the level throughout patient's treatment. Surveyor: 21174 4. On 8/3/10 at 12:50 p.m. observation showed the arterial chamber of the dialysis machine at Station 9 showed a little over half full. At 1 p.m., observation showed the arterial chamber remained just over half full. CHT N was nearby. She was asked if the arterial chamber level was appropriate. She stated, "It should be 3/4 full" and adjusted the arterial level to 3/4 full.	V 715			
V 726	494.170 MR-COMPLETE, ACCURATE, ACCESSIBLE The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.	V 726		9/1/10	

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V 726	<p>Continued From page 28</p> <p>This STANDARD is not met as evidenced by: Surveyor: 05189 Based on interview and record review, the facility failed to maintain complete and accurate records for six of eight sampled patients (Patients 1, 2, 3, 4, 5, 6, 7 and 8). The failure of staff to document complete and accurate records increased patients' potential for adverse outcomes, and did not reflect the actual care given to the patients.</p> <p>Findings:</p> <p>1. On 8/2/10 at approximately 3:30 p.m., during the initial tour in the presence of facility director, it was observed that Patient 1's treatment settings showed a 800 ml/min dialysate flow rate. Review of the treatment order on the chairside computer screen showed a prescription for only a 600 ml/min dialysate flow rate. Facility Director stated all the physicians ordered 800 ml/min dialysate flow rate for all treatments, and all machines in the facility delivered a 800 ml/min. dialysate flow rate.</p> <p>Record review on 8/2/10 showed Patient 1 was admitted to the facility on 7/6/10 with an order for "600-800 dialysate flow rate". In an interview on 8/2/10, Clinical Manger stated that when the physician order was entered into the computer system, only the first three digits of the dialysate flow rate were entered.</p> <p>2. Review of the treatment flowsheet, dated 8/2/10, showed Patient 2 had a prescription for 180 minute (3 hour) treatment. Patient 2's treatment was started at 1:40 p.m. There was a note on the flowsheet indicating that an attempt to remove 2.5 kg fluid will be made. The UFR was</p>	V 726			

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V 726	<p>Continued From page 29</p> <p>set at 0.8. At 3:30 p.m., the staff documented that the UFR was decreased to 0.3, without documenting the reason for such change. The UFR was decreased further to 0.2 at 4 p.m., again with no documented rationale for the change. Further review showed that only 2 kg of fluid were removed during Patient 2's treatment, instead of the set goal of 2.5 kg.</p> <p>Facility Director acknowledged the deficient practice on 8/3/10 and state that he was not sure why staff documented the decreased UFRs with no explanation.</p> <p>3. Review on 8/3/10 of the facility policy "Preparation and Administration of Intravenous Epogen", dated September 2007, showed that 50 ml saline flush was to be given prior to the Epogen (drug that stimulates the formation of red blood cells) administration, and 50 ml saline flush after Epogen administration (for a total of 100 ml of normal saline flush). The facility policy "Preparation and administration of Parenteral Medications [Non-Epogen]", dated September 2009, instructed the staff to flush the lines with 50 ml of saline solution prior and after the administration of medication. "If more the one (1) medication is being administered, flush the saline line with 50 ml of saline between each medication", the policy further instructed.</p> <p>a. Record review on 8/3/10 showed Patient 3 had orders for Epogen (stimulates the formation of red blood cells) and Zemplar (for the prevention and treatment of secondary hyperparathyroidism associated with renal failure. Review of the flowsheets, dated 7/12/10, 7/14/10, 7/16/10, 7/26/10, 7/28/10, 7/30/10 and 8/2/10, showed staff documented that a 50 ml normal saline flush</p>	V 726			

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V 726	<p>Continued From page 30</p> <p>was given with Epogen, and a 50 ml normal saline flush was given with Zemplar. Therefore, the staff documented that a total amount of 100 (50 ml and 50 ml) saline flush was used for the administration of the two medications.</p> <p>b. Clinical record review on 8/4/11 indicated that Patient 4 received treatment at the facility, as a temporary patient from 7/21/10 to 7/24/10 and had an order for Epogen. The flowsheets, dated 7/21/10 and 7/23/10, showed staff documented that a 50 ml normal saline flush was given with Epogen. There was no documentation that a 50 ml normal saline flush was administered after the Epogen administration.</p> <p>Surveyor: 21174</p> <p>4. Review of treatment flowsheets for Patients 5, 6, 7, and 8 showed a normal saline flush of 50 ml was documented for Epogen administration. During an interview with the Clinical Manager on 8/5/10 at 10:30 a.m., he confirmed 100 ml of normal saline flush; 50 ml prior to the administration of Epogen and 50 ml after the administration of EPO, should have been given and documented.</p>	V 726			