

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

PRINTED: 02/11/2011  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>552513</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>08/02/2010</b>
NAME OF PROVIDER OR SUPPLIER  <b>COLLEGE DIALYSIS</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>6535 UNIVERSITY AVENUE SAN DIEGO, CA 92115</b>	
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V 000	<p><b>INITIAL COMMENTS</b></p> <p>The following represents the findings of the California Department of Public Health during a recertification visit from 7/27/10 through 8/2/10. The facility census at the time of the visit was 55 hemodialysis patients and 20 peritoneal dialysis patients. The sample size was 8 patients.</p> <p>Representing the Department were HFEN's: #15930 and #17130.</p> <p>Glossary of Abbreviations:</p> <p>AAMI Association for Advancement of Medical Instrumentation CC Clinical Coordinator CSS Clinical Services Specialist CVC Central Venous Catheter FA Facility Administrator mcg micrograms mEq milliequivalence mg milligrams ml milliliters mg/L milligrams per liter PD Peritoneal Dialysis PCT Patient Care Technician P&amp;P Policy and Procedure RN Registered Nurse</p>	V 000		
V 113	<p><b>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE</b></p> <p>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>	V 113		10/18/10

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 113	<p>Continued From page 1</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure that all staff washed their hands in sinks designated as clean areas. The facility failed to ensure that all staff and physician's performed hand hygiene after providing care, and when moving from dirty areas to clean areas.</p> <p>Finding:</p> <ol style="list-style-type: none"> <li>On 7/28/10 at 8:45 A.M., PCT 3 washed his hands in a sink that was designated as a dirty area. Upon interview, PCT 3 acknowledged that he should have washed his hands in the clean sink area.</li> <li>On 7/28/10 at 8:54 A.M., the CSS washed her hands in a sink designated as a dirty area. Upon interview, the CSS acknowledged that she should have washed her hands in the clean sink area.</li> <li>On 7/28/10 at 9:15 A.M., RN 3 washed her hands in a sink that was designated as a dirty area. Upon interview, RN 3 acknowledged that should have washed her hands in the clean sink area.</li> <li>On 7/28/10 at 8:30 A.M., Physician 1 was observed visiting with 12 patients during their dialysis treatments at stations 4, 5, 6, 7, 8, 9, 13, 14, 15, 16, 18 and 19. The Physician moved from one patient to the next, touching each patient either on the shoulder, hand, or on their access site. After Physician 1 touched each patient, he went to their shared computer station and picked up a clip board, which held the patient's prescription treatment sheet. Physician 1 then placed the patient prescription back onto the</li> </ol>	V 113			

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V 113	<p>Continued From page 2</p> <p>computer station. Physician 1 did not wash his hands between touching the 12 patients and the six shared computer stations and clip boards, which were stored on the computer stations. The treatment area is considered a dirty area. The shared computer stations and clipboards are considered clean areas. Hand hygiene is required after each patient contact and prior to moving from an area designated as a dirty area to an area designated as a clean area.</p> <p>Physician 1 was interviewed on 7/28/10 at 8:45 A.M. He stated, "I did not realize that I wasn't using the hand sanitizer. I thought that I washed my hands a lot."</p> <p>On 7/28/10 at 10:00 A.M., RN 3 stated that the computer consoles were considered a clean area, and hand sanitizer should be used before touching the patient prescription clip boards that were stored on the console.</p> <p>On 7/29/10 at 2:30 P.M., the facility provided the P&amp;P titled Infection Control for Dialysis Facilities. The P&amp;P read in part, "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, before touching clean areas such as supplies and before leaving the patient care area..."</p> <p>5. During observations on 7/28/10 from 10:19 A.M. to 10:26 A.M., RN 1 was observed providing care to Patient 10 in Station 1. RN 1 made changes to the settings on the dialysis machine without gloves on and then typed on the computer</p>	V 113			

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V 113	Continued From page 3 keyboard. RN 1 did not cleanse her hands between touching the front of the dirty dialysis machine and typing on the clean computer keyboard. RN 1 repeated this same action an additional 3 times.  On 7/28/10 at 11:41 A.M., RN 1 stated that the front of the machine was dirty and the computer keyboard was clean. RN 1 said that the front of the dialysis machine could be touched with bare hands if hands were cleansed before touching the clean computer keyboard.  During a joint interview on 7/28/10 at 5:07 P.M., the Administrator, the CSS and the Group Facility Administrator all stated that staff should touch the front of the dialysis machine with gloved hands only. Staff should type on the computer keyboards with clean, bare hands only.  On 7/29/10 at 10:30 A.M., the facility provided the P&P titled Infection Control for Dialysis Facilities. The policy specified that the computer keyboard was considered clean. In addition, the policy included, "Gloves are to be removed and hands washed or alcohol based hand rubs used before and after touching the keyboard."	V 113			
V 117	494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS  Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.	V 117		10/18/10	

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V 117	<p>Continued From page 4</p> <p>When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.</p> <p>Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to discard expired medications that were used as samples for PD patients. The facility failed to store 1 vial of multidose heparin according to the facility P&amp;P and manufacturer's recommendations.</p> <p>Findings:</p> <p>1. On 7/27/10 at 3:45 P.M., the medication cupboards in the PD area were observed. The cupboards contained the following expired medications:</p> <p>a. 18 boxes of Hectorol (a vitamin D supplement) 2.5 mcg., with an expiration date of May 2010.</p> <p>b. 7 boxes of Hectorol 0.5 mcg, 12 capsules in each container, with an expiration date April 2010.</p> <p>c. Fosrenol (a phosphate binder) chewables 1000 mg., with an expiration date of February 2010.</p> <p>On 07/27/10 at 4:05 P.M., the PD RN stated the expired medications were sample medications. She further stated that expired medications should not be in the cabinet.</p>	V 117			

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V 117	Continued From page 5 On 7/29/10 at 2:30 P.M., the facility provided the P&P titled Medication Policy. The policy read in part, "Disposal of expired medications, including all over the counter and nutritional product samples are removed from the treatment and inventory areas and disposed of per state/local regulations..."  2. On 7/27/10 at 3:47 P.M., the refrigerator in the PD department was observed. The refrigerator contained an open 30 ml vial of heparin 1000 units/ml. The thermometer in the refrigerator registered 44° F (Fahrenheit). The manufacturers' label on the bottle of heparin specified storage at 68 to 77 degrees F (room temperature).  On 7/27/10 at 4:30 P.M., the PD Nurse stated she administered the heparin to a patient several days ago. She said that heparin was "not usually" refrigerated. The PD Nurse stated, "I did not want to place it in the cupboard above the refrigerator. The PD Nurse acknowledged that the cupboard had a lock preventing access to unauthorized personnel.  On 7/28/10 at 5:00 P.M., the CSS stated that heparin should not be refrigerated.  On 7/29/10 at 9:11 A.M., the facility provided the P&P titled Medication Policy, that was reviewed and approved by the Governing Body in June 2010. The policy specified in part, "Non-refrigerated medications are to be stored in cabinet(s)...."	V 117			
V 147	494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE  Recommendations for Placement of Intravascular Catheters in Adults and Children	V 147		10/18/10	

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V 147	Continued From page 6  I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters.  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.  Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.  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].  This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure that the licensed nurse cleansed the skin surrounding the CVC (a catheter placed into a large vein leading into the heart) site on 1 of 8 sampled patients (5) with an antiseptic wound cleanser, according to manufacturers' directions. The facility failed to ensure that the licensed nurse cleansed 1 of 8	V 147		

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V 147	<p>Continued From page 7</p> <p>sampled patients (5) CVC ports (openings) with a high level disinfectant, according to manufacturers' directions. The facility P&amp;P for using the high level disinfectant failed to accurately reflect the manufacturers' directions.</p> <p>Findings:</p> <p>1. On 7/28/10 at 1:40 P.M., RN 1 removed Patient 5's CVC dressing. RN 1 cleansed the skin at the CVC site with a gauze pad soaked in an antiseptic for 20 seconds. After cleansing, RN 1 immediately applied a sterile dressing to the site and secured the dressing with tape. RN 1 did not allow the antiseptic to air dry. RN 1 then wiped both the venous and arterial ports of the CVC with a high level disinfectant for 5 seconds. RN 1 did not wrap the ports in disinfectant soaked gauze pads.</p> <p>a. On 7/28/10, the facility provided the manufacturers' directions for use of the antiseptic wound cleanser to clean the CVC skin site. The directions specified that after cleaning the site, "Wait two minutes for site to dry."</p> <p>On 7/28/10, the facility provided the P&amp;P titled PreDialysis Central Venous Catheter (CVC) Care, reviewed and approved by the Governing Body in June 2010. The policy specified that the antiseptic wound cleanser should remain on the skin for 60 seconds and should air dry for 2 minutes.</p> <p>During an interview on 7/28/10 at 2:30 P.M., RN 1 stated that the contact time for the antiseptic wound cleanser was "3 minutes", contrary to observed practice and manufacturers' directions.</p>	V 147			

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V 147	Continued From page 8  b. On 7/28/10, the facility provided manufacturers' directions for use of the high level disinfectant to clean the CVC ports. The directions specified to place both ports in disinfectant saturated gauze pads and scrub each catheter end and port for 1 minute. In addition, "Make sure to rub in an agitating motion when cleaning ports." The directions specified to wrap each port in a disinfectant saturated gauze pad and leave wrapped for at least 1 minute.  During an interview on 7/28/10 at 2:35 P.M., RN 1 stated that the disinfectant did not require waiting time to ensure proper disinfection of the ports, contrary to both manufacturers' directions.  2. On 7/28/10, the facility provided the P&P titled PreDialysis Central Venous Catheter (CVC) Care, reviewed and approved by the Governing Body in June 2010. The policy specified that high level disinfectant should remain on the ports for 60 seconds, contrary to observed staff practice. The facility P&P did not address wrapping the ports in disinfectant soaked gauze as specified in the manufacturers' directions.	V 147			
V 175	494.40 CFC-WATER & DIALYSATE QUALITY  This CONDITION is not met as evidenced by: Based on observation, interview and record review, the facility failed to ensure staff adjusted the bicarbonate levels on the hemodialysis machines to match the physician's order for 55 of 55 hemodialysis patients (Refer to V248). The facility failed to train the staff on how to change the bicarbonate settings on the hemodialysis machines (Refer to V260). The facility failed to address out of range chemical analysis results of	V 175		10/18/10	

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V 175	Continued From page 9 the water used for dialysis in a timely manner (Refer 274). The alternating medical directors failed to ensure that 7 of 8 staff received initial and ongoing training on the hemodialysis machines (Refer 713).The cumulative effects of these systemic problem resulted in the facility's inability to ensure the provision of quality health care in a safe environment.	V 175			
V 248	494.40(a) DIALYS PROPORT-MATCH RATIO-ALL CONC/MACHINE  5.6 Dialysate proportioning: match ratio all conc/machine The acid and bicarbonate concentrates [must] be matched with respect to the proportioning ratio and with the model and setup configuration of the dialysis machine. Several types of three-stream concentrates are available, with different ratios of acid concentrate to bicarbonate concentrate to water (see Table 3). The different proportioning types are not compatible with one another.  This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure the bicarbonate settings on the hemodialysis machines were changed before each treatment to match the physician's prescribed orders for 55 of 55 patients (1-55).  Findings:  1. Bicarbonate is the buffer used in dialysis to maintain the pH of the patients' blood and the dialysate. Healthy kidneys keep the body's pH with in the very tight limits that cells need to survive. The kidneys do this by making and regulating bicarbonate. Bicarbonate is added to	V 248		10/18/10	

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V 248	<p>Continued From page 10</p> <p>to dialysate to help maintain patients' pH.</p> <p>On 7/28/10 at 08:50 A.M., RN 2 was observed providing care to Patient 4 in Station 16. RN 2 was asked to display Patient 4's bicarbonate setting on the dialysis machine. The machine setting showed a bicarbonate setting of 3.6. RN 2 stated that all patients were dialyzed at 3.6 in the facility. RN 2 could not explain the meaning of 3.6.</p> <p>2. On 7/28/10 at 8:45 A.M., PCT 3 was observed providing care to Patient 9 in Station 19. PCT 3 was asked to display Patient 9's bicarbonate setting on the dialysis machine. The machine setting showed a bicarbonate setting of 3.6. PCT 3 stated he never changed the bicarbonate setting and he did not know how to change the setting.</p> <p>On 7/29/10 at 4:00 P.M., the Administrator provided the Operator's Manual for the dialysis machines used in the facility. According to the Manual, the machines displayed the bicarbonate conductivity in mS/cm, a standardized measurement of conductivity units. A bicarbonate conductivity of 3.6 (mS/cm) yielded bicarbonate value of 40 mEq/L.</p> <p>During an interview on 7/30/10 at 8:30 A.M., the Manufacturer's Representative for the dialysis machine stated that bicarbonate levels could be changed by direct care staff members. She stated that the machine was Italian and displayed the bicarbonate conductivity in mS/cm equivalents, not in meq/L as ordered by the physician.</p> <p>During an interview on 7/30/10 at 8:45 A.M., the</p>	V 248			

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V 248	<p>Continued From page 11</p> <p>Administrator stated that the facility used the current machines for approximately 6 years. The Administrator was not aware that the bicarbonate conductivity reading on the machine could be changed by direct care staff. He stated that he understood that only the Biomedical Technician could make those changes.</p> <p>3. On 7/28/10 at 8:30 A.M., during observations of patient treatment, PCT 2 was asked to display the bicarbonate level on the hemodialysis machine at station 8. The bicarbonate level was set at 3.6. The PCT stated that the bicarbonate levels were set internally and only the biomedical technicians could adjust the levels. He further stated that all the machines were set at 3.6. Machines at stations 8, 9, 10, 12, 15, and 16 were reviewed and all had bicarbonate settings of 3.6.</p> <p>On 7/28/10 at 9:00 A.M., the Administrator stated that the default on the hemodialysis machines for bicarbonate was set at 3.6. He further stated that the setting could only be adjusted by the biomedical technicians. The Administrator provided literature from the manufacture of the dialysis machines, which indicated that the setting of 3.6 milliseamens converted to the equivalent of 40 mEq of bicarbonate.</p> <p>On 7/29/10 at 4:30 P.M., the facility provided the hemodialysis prescriptions for all hemodialysis patients prior to 7/28/10. In review of the prescriptions, 52 of 55 hemodialysis patients had bicarbonate prescriptions for 35 mEq and 3 of 55 patients had bicarbonate prescriptions for 36 mEq, which was contrary to the settings on the facility machines of 40 mEq.</p> <p>On 7/29/10 at 5:15 P.M., the Medical Director of</p>	V 248			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>552513</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/02/2010</b>
NAME OF PROVIDER OR SUPPLIER  <b>COLLEGE DIALYSIS</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>6535 UNIVERSITY AVENUE SAN DIEGO, CA 92115</b>		
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V 248	Continued From page 12 hemodialysis was interviewed via telephone. He stated he did not know before he received a phone call last night (7/28/10) from the Administrator that all the machines has a bicarbonate setting of 40 mEq, which was contrary to the bicarbonate prescriptions for all 55 patients. He stated that he was also not aware that the safety checks, which consisted of 2 persons checking the prescription against the machine settings prior to starting dialysis, were not conducted.  On 7/30/10 at 9:30 A.M., the Biomedical Technician stated that staff could change the bicarbonate settings on the machines at the chairside.  On 7/30/10 at 12:55 P.M., the PD Medical Director was interviewed via telephone. He stated that he did not know that the dialysis machine were all set at 40 mEq's of bicarbonate prior to the phone call he had received from the facility Administrator on 7/28/10.	V 248			
V 260	494.40(a) PERSONNEL-TRAINING PROGRAM/PERIODIC AUDITS  9 Personnel: training program/periodic audits A training program that includes quality testing, the risks and hazards of improperly prepared concentrate, and bacterial issues is mandatory.  Operators should be trained in the use of the equipment by the manufacturer or should be trained using materials provided by the manufacturer.  The training should be specific to the functions performed (i.e., mixing, disinfection, maintenance, and repairs).	V 260		10/18/10	

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

PRINTED: 02/11/2011  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>552513</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/02/2010</b>
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V 260	<p>Continued From page 13</p> <p>Periodic audits of the operators' compliance with procedures should be performed.</p> <p>The user should establish an ongoing training program designed to maintain the operator's knowledge and skills.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview and record review, the facility failed to ensure 7 of 8 staff members received initial and ongoing training and education on the facility hemodialysis machines (RN's 1, 2, 3 PCT's 1, 2, 3 and LVN 2).</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. On 7/28/10 at 08:50 A.M., RN 2 was observed providing care to Patient 4 in Station 16. RN 2 was asked to display Patient 4's bicarbonate setting on the dialysis machine. The machine setting showed a bicarbonate setting of 3.6. RN 2 stated that all patients were dialyzed at 3.6 in the facility. RN 2 could not explain the meaning of 3.6.</li> <li>2. On 7/28/10 at 8:45 A.M., PCT 3 was observed providing care to Patient 9 in Station 19. PCT 3 was asked to display Patient 9's bicarbonate setting on the dialysis machine. The machine setting showed a bicarbonate setting of 3.6. PCT 3 stated he never changed the bicarbonate setting and he did not know how to change the setting.</li> <li>3. On 7/28/10 at 8:30 A.M., during observations of patient treatments, 7 of the hemodialysis</li> </ol>	V 260			

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

PRINTED: 02/11/2011  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>552513</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/02/2010</b>
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V 260	<p>Continued From page 14</p> <p>machines (8, 9, 10, 12, 15, 16, and 19) had a bicarbonate level setting of 3.6. PCT 2 was asked to display the bicarbonate level on the hemodialysis machine at station 8. PCT 2 brought up the screen on the hemodialysis machine that listed the bicarbonate level, the screen indicated 3.6 as the bicarbonate setting. The PCT stated that the bicarbonate settings were were set on the machines internally and that only the Biomedical Technicians could adjust the bicarbonate levels. He further stated that all the machines were set at 3.6.</p> <p>On 7/28/10 at 9:00 A.M., the Administrator stated that the default on the hemodialysis machines for bicarbonate was set at 3.6. He further stated that the setting could only be adjusted by the Biomedical Technicians. The Administrator provided literature from the manufacture of the dialysis machines, which indicated that the setting of 3.6 milliseamens converted to the equivalent of 40 mEq of bicarbonate.</p> <p>On 7/29/10 at 4:30 P.M., the facility provided the hemodialysis prescriptions for all hemodialysis patients prior to 7/28/10. In reviewing the prescriptions, 52 of 55 hemodialysis patients bicarbonate prescriptions were for 35 mEq and 3 of 55 patients bicarbonate prescriptions were for 36 mEq, which was contrary to the settings on the facility machines of 40 mEq.</p> <p>On 7/30/10 at 9:30 A.M., the Biomedical Technician stated that staff could change the bicarbonate settings on the machines at the chairside.</p> <p>On 7/30/10 at 4:00 P.M., the facility Administrator and the Group Facility Administrator were</p>	V 260			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>552513</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/02/2010</b>
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V 260	Continued From page 15 interviewed concerning the above information. The Administrator stated that the facility used the current machines for approximately 6 years. He stated the staff were last trained on the dialysis machines about 3 years ago, however he could not provide sign in sheets or what was covered during that training.	V 260			
V 274	On 8/2/10 at 10:00 A.M., the Group Facility Administrator provided machine training, dated 2005, for 1 staff member (LVN 2). 494.40(c) H2O TEST-DEVIATIONS REQUIRE RESPONSE  Water testing results including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards must be addressed with a corrective action plan that ensures patient safety.  This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to address in a timely manner the elevated level of chemical contaminants in dialysis product water, creating the potential to cause harm to 55 of 55 patients (1-55) receiving hemodialysis treatments.  Findings:  On 8/02/10, the product water chemical analysis, drawn on 3/08/10, was reviewed. The showed results for aluminum, fluoride, and sulfate above the maximum allowable levels of contaminants for dialysis water according to AAMI standards. The results, dated 3/10/10, were as follows:  Contaminant                      Maximum Allowable Level	V 274		10/18/10	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>552513</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/02/2010</b>
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V 274	<p>Continued From page 16</p> <p>Aluminum =1.013 mg/L      0.01</p> <p>Fluoride = 0.41 mg/      0.20</p> <p>Sulfate =206.5 mg/L      100.00</p> <p>On 8/02/10, the facility provided an invoice, dated 3/23/10, that showed an order for replacement membranes for the RO (reverse osmosis) water system. The invoice specified that the membranes failed and needed to be replaced. Per the invoice, the facility received the replacement membranes and the facility technician replaced the membranes on 3/23/10, the same day they were ordered.</p> <p>For a period of 13 days, from 3/10/10 to 3/23/10, the facility failed to address the elevated levels of aluminum, fluoride, and sulfate in the product water. The facility continued to dialyze patients with product water that tested above the maximum allowable levels.</p> <p>During an interview on 8/02/10 at 2:10 P.M., the Biomedical Technician stated that staff should have rechecked the out of range levels "right away."</p> <p>During a joint interview on 8/02/10 at 2:20 P.M., the Group Facility Administrator and the Biomedical Technician acknowledged that the facility failed to address the out of range contaminant levels for 13 days.</p> <p>On 8/02/10 at 2:51 P.M., the facility provided a list of 14 of 44 patients with elevated aluminum levels from 1/20/10 through 3/03/10.</p> <p>Aluminum, fluoride and sulfate have been clearly</p>	V 274			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>552513</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/02/2010</b>
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V 274	Continued From page 17 shown to be toxic to dialysis patients at concentrations not necessarily toxic to the general population. Uptake of aluminum from the dialysate can be associated with bone disease and anemia. Elevated levels of fluoride in the water used to prepare dialysate can be toxic to dialysis patients and have resulted in patient deaths. Sulfate levels above 200 mg/L have been related to nausea, vomiting, and metabolic acidosis.	V 274			
V 402	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.  This STANDARD is not met as evidenced by: Based on observation, interview and record review, the facility failed to maintain the patient care area and offices free of flying insects.  Findings:  On 7/26/10 at 7:30 A.M., upon the entry of the	V 402		10/18/10	

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

PRINTED: 02/11/2011  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>552513</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/02/2010</b>
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V 402	<p>Continued From page 18</p> <p>facility, the team set up in the Medical Director's office. During the initial tour of the facility, small black flies were seen in the PD waiting area and upon return to the Medical Director's office, a few (1-3) flies were in the office.</p> <p>Adult drain flies are tiny (1/5 to 1/6 inch long), fuzzy, dark or grayish insects with the body and wings densely covered with hairs. Drain flies sometimes appear suddenly and mysteriously, becoming a nuisance. Adult flies may become so numerous indoors that they congregate, fall into food, sinks, and floor drains.</p> <p>On 7/27/10 from 7:30 A.M. to 5:00 P.M., a few small black flies were observed in the Medical Director's office, the kitchen, the dietitian and social workers office, and on the north end of the patient treatment area in the hemodialysis area.</p> <p>On 7/27/10 at 3:30 P.M., Patient 50 stated that he noticed small flies on the other side of the treatment area (referring to the north end of the hemodialysis treatment area). A second patient (12) seated on the north end of the treatment area stated, he noticed more flies last year than there were this year.</p> <p>During an interview on 7/28/10 at 8:05 A.M., the Administrator stated the facility contracted with a local pest control company to treat for "drain flies" every month. The Administrator stated, "The flies were gone and just came back last week."</p> <p>The Pest Control Representative was observed treating the drains in the patient care area on 7/29/10 at 8:45 A.M. During an interview on 7/29/10 at 8:47 A.M., the Pest Control Representative stated that on 7/08/10 he</p>	V 402			

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

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V 402	Continued From page 19 recommended the facility use a "concentrated pest control solution" in the drains and on the facility floors to prevent the gnats (flies).  On 7/29/10, the facility provided an invoice from the pest control company dated 7/08/10. According to the invoice, the regular service included treating 20 drains in the patient care area and restrooms for gnats.  During an interview on 7/29/10 at 8:50 A.M., the Administrator stated that he just found out the janitor ran out of the concentrate to control the flies. The Administrator did not know when the janitor ran out of the product. The Administrator acknowledged that the system failed because the janitor did not notify him that he was out of the concentrate.	V 402			
V 403	494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU  The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.  This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to secure 3 portable E-size oxygen tanks to prevent potential injury in the event of a natural disaster.  Findings:  On 7/27/10 at 2:45 P.M., the facility stored oxygen tanks in a small alcove adjacent to the patient	V 403		10/18/10	

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

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V 403	Continued From page 20 care area. Three E-size tanks with regulators stood upright and unsecured in the alcove. A bungee cord lay on the floor next to the tanks. One of 2 hooks in the wall was pulled out.	V 403			
V 541	During an interview on 7/27/10 at 4:03 P.M., the Administrator stated that the tanks should be secured in the event of an earthquake with more than a bungee cord.  494.90 POC-GOALS=COMMUNITY-BASED STANDARDS  The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.  This STANDARD is not met as evidenced by: Based on observations, interview, and record review, the facility failed to ensure that 1 of 8 sampled patients (9) received dialysis using the dialyzer ordered by the physician. The facility failed to ensure heparin dosages were given as ordered and that the heparin infusion was complete 60 minutes prior to the completion of the dialysis treatment for 2 of 8 sampled patients (7, 8). The facility failed to ensure staff implemented a physician's order for blood glucose testing prior to dialysis treatment for 1 of	V 541		10/18/10	

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

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V 541	<p>Continued From page 21 8 sampled patients (7).</p> <p>Findings:</p> <p>1. On 7/28/2010 at 8:45 A.M., Patient 9 received dialysis in station 19 using a Polyflux 24 dialyzer. The physician's orders for hemodialysis located at chairside specified that the patient should be dialyzed on a smaller size Polyflux 21R dialyzer.</p> <p>On 7/28/2010 at 8:56 A.M., PCT 3 said that the staff member in the Reuse department checked the size of the dialyzer.</p> <p>On 7/28/2010 at 9:01 A.M., the CC was interviewed regarding the discrepancy in the size of the dialyzer in use and the physician's order. The CC stated that Patient 9 should be on the Polyflux 21R dialyzer ordered by the physician. The CC stated that direct care staff were responsible for checking the size of the dialyzer, not the Reuse Technician.</p> <p>On 7/29/2010, the facility provided the P&amp;P titled Predialysis Dialyzer Inspection, reviewed by the Governing Body in June 2010. The policy ensured that the patient received the prescribed, correct and properly inspected dialyzer. The policy further specified, "The dialyzer should be checked to ensure: It is the correct dialyzer for the correct patient." The procedure showed, "Trained teammates will verify the dialysis prescription..." The Rationale for the procedure was, "Prescription verification and safety checks are performed so patient will receive a safe and effective treatment as prescribed."</p> <p>During a joint interview on 7/29/10 at 10:58 A.M., the Group Facility Administrator and the CSS</p>	V 541			

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

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V 541	<p>Continued From page 22</p> <p>stated that 2 staff members must check the dialyzer prior to starting the treatment.</p> <p>Review of Patient 9's medical record on 7/29/10 showed that the incorrect size dialyzer had been used 16 times. The record showed that 2 staff members checked the dialyzer and signed on the Treatment Sheets that the dialyzer was correct when it was actually the wrong size.</p> <p>2. The facility provided Patient 7's medical record on 7/30/10 at 11:10 A.M. for review. The dialysis treatment sheet dated 5/3/10, contained an order for blood glucose tests every dialysis treatment. The dialysis treatment sheet dated 5/3/10, did not contain documentation that blood glucose tests were collected.</p> <p>On 7/30/10 at 11:00 A.M., RN 3 acknowledged that the dialysis treatment sheet dated 5/3/10, contained no documentation for the pretreatment blood glucose tests.</p> <p>3. The facility provided Patient 7's medical record for review on 8/2/10 at 10:44 A.M. The dialysis treatment sheet dated 4/28/10, contained orders for Heparin 2400 units maintenance (800 units/hr). The stop time for the Heparin was 60 minutes before the end of dialysis.</p> <p>The same orders continued for dialysis treatments on 4/28/10, 5/3/10, 5/5/10, 5/12/10, 5/12/10 and 5/19/10. According to the documentation, the prescribed amount of Heparin was not infused during the treatments. In addition, documentation on the dialysis treatment sheets dated 4/28/10, 5/3/10, 5/5/10, 5/7/10 and 5/19/10, did not indicate the Heparin was stopped 60 minutes prior the end of the dialysis treatment as</p>	V 541			

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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V 541	Continued From page 23 ordered.  On 8/2/10 at 1:20 P.M., RN 3 reviewed all of the dialysis treatment sheets. RN 3 acknowledged that the documentation did not indicate that the Heparin was given as ordered by the physician.  4. On 8/2/10 10:44 A.M., the facility provided Patient 8's medical record for review. The dialysis treatment sheets dated 7/5/10, contained orders for Heparin 2000 units maintenance (800 units/hr). The stop time for the Heparin was 60 minutes prior to the completion of dialysis.  The same orders continued for dialysis treatment on 7/5/10, 7/7/10, 7/12/10, 7/16/10, 7/21/10, 7/23/10, 7/26/10. According to the documentation, the prescribed amount of Heparin was not infused during the treatments. On the dialysis treatment sheet dated 7/19/10, there was no documentation that Heparin given as ordered. The dialysis treatment sheets dated 7/5/10 and 7/12/10, did not indicate the Heparin was stopped 60 minutes prior the end of the dialysis treatment as ordered.	V 541			
V 587	494.100(b)(2),(3) H-FAC RECEIVE/REVIEW PT RECORDS Q 2 MONTHS  The dialysis facility must - (2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and (3) Maintain this information in the patient ' s	V 587		10/18/10	

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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V 587	Continued From page 24 medical record.  This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure that 1 of 2 sampled PD patients (1) maintained complete home treatment records. The facility failed to develop a plan when 1 of 2 sampled PD patients (1) did not document daily weights and/or blood pressures.  Findings:  On 7/30/10 at 11:00 A.M., the facility provided Patient 1's medical record for review. Patient 1's progress notes and daily treatment sheets from May through July 2010 indicated that Patient 1 was not documenting weights and/or blood pressures on a daily basis. The treatment sheets had sporadic entries of both the weights and blood pressures.  On 8/2/10 at 2:00 P.M., the PD nurse acknowledged that Patient 1 did not document weights and blood pressures, and further stated she had not developed a care plan to address this issue.	V 587			
V 597	494.100(c)(1)(vi) H-PROVIDE ORDERED SUPPLIES/EQUIPMENT  Services include, but are not limited to, the following: (vi) Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.  This STANDARD is not met as evidenced by:	V 597		10/18/10	

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V 597	Continued From page 25 Based on interview and record review the facility failed to provide oversight for the ordering of supplies for 1 of 2 PD patients (1).  Findings:  On 7/29/10 2:30 P.M., the PD nurse was interviewed regarding tracking of ordered supplies for PD patients. She was unable to produce invoices for supplies for PD patients. She stated that the manufacturer had not been sending the invoices for the past year. The PD nurse further stated that during the patients training period, she ordered the supplies, then the patient ordered supplies with her supervision. Once the patient was comfortable ordering their own supplies, the patient was responsible for conducting the manufacturer.  On 7/30/10 at 3:00 P.M., the PD nurse provided the invoices for Patient 1 and stated that she had not been tracking the patients supplies for home PD.	V 597			
V 713	494.150(b) MD RESP-STAFF ED, TRAINING & PERFORM  Medical director responsibilities include, but are not limited to, the following: (b) Staff education, training, and performance.  This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the alternating Medical Directors failed to ensure the competency of 7 of 8 staff members (RN's 1, 2, 3 and PCT's 1, 2, 3) in making adjustments to the bicarbonate levels on the hemodialysis machines for 55 of 55 patients (1 to 55). The alternating Medical Directors failed to ensure 8 of 8 staff members	V 713		10/18/10	

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V 713	<p>Continued From page 26</p> <p>received ongoing training and education on the facility hemodialysis machines (RN's 1, 2, 3 PCT's 1, 2, 3 and LVN 2).</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>On 7/28/10 at 08:50 A.M., RN 2 was observed providing care to Patient 4 in Station 16. RN 2 was asked to display Patient 4's bicarbonate setting on the dialysis machine. The machine setting showed a bicarbonate setting of 3.6. RN 2 stated that all patients were dialyzed at 3.6 in the facility. RN 2 could not explain the meaning of 3.6.</li> <li>On 7/28/10 at 8:45 A.M., PCT 3 was observed providing care to Patient 9 in Station 19. PCT 3 was asked to display Patient 9's bicarbonate setting on the dialysis machine. The machine setting showed a bicarbonate setting of 3.6. PCT 3 stated he never changed the bicarbonate setting and he did not know how to change the setting.</li> <li>On 7/28/10 at 8:30 A.M., during observations of the patient treatment, the hemodialysis machines had a bicarbonate level setting of 3.6. PCT 2 was asked to display the bicarbonate level on the hemodialysis machine at station 8. PCT 2 brought up the screen on the hemodialysis machine that listed the bicarbonate level, the screen indicated 3.6 as the bicarbonate setting. The PCT stated, only the biomedical technicians could adjust the bicarbonate levels, the adjustments were made internally. He further stated that all the machines were set at 3.6. The following machines were reviewed for the bicarbonate settings, station 8, 9, 10, 12, 15, and 16 had bicarbonate settings of</li> </ol>	V 713			

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V 713	<p>Continued From page 27</p> <p>3.6.</p> <p>On 7/29/10 at 4:00 P.M., the Administrator provided the Operator's Manual for the dialysis machines used in the facility. According to the Manual, the machines displayed the bicarbonate conductivity in mS/cm, a standardized measurement of conductivity units. A bicarbonate conductivity of 3.6 (mS/cm) yielded a bicarbonate value of 40 mEq/L.</p> <p>On 7/29/10 at 4:30 P.M., the facility provided the hemodialysis prescriptions for all hemodialysis patients prior to 7/28/10. In reviewing the prescriptions, 52 of 55 hemodialysis patients had bicarbonate prescriptions for 35 mEq and 3 of 55 patients had bicarbonate prescriptions for 36 mEq, which was contrary to the settings on the facility machines of 40 mEq.</p> <p>On 7/29/10 at 5:15 P.M., the Medical Director of hemodialysis was interviewed via telephone. He stated he did not participate in staff training.</p> <p>During an interview on 7/30/10 at 8:45 A.M., the Administrator stated that the facility used the current machines for approximately 6 years. The Administrator stated that the staff were last trained on the dialysis machines about 3 years ago, however he could not provide sign in sheets or what was covered during that training.</p> <p>On 7/30/10 at 12:55 P.M., the PD Medical Director was interviewed by telephone. He stated that he did not participate in staff training.</p> <p>On 8/2/10 at 10:00 A.M., the Group Facility Administrator provided machine training, dated 2005, for 1 staff member (LVN 2).</p>	V 713			

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