

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 052503	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 07/02/2010
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NAME OF PROVIDER OR SUPPLIER MAINPLACE DIALYSIS CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 972 TOWN & COUNTRY ROAD ORANGE, CA 92868
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V 000	<p>INITIAL COMMENTS</p> <p>The following reflects the findings of the California Department of Public Health during a RECERTIFICATION survey.</p> <p>The surveyors entered the facility on 6/29/10 at 0800 hours. The facility census at the time of the survey was 97 in-center hemodialysis patients with four peritoneal dialysis patients and three home hemodialysis patients. The patient sample consisted of 19 in-center hemodialysis patients, two peritoneal dialysis patients and two home hemodialysis patients for a total of 23.</p> <p>The Acting Facility Administrator, Designated Facility Administrator and Clinical Services Specialist were the facility coordinators for this survey.</p> <p>Representing the Department of Public Health: Raul Reyes, HFEN; Phyllis Weaver, HFEN and Leontine Smith, HFEN Observer.</p> <p>GLOSSARY:</p> <p>AED - Automatic External Defibrillator AMA - Against Medical Advice BP - Blood Pressure BFR - Blood Flow Rate CM - Clinical Manager CSS - Clinical Services Specialist CVC - Central Venous Catheter DFR - Dialysate Flow Rate Diastolic - lower number of the blood pressure reading EDW - Estimated Dry Weight FA- Facility Administrator Kg. - kilograms (equal to 2.2 pounds)</p>	V 000		
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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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>Kt/V is a number used to quantify dialysis treatment adequacy. (K - dialyzer clearance of urea X t - dialysis time/ V - patient's total body water) mL - milliliters mL/minute - Milliliters per minute NP - Nurse Practitioner PPE - Personal Protective Equipment P&P - Policy and Procedure PCT - Patient Care Technician QAPI - Quality Assurance and Performance Improvement RN - Registered Nurse Systolic - upper number of the blood pressure reading</p> <p>HSC 1205. Except as provided in Section 1206, no person, firm, partnership, association, corporation, or public agency shall operate, establish, manage, conduct or maintain a clinic in this state without first obtaining a license therefor as provided in this chapter; nor shall any such person, firm, partnership, association, corporation, or public agency provide any special service without obtaining a special permit therefor. However, any licensed clinic offering any service which is later designated by regulation of the state department as a special service shall be allowed to continue offering of such service and issues a special permit therefor or notifies the licensee that it is not eligible for a special permit and must cease and desist from offering such service.</p> <p>HSC 1207. The state department shall inspect and license clinics, and shall inspect and approve clinics to offer special services.</p> <p>Based on staff interview, record review and</p>	V 000			

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V 000	Continued From page 2 observation, the facility failed to obtain licensure prior to providing home hemodialysis training to patients. Upon entry to the facility on 6/29/10 at 0800 hours, during the initial interview with the acting Facility Administrator (FA) and the designated Facility Administrator, it was determined that the facility had trained the first patient to perform home hemodialysis treatments on 9/09. As of the date of entry, the facility had not been licensed to provide this service.	V 000			
V 111	494.30 IC-SANITARY ENVIRONMENT The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas. This STANDARD is not met as evidenced by: Based on observation, staff interview and document review, the facility failed to provide and continuously monitor for a sanitary environment to minimize the transmission of infections within and between the units of the facility. The pervasive presence of gnats for a number of months from the treatment area to the conference room to the water treatment area could serve as carriers of diseases and/or indirectly cause infection from one patient to another or from a patient to another staff. Findings: On 6/29/10 at 0800 hours, during the initial tour of the facility conducted with the charge nurse, 2-3 gnats were noted crawling on top of the emergency crash cart. The gnats were shown to the charge nurse who responded that the facility had known about these flying and biting insects	V 111		8/1/10	

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V 111	Continued From page 3 but had been unable to fully eradicate the problem. On 6/30/10 at 0630 hours, Patient 17 verbalized they had already complained to the staff about the annoying gnats. Patient 9, who was having his dialysis treatment in the next chair, said the same thing. In an interview with Biomed 1 on 6/30/10 at 1200 hours, more gnats were observed flying around the sink and crawling on the intravenous bags on the counter at the treatment area. Biomed 1 acknowledged the presence of the flying insects and stated the pest control company had been working to eradicate the problem. On 6/30/10 at 1400 hours, during review of the proof of services by the pest company submitted by the designated Facility Administrator, more gnats were observed in the conference room. Per review of the pest control services, the facility drain had been treated since 11/7/09 to control drain flies. On 3/17/10, it was advised recycled cans be removed from the lunch room which were possible hosts for gnats. By 4/21/10, all drains were treated again to control drain flies. By 5/19/10, recommendations were made to weatherproof back exit doors by attaching door sweeps by the storage area and the lunch room. Both doors faced a shallow pond with recycled water. However, both doors at time of survey did not have door sweeps as acknowledged by Biomed 1.	V 111			
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	V 113		8/1/10	

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V 113	<p>Continued From page 4</p> <p>dialysis station. Staff must remove gloves and wash hands between each patient or station.</p> <p>This STANDARD is not met as evidenced by: Based on observation, facility policy review and staff interview, the facility failed to ensure that glove changes were done per facility policy when catheter dressing changes were being performed, for one of 19 sampled in-center hemodialysis patients (Patient 20), which could lead to the spread of infectious agents.</p> <p>Findings:</p> <p>On 6/30/10, review of the facility Procedure 1-04-02C for Central Venous Catheter (CVC) Cleaning and Dressing Change, showed that with clean gloved hands the old dressing should be removed and the exit site checked for infection. The gloves should then be removed and discarded, the staff member was to wash their hands and put on new gloves.</p> <p>On 7/1/10 at 1905 hours, RN 3 was observed removing a CVC dressing and assessing the site for infection. After assessing the site, RN 3 did not remove their gloves, but cleaned the CVC exit site and placed a clean dressing over the exit site using the same gloves that were used to remove the old dressing.</p> <p>On 7/1/10 at 1345 an interview regarding CVC care was done with RN 1 and RN 2. Both RNs stated that after the old dressing had been removed and the site checked for infection, the gloves were to be removed and new gloves put on prior to cleaning the site and applying the new</p>	V 113			

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V 113	Continued From page 5	V 113			
V 116	<p>494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT</p> <p>Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.</p> <p>-- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient.</p> <p>-- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.</p> <p>This STANDARD is not met as evidenced by: Based on observation, the facility failed to ensure that a reusable item taken into a dialysis station was disinfected prior to being returned to a common area or used on another patient which could serve as a vehicle of transmission to other patients.</p> <p>Findings:</p> <p>On 6/30/10, review of facility Policy 1-05-01 for Infection Control for Dialysis Facilities last revised 9/09 showed that non-disposable items, such as stethoscopes, were not to be shared unless disinfected between patients, and that items taken into a dialysis station should be disinfected before being returned to a common clean area or used on another patient.</p>	V 116		10/23/10	

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V 116	Continued From page 6	V 116			
V 117	<p>On 7/2/10 at 0753 hours, Nurse Practitioner (NP) 1 was observed in the treatment area using a stethoscope to assess a patient. After finishing the assessment, NP 1 placed the stethoscope around his neck and proceeded to another patient receiving their dialysis treatment. NP 1 then used the stethoscope to assess the second patient. After using the stethoscope, NP 1 placed the stethoscope on top of the patient's dialysis machine while he continued to futher assess the patient. After completion of the assessment, he removed the stethoscope from the top of the dialysis machine, walked over to the nurses' station and placed the stethoscope on the disinfected medication preparation area, next to the boxes of medications. The NP then exited the unit without cleaning his hands. The stethoscope was pointed out to RN 5 who stated it was his stethoscope and NP 1 had borrowed it. RN 5 immediately disinfected the stethoscope and the medication area.</p> <p>The NP failed to disinfect the stethoscope per policy.</p> <p>494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS</p> <p>Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.</p> <p>When multiple dose medication vials are used</p>	V 117		8/1/10	

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V 117	<p>Continued From page 7</p> <p>(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, facility policy review and staff interview, the facility failed to ensure the medication preparation area remained free of objects that could potentially become contaminated while medications were being prepared and possibly cause infections.</p> <p>Findings:</p> <p>On 6/30/10, review of facility Procedure 1-06-01A for Preparation and Administration of Parenteral Medications (Non-EPO) last revised 9/09 showed that prior to each medication preparation, the medication preparation surface area must be disinfected with a 1:100 bleach solution, and the required supplies placed on the disinfected medication preparation area.</p> <p>During observation of the treatment area on 6/30/10 at 0840 hours, and on 7/2/10 at 0730 hours, blue chux pads had been placed over the disinfected medication preparation area. The blue chux pads had an absorbable middle area and a water resistant backing. Any fluids dropped on the pads would be absorbed and trapped inside the middle area. The trapped fluids could cause the growth of bacteria.</p>	V 117			

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V 117	Continued From page 8	V 117			
V 143	<p>On 7/2/10 at 1010 hours, the Clinical Services Specialist and the acting FA were asked about the use of the blue chux pads on the medication preparation area. They stated the pads were not to be used.</p> <p>494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS</p> <p>[The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and</p> <p>This STANDARD is not met as evidenced by: Based on observation, the facility failed to dispose of items that had expired per the manufacturer's time frame.</p> <p>Findings:</p> <p>On 6/29/10 at 0815 hours, a box containing approximately 40 to 50 laboratory tubes was observed at the nurses station with an expiration date of 9/09.</p> <p>On 6/29/10 at 0830 hours, during observation of the storage room, a box of hemocult tests were found with an expiration date of 5/09.</p>	V 143		8/1/10	
V 353	<p>494.50(b)(1) TEST FOR RESID GERM/MAX TIME RINSE TO USE</p> <p>12.4.1 Testing for residual germicide: max time rinsed to use Residual germicide shall be measured by a test of appropriate sensitivity according to a written</p>	V 353		10/23/10	

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V 353	<p>Continued From page 9</p> <p>procedure to ensure that the germicide level is below the maximum recommended residual concentration. Completion of this step shall be documented, along with the signature or other unique means of identifying the person performing the test.</p> <p>A written policy should establish the maximum allowable time between rinsing the germicide from the dialyzer and beginning dialysis. The priming, removal, and residual testing process should be reinstated after a delay sufficient to bring concentrations of germicide above the recommended level (rebound). Additional rinsing should be performed to yield a germicide level below the maximum recommended concentration before initiating of dialysis.</p> <p>A rinse procedure should be defined and documented step by step, and all personnel should be familiar with and follow it.</p> <p>If heat disinfection is used, the dialyzer should be cool to the touch before it is primed with saline.</p> <p>This STANDARD is not met as evidenced by: Based on observation and facility policy review, the facility failed to ensure that reused dialyzers were primed according to written facility procedures to ensure that residual germicide in the dialyzer was prevented from being infused into the patient when treatment was initiated. The treatments for three of 19 sampled in-center hemodialysis patients (Patients 8, 17 and 18) were observed being initiated with dialyzers that had not been rotated per policy.</p> <p>Findings:</p>	V 353			

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V 353	<p>Continued From page 10</p> <p>Facility policy and procedure review was initiated on 6/30/10. Procedure 1-03-04A for Priming a Reprocessed Dialyzer Free of Peracetic Acid Utilizing Fresenius 2008H and 2008K Dialysis Delivery Systems last revised 9/09, showed that after the dialyzer had been primed and the dialysate connectors were attached to the dialyzer, the dialyzer should be held and watched to see the dialyzer fill with dialysate. After it was filled it should be placed in the dialyzer holder with the venous (blue) end up. Recirculation was then started for 15 minutes. Approximately halfway through the recirculation procedure, the dialyzer was to be rotated so the arterial end (red) was up and the venous end (blue) was down. Rotation of the dialyzer reduces the possibility of any germicide being retained in the dead space of the dialysate compartment. Once recirculation was done, treatment could be initiated after the test for residual germicide was done and was confirmed as negative.</p> <p>Observation of the treatment floor on 6/29/10 at 1012 and 1251 hours, and on 6/30/10 at 1340 hours, showed Patients 8, 17 and 18 were being prepped for initiation of their treatments. The front of the dialysis machines showed that dialyzer recirculation had been completed. The venous end (blue) of the dialyzers were still up. The dialyzers had not been rotated during recirculation per policy. The germicide residual tests were performed with the venous end of the dialyzers still up, the blood lines were attached and treatments were initiated. The dialyzers were rotated to arterial side (red) up after the blood had entered the dialyzer.</p> <p>On 6/29/10 at 1007 hours on Station 9, at 1250 hours on Station 10, at 1255 hours on Station 5,</p>	V 353			

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V 353	Continued From page 11 on 6/30/10 at 0650 hours on Station 15, at 0843 hours on Station 14, at 1247 hours on Station 7 and at 0902 hours on Station 3, the dialysis machines showed that recirculation had been completed and the venous end of the dialyzers were still turned up. The dialyzers had not been rotated per policy to arterial end up halfway through the recirculation process.	V 353			
V 401	494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment. This STANDARD is not met as evidenced by: Based on observation and staff interview, the facility failed to maintain a safe and functional environment for dialysis patients and the staff. Aside from the continuous presence of gnats in the treatment area, the raised areas in the flooring and the accumulation of rusty granulates seen in the gap of the warped wall and baseboard areas of the water treatment room could harbor infection. The accumulation of bicarbonates and acids on the metal pipe joints at the back counter (chaise area) of the treatment area predisposed the facility to non-functional delivery of quality dialysis water. This included the ceiling tiles that were exposed to water as evidenced by the water stains. Findings: 1. On 6/29/10 at 0800 hours, during the initial tour of the facility conducted with the charge nurse,	V 401		8/1/10	

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V 401	<p>Continued From page 12</p> <p>2-3 gnats were noted crawling on top of the emergency crash cart. The gnats were shown to the charge nurse who responded that the facility had known about these flying and biting insects, but had been unable to fully eradicate the problem.</p> <p>On 6/30/10 at 0630 hours, Patient 17 verbalized they had already complained to the staff about the "annoying gnats." Patient 9, who was having his dialysis treatment in the next chair, verbalized the same complaint.</p> <p>On 6/30/10 at 1200 hours, Biomed 1 acknowledged the presence of the flying insects in the different units of the facility and stated the pest control company had been working to eradicate the problem.</p> <p>On 6/30/10 at 1400 hours, per review of the pest control services, the facility drain had been treated since 11/7/09 to control the drain flies. On 3/17/10, possible hosts for gnats were recommended to be removed from the lunch room such as recycled cans. By 4/21/10, all drains were treated again to control drain flies. By 5/19/10, recommendations were made to weatherproof back exit doors by attaching door sweeps by the storage area and the lunch room to prevent possible entry of gnats. However at time of survey, both doors did not have door sweeps as acknowledged by Biomed 1.</p> <p>2. On 6/29/10 at 0830 hours, during the initial tour of the water treatment room conducted with Biomed 1, the ceiling tiles were noted to have been exposed to a water leak as evidenced by the water stains. The linoleum floor beside the floor drain located after the secondary tanks was</p>	V 401			

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V 401	Continued From page 13 warped and peeling off the floor, which could serve as hosts for bacteria. By the bicarbonate mixing tank, the baseboards and the warped wall had a 2-inch gap approximately three feet long with an accumulation of rusty granulates, another possible host for fungi. The pipe joints underneath the bicarbonate distribution tank had an accumulation of powdery granulates causing erosion of the pipes that could contribute to failed water delivery system.	V 401			
V 403	3. Further inspection of the pipe connections in the chaise area revealed more accumulation of bicarbonate and acids on the joints causing erosion of the metal that could cause possible leaks or bursting of the delivery pipes. The floor stains revealed evidence of water leaks. 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, record review and staff interview, the facility failed to maintain their program to ensure the emergency crash cart and its emergency equipment were functional and available at all times. Such failure threatened patients' health and safety during medical emergencies. Findings:	V 403		8/1/10	

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V 403	<p>Continued From page 14</p> <p>On 6/30/10, review of the facility's P&P on Emergency Equipment Checks showed in order to ensure emergency equipment was available and functional, the emergency equipment should be checked by a licensed nurse on a WEEKLY basis. The list of equipment to be checked was: whether the oxygen tank supply was adequate, airways were available, suction machine and AED were operational, supplies were not expired and a functional artificial respirator (ambu bag) was always available.</p> <p>The part of the cart containing medications and other supplies would be sealed with a break away lock. In the event supplies were used from the emergency cart, replacement supplies would be obtained and the cart should be locked again.</p> <p>On 6/29/10 at 0830 hours, during the initial tour of the facility conducted with RN 2, the emergency crash cart was found unlocked. The AED and the suction machine, described by the crash cart checklist to be located on top of the cart were missing. Two intravenous bags of normal saline were expiring on 6/10. The intravenous bags were replaced, however, the cart was not locked, and/or the cart was not checked for missing items. A box of break away locks was sitting on top of the cart. Review of the equipment checklist revealed the last time the emergency cart had been checked was on 4/24/10.</p> <p>On 6/30/10 at 0730 hours, the emergency cart remained unlocked. When RN 5 was notified, he responded by locking the cart using the break away locks on top of the cart. However, RN 5 did not check the list of cart contents to verify availability of supplies and emergency equipment including its operational status.</p>	V 403			

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V 407	<p>494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS</p> <p>Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement).</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the facility failed to ensure patients safety by allowing patients to cover their vascular access sites and bloodline connections. Accidental needle dislodgement or line disconnection could go undetected if the vascular access sites were covered that could result in lethal exsanguination (profuse bleeding) and death in minutes.</p> <p>Findings:</p> <p>On 6/29/10 at 1100 hours, during the initial tour of the facility's treatment area conducted with RN 2, the patient in station 20 had his vascular access site covered with his blanket. When the surveyor made a comment, RN 2 responded by uncovering the access site.</p> <p>On 6/30/10 at 0630 hours, upon entry to the treatment area, patients in stations 20, 21 and 12 had their vascular access sites covered. RN 5 was approached and asked who was taking care of the patients in stations 20 and 21. RN 5, who was relieving the assigned staff on break, looked at the patients and asked why. When RN 5 was notified regarding the patients' covered vascular access sites, he responded by approaching the patients to uncover their access sites. RN 5 had to explain to the inquiring patients the reasons why the access site needed to be uncovered throughout the dialysis treatment.</p>	V 407		10/23/10	

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V 408	<p>494.60(d) PE-EMERGENCY PREPAREDNESS-PROCEDURES</p> <p>The dialysis facility must implement processes and procedures to manage medical and non medical emergencies that are likely to threaten 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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the facility failed to demonstrate staff knowledge and readiness to respond to medical emergencies, natural disasters and/or man-made disasters such as fires, power or water supply disruptions. Failure to implement such processes and procedures to manage emergency situations, medical and non-medical, were likely to threaten the health or safety of the patients, the staff or the public.</p> <p>Findings:</p> <p>1. On 6/29/10 at 0830 hours, during the initial tour of the facility conducted with RN 2, the emergency crash cart was found unlocked. The AED and the suction machine, described by the crash cart checklist to be located on top of the cart, were missing. Two intravenous bags of normal saline were expiring on 6/10. The intravenous bags were replaced, however, the cart was not locked even though a box of break away locks was sitting on top of the cart. Review of the equipment checklist revealed the last time the emergency cart had been checked was on</p>	V 408		8/1/10	

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V 408	<p>Continued From page 17 4/24/10.</p> <p>On 6/30/10 at 0730 hours, the emergency cart remained unlocked. When RN 5 was notified, he responded by locking the cart using the break away locks on top of the cart. However, RN 5 did not check the list of cart contents to verify availability of supplies and operational status of the emergency equipment.</p> <p>The emergency cart was not maintained to ensure all equipment and supplies were available and functional to be able to respond to emergent patient medical conditions.</p> <p>2. On 6/30/10 at 1400 hours, Biomed 1 and 2 were asked where the main water and gas shut off valves were located. Both failed to verbalize the location. Biomed 1 paged the building maintenance staff and the location of the valves were shown to the surveyor. However, there was no key available to the facility staff to shut off the gas valve in case of emergency.</p> <p>3. On 7/1/10 at 1800 hours, the facility's nocturnal shift, "providing dialysis treatment while patients sleep," was surveyed. Patients' vital signs were to be assessed every 30 minutes before and after "lights out" which was scheduled at 2030 hours. The last patient to be taken off dialysis treatment would be 0430 hours.</p> <p>Staffing consisted of RN 3 and PCT 3 to provide dialysis treatment for ten patients. This meant that one staff would have to watch 10 patients when the other staff took a break. RN 3 pointed out the break must be taken inside the same building. When asked if they needed help, RN 3 responded that the Facility Administrator would be</p>	V 408			

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V 408	Continued From page 18 informed to send extra staff at an unspecified length of time. On 7/1/10 at 1900 hours, PCT 3 readily located the main electrical switch when asked. When asked about the water and gas shut off valves, PCT 3 failed to locate these areas. PCT 3 stated the staff relied on biomedical staff for assistance with regard to water and other mechanical problems. When asked to contact the biomedical staff, PCT 3 paged the biomedical staff on call. There was no response after 15 minutes. The biomedical staff was paged again but 20 minutes had passed and still there was no response.	V 408			
V 413	On 7/2/10 at 1030 hours, Biomed 3 was asked regarding on-call protocol. Biomed 3 responded that the staff on call was expected to respond within 15 minutes. The second page should had been received by the biomedical supervisor to cover any possible missed communication during emergencies. Unfortunately, he stated, the biomedical supervisor was on vacation this week. 494.60(d)(3) PE-ER EQUIP ON PREMISES-02, AED, SUCTION Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available. This STANDARD is not met as evidenced by: Based on observation and staff interview, the facility failed to ensure that emergency equipment was accessible and ready to use in case of medical emergencies as evidenced by an unchecked crash cart. In addition, there was lack	V 413		8/1/10	

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V 413	<p>Continued From page 19</p> <p>of staff and support staff, on the premises and immediately available, for the nocturnal shift. The failures threatened patients' health and safety.</p> <p>Findings:</p> <p>1. On 6/29/10 at 0830 hours, during the initial tour of the facility conducted with RN 2, the emergency crash cart was found unlocked. The AED and the suction machine, described by the crash cart checklist to be located on top of the cart were missing. Two intravenous bags of normal saline were expiring on 6/10. The intravenous bags were replaced, however, the cart was not locked despite of a box of break away locks sitting on top of the cart. Review of the equipment checklist revealed the last time the emergency cart had been checked was on 4/24/10.</p> <p>On 6/30/10 at 0730 hours, the emergency cart remained unlocked. When RN 5 was notified, he responded by locking the cart using the break away locks on top of the cart. However, RN 5 did not check the list of cart contents to verify availability of supplies and operational status of the emergency equipment.</p> <p>The emergency cart was not maintained to ensure all equipment and supplies were available and functional to respond to emergent patient medical conditions.</p> <p>2. On 6/30/10 at 1400 hours, Biomed 1 and 2 were asked where the main water and gas shut off valves were located. Both failed to verbalize the location. Biomed 1 paged the building maintenance staff and the location of the valves was shown to the surveyor. However, there was</p>	V 413			

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V 413	<p>Continued From page 20</p> <p>no key available to the facility staff to shut off the gas valve in case of emergency.</p> <p>3. On 7/1/10 at 1800 hours, the facility's nocturnal shift, "providing dialysis treatment while patients sleep," was surveyed. Patients' vital signs were to be assessed every 30 minutes before and after "lights out" which was scheduled at 2030 hours. The last patients to be taken off dialysis treatment would be 0430 hours.</p> <p>Staffing consisted of RN 3 and PCT 3 to provide dialysis treatments for ten patients. This meant that one staff would have to watch 10 patients when the other staff took a break. RN 3 pointed out the break should be taken inside the same building. When asked if they needed help, RN 3 responded that the Facility Administrator would be informed to send extra staff at an unspecified length of time.</p> <p>On 7/1/10 at 1900 hours, PCT 3 readily located the main electrical switch when asked. When asked about the water and gas shut off valves, PCT 3 failed to locate these areas. PCT 3 stated the staff relied on biomedical staff for assistance with regard to water and other mechanical problems. When asked to contact the biomedical staff, PCT 3 paged the biomedical staff on call. There was no response after 15 minutes. The biomedical staff was paged again but 20 minutes had passed and still there was no response.</p> <p>On 7/2/10 at 1030 hours, Biomed 3 was asked regarding on-call protocol. Biomed 3 responded that the staff on call was expected to respond within 15 minutes. The second page should have been received by the biomedical supervisor to cover any possible missed communication during</p>	V 413			

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V 413	Continued From page 21	V 413			
V 503	<p>emergencies. Unfortunately, he stated, the biomedical supervisor was on vacation this week.</p> <p>494.80(a)(2) PA-APPROPRIATENESS OF DIALYSIS RX</p> <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: Based on medical record review, staff interview and facility policy review, the facility failed to ensure the blood flow rates (BFR), dialysate flow rates (DFR) and the related components, such as patients' estimated dry weights (EDW) were assessed, that patient weight gains were calculated per policy for accurate fluid removal, and treatments evaluated to determine if it met the patients' needs for 10 of 19 sampled in-center hemodialysis patients (Patients 1, 2, 3, 4, 5, 6, 7, 8, 10 and 21). As a result, patients were being discharged above or below their EDWs which could potentially lead to hypertensive (high blood pressures) or hypotensive (low blood pressure) episodes.</p> <p>Findings:</p> <p>On 6/30/10, review of the facility's Policy 1-07-03 for Adequacy Management Guidelines, last revised 9/09, showed factors that could effect the patients' adequacy of treatment and how to evaluate if the patient met their treatment goals. It also showed that if the patient's post-weight was consistently different than the EDW by more than</p>	V 503		10/23/10	

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V 503	<p>Continued From page 22</p> <p>1.0 Kg. (+ or minus 1.0 Kg.), the EDW should be adjusted as needed per physician order. The patient must be dialyzed on the correct dialysate flow based on the prescription. The prescribed treatment time must be evaluated to determine if the patient was dialyzing their full time.</p> <p>Facility Procedure 1-03-08B for Fluid Removal Calculations dated 9/07, showed the patient's intradialytic fluid removal was determined by subtracting the EDW from the pre-dialysis weight, and to add the total amount of fluids to be received during treatment to the intradialytic weight removal to determine the total amount of fluid to be removed. The facility used 0.5 Kg. for the total amount of fluids received during treatment.</p> <p>Facility Procedure 1-09-01 for Hypotension, dated 9/07, showed that normal saline should be administered, the ultrafiltration (UF) discontinued to prevent further loss of fluid volume and the patient should be reassessed.</p> <p>Review of the patients' treatment sheets containing the EDWs, calculated weight gains and fluid removal volumes were reviewed with the designated Facility Administrator (FA) on 6/30, 7/1 and 7/2/10 with the following findings:</p> <p>1a. Review of the records for 14 treatments for Patient 2 from 5/17 to 6/28/10 showed the patient had an ordered EDW of 110.0 Kg. For seven treatments, the patient was discharged 0.5 Kg. to 3.0 Kg. below his EDW. For six treatments, the patient was discharged 0.3 Kg. to 5.5 Kg. over his EDW. The weight gains calculated for the patient and the fluid volume removed were not per policy. For example:</p>	V 503			

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V 503	<p>Continued From page 23</p> <p>* On 6/2/10, the pre-treatment weight was 119.0 Kg. Weight gain was calculated as 4.9 Kg. and the fluid volume removed was 3.7 Kg. Patient 2 was discharged 5.3 Kg. over his EDW.</p> <p>* On 6/7/10, the pre-treatment weight was 116.4 Kg. The weight gain calculated was 1.1 Kg. and the fluid volume removed was 0.9 Kg. Patient 2 was discharged 5.5 Kg. over his EDW.</p> <p>* On 6/25/10, the pre-treatment weight was 114.6 Kg. The weight gain calculated was 3.6 Kg. and the fluid volume removed was 5.1 Kg. Patient 2 was discharged 0.5 Kg. under his EDW.</p> <p>1b. On 5/21/10, the patient's treatment was administered for 65 minutes. Patient 2 had an ordered treatment time of 180 minutes. The treatment sheet showed an Against Medical Advice (AMA) form was signed by Patient 2, however, there was no documentation the physician was notified of the shortened treatment. On 5/26/10, Patient 2's treatment was administered for 138 minutes but there was no documentation provided to show an AMA form was signed by the patient.</p> <p>1c. Patient 2 had an ordered BFR of 400 mL per minute (mL/min), and a DFR of 600 mL/min. The treatment sheet for Patient 2, dated 5/17/10, showed the patient had a BFR of 450 mL/min and a DFR of 700 mL/min. There was no physician's order for the increased BFR and DFR.</p> <p>2a. Review of 14 treatments for Patient 4 from 5/29 to 6/29/10 showed the patient had an ordered EDW of 76.0 Kg. For all 14 treatments the patient's post-treatment weight was 3.8 Kg. to 6.7 Kg. under his EDW. There was no documentation the EDW had been assessed to ensure it was appropriate for the patient.</p>	V 503			

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V 503	Continued From page 24 2b. Review of the calculated weight gains and fluid volume removed for Patient 4 were not per policy. For example: * On 6/10/10, the pre-treatment weight was 72.5 Kg. The calculated weight gain was 0.9 Kg. and the total amount of fluid removed was 2.1 Kg. Patient 4 was discharged 5.6 Kg. under his EDW * On 6/22/10, the pre-treatment weight was 73.3 Kg. The calculated weight gain was 1.9 Kg. and the total amount of fluid removed was 3.1 Kg. The patient was discharged 5.8 Kg. under his EDW. 2c. Patient 4 had physician's orders for a BFR of 400 mL/min. and a DFR of 600 mL/min. Review of the treatment sheet, dated 6/15/10, showed 30 minutes prior to the end of the treatment, the DFR had been decreased to 400 mL/min. There was no documentation to show why it had been decreased. The treatment sheet for 5/29/10 showed the patient's maximum BFR for the treatment was 300 mL/min. There was no documentation to show why the BFR was decreased. 3a. Review of 14 treatments for Patient 6 showed the patient had an ordered EDW of 57.0 Kg. For 10 treatments, from 5/26 to 6/18/10, the patient was discharged 0.3 Kg. to 4.1 Kg. over her EDW. The four treatments from 6/21 to 6/28/10 showed the patient was discharged 0.3 Kg to 1.1 Kg. under her EDW. There was no documentation Patient 6's EDW had been assessed. 3b. The calculated weight gains and fluid volume removed for Patient 6 were not per policy. For example: * On 6/2/10, the pre-treatment weight was 63.0	V 503			

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V 503	<p>Continued From page 25</p> <p>Kg. The weight gain calculated was 1.1 Kg. and the fluid volume removed was 1.0 Kg. The patient was discharged 5.0 Kg. over her EDW. * On 6/11/10, the pre-treatment weight was 62.2 Kg. The weight gain calculated was 1.2 Kg. and the fluid volume removed was 1.9 Kg. The patient was discharged 3.3 Kg. over her EDW. * On 6/25/10, the pre-treatment weight was 58.5 Kg. The weight gain calculated was 2.3 Kg. and the fluid volume removed was 2.6 Kg. Patient 6 was discharged 1.1 Kg. under her EDW.</p> <p>3c. Patient 6 had an ordered BFR of 300 mL/min. and DFR of 500 mL/min. On 5/26, 5/28, 6/2, 6/9, 6/16 and 6/25/10 the patient had a BFR of 350 to 375 mL/min. On 5/26, 5/28, 6/9 and 6/25/10 the patient had a DFR of 600 mL/min. There were no physician's orders for the increased BFRs and DFRs.</p> <p>4a. The 14 treatments for Patient 5, from 5/28 to 6/28/10, showed the patient had an ordered EDW of 61.0 Kg. For 11 treatments, the patient had been discharged from 0.3 Kg. to 2.6 Kg. over his EDW. Review of the calculated weight gains and fluid removal volumes showed the following: * On 6/7/10, the pre-treatment weight was 66.1 Kg. The weight gain calculated was 3.9 Kg. and the fluid volume removed was 2.9 Kg. Patient 5 was discharged 2.6 Kg. over his EDW. * On 6/14/10, the pre-treatment weight was 66.2 Kg. The weight gain calculated was 2.8 Kg. and the fluid volume removed was 3.5 Kg. Patient was discharged 1.7 Kg. over EDW. * On 6/25/10, Patient 5's EDW was increased to 62.5 Kg. The pre-treatment weight was 64.5 Kg. The weight gain calculated was 3.5 Kg. and the fluid volume removed was 3.0 Kg. The patient was discharged under his EDW at 61.5 Kg.</p>	V 503			

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V 503	Continued From page 26 4b. Patient 5 had a ordered BFR of 450 mL/min. and a DFR of 700 mL/min. On 5/31/10, the maximum BFR was 350 mL/min and DFR was 800 mL/Min. On 6/9, 6/11 and 6/18/10, the DFR was 800 mL/min. On 6/14/10, the DFR was 600 mL/min. On 6/23, 6/25 and 6/28/10, the maximum BFR was 400 mL/min. There was no documentation to show why the BFRs and DFRs were not per physician's orders. 5a. Review of 14 treatments for Patient 7 from 5/29 to 6/29/10 showed the calculated weight gains and fluid removal volumes were not calculated per policy. For example: * On 6/3/10, the patient had an ordered EDW of 68.0 Kg. The pre-treatment weight was 70.6 Kg. The weight gain calculated was 0.0 Kg. and the total fluid removed was 0.4 Kg. Patient was discharged 2.2 Kg. over her EDW. * On 6/12/10, the patient had an ordered EDW of 70.0 Kg. The pre-treatment weight was 71.8 Kg. The calculated weight gain was 0.0 Kg. and the total fluid volume removed was 0.4 Kg. The patient was discharged 1.4 Kg. over her EDW. * On 6/29/10, the patient had an ordered EDW of 72.5 Kg. The pre-treatment weight was 70.9 Kg. The calculated weight gain was 0.4 Kg. and the fluid volume removed was 0.4 Kg. The patient was discharged 2.0 Kg. below her EDW. Review of Patient 7's clinical record on 5/11/10 showed the physician changed the EDW to 68.0 Kg. On 5/19/10 the physician changed the patient's EDW to 69.5 Kg. The increased EDW to 69.5 Kg. was not reflected in the patient's treatment orders. The clinical record showed an EDW of 68.0 Kg for the patient until 6/10/10. On 6/12/10, the patient's EDW was increased to 70.0	V 503			

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V 503	Continued From page 27 Kg. 5b. Patient 7 had an ordered DFR of 600 mL/min. The treatment sheet for 6/8/10 showed the patient's DFR was 800 mL/min. There was no documentation to show why the DFR was greater than the ordered 600 mL/min. 6a. Review of 14 treatments for Patient 3, from 3/3 to 4/16/10, showed the patient had an EDW of 84.5 Kg. All 14 treatments showed the patient had been discharged 2.4 Kg. to 13.5 Kg. below his EDW. There was no documentation to show that the patient's EDW was assessed. On 3/29/10, the patient was hospitalized for pulmonary edema. 6b. Review of the calculated weight gains and total fluid removal for Patient 3 were not to policy. For example: * On 3/17/10, the pre-treatment weight was 66.7 Kg. The calculated weight gain was -13.5 Kg. and the total fluid removed was -12.0 Kg. The patient's discharge weight was 78.7 Kg., 12.0 Kg. over his pre-treatment weight. * On 3/19/10, the pre-treatment weight was 80.5 Kg. (1.8 Kg. over his discharge weight on 3/17). The calculated weight gain was 1.8 Kg. and the total fluid removed 1.1 Kg. The patient was discharged at 79.4 Kg., which was 0.7 Kg. greater than the discharge weight on 3/17/10. * On 4/14/10, the pre-treatment weight was 80.4 Kg. and the calculated weight gain was 2.9 Kg. The fluid volume removed was 8.7 Kg. The patient was discharged at 71.7 Kg. * On 4/16/10, the pre-treatment weight was 78.8 Kg. and the calculated weight gain was 7.1 Kg. The fluid volume removed was 4.0 Kg.	V 503			

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V 503	<p>Continued From page 28</p> <p>6c. Patient 3 had an ordered BFR of 450 mL/min. and a DFR of 700 mL/min. The treatment sheet for 3/17/10 showed the highest BFR during the treatment was 350 mL/min with BFRs decreased to 300 and then to 260 mL/min. The DFR for the treatment was 350. There was no documentation to show why the BFR and DFR were not to physician's orders. The treatment sheets for 3/19, 3/24, 4/12, 4/14 and 4/16/10 showed the ordered BFR of 450 mL/min. was not achieved. The treatment sheets for 3/24, 4/12, and 4/14/10 showed the DFR for these treatments were not per physician's orders. There was no documentation to show why the ordered DFR was not achieved.</p> <p>7a. The Patient Review Report for Patient 10 showed the patient had treatments on 6/9, 6/10,6/11, 6/21, 6/22 and 6/23/10. On 6/30/10 at 0920 hours, the designated FA was asked about the extra patient treatments. The surveyor was given documentation on 6/30/10 which showed the patient received extra treatments related to increased fluid gains and there were physician's orders for the treatments. Review of Patient 10's chart revealed a physician's order, dated 6/3/08, for the patient to receive treatments four times a week for two months for fluid gains, but there was no current order for the extra treatments.</p> <p>7b. Review of the calculated weight gains and total fluid removal volumes for Patient 10 were not to policy. For example: * On 6/4/10, the patient had an EDW of 107.5 Kg. The pre-treatment weight was 110.6 Kg. The calculated weight gain was 1.9 Kg. and the total fluid volume removed was 4.0 Kg. The patient was discharged 0.9 Kg. below his EDW. * On 6/18/10, the patient had an EDW of 108.5</p>	V 503			

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V 503	<p>Continued From page 29</p> <p>Kg. The pre-treatment weight was 113.6 Kg. and the calculated weight gain was 2.5 Kg. The total fluid volume removed was 3.3 Kg. The patient was discharged at 110.3 Kg., 1.8 Kg. over his EDW.</p> <p>* On 6/25/10, the patient had an EDW of 108.5 Kg. The pre-treatment weight was 113.9 Kg. and the calculated weight gain was 7.0 Kg. The total fluid volume removed was 4.3 Kg. The patient was discharged at 109.5 Kg, 1.1 Kg. over his EDW.</p> <p>7c. Patient 10 had an ordered BFR of 450 mL/min. and a DFR of 700 mL/min. On 6/9 and 6/10/10, the treatment sheets showed the patient had a BFR of 400 mL/min. and a DFR of 800 mL/min. There was no documentation to show why the BFR and DFR were not to physician's orders.</p> <p>7d. The treatment sheet for 6/9/10 showed Patient 10 had a BP of 171/87 during initiation of treatment at 0557 hours. The target fluid removal goal was 5.50 Kg. At 0625 hours, the BP had decreased to 159/95. At 0707 hours, the BP dropped to 114/71. There were no changes made on the treatment setting. The BP continued to decrease, and at 0830 hours, was 73/46. It was documented the patient complained of sweating and was given a 400 mL normal saline bolus, the UF was turned off, and the nurse was notified. However, there was no reassessment of the BP until 0900 hours. The BP was 76/47. The patient was assessed every 30 minutes for the last hour and discharged with a BP of 98/59. There was no documentation to show that the nurse had assessed the patient.</p> <p>8a. Review of 14 treatments from 5/25 to 6/26/10</p>	V 503			

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V 503	<p>Continued From page 30</p> <p>for Patient 8 showed the patient had an ordered EDW of 180.0 Kg. For 13 of the 14 treatments, the patient had been discharged 2.4 Kg. to 8.2 Kg. over his EDW. There was no documentation to show the patient's EDW had been assessed. The calculated weight gains and total fluid removal was not to policy. For example:</p> <p>* On 6/6/10, the pre-treatment weight was 183.4 Kg., the calculated weight gain was 0.6 Kg. and the total fluid removed was 0.7 Kg. The patient was discharged at 182.7 Kg.</p> <p>* On 6/15/10, the pre-treatment weight was 189.6 Kg. and the calculated weight gain was 1.4 Kg. and total fluid removed was 2.1 Kg. The patient was discharged at 187.5 Kg., 8.75 Kg over his EDW.</p> <p>* On 6/26/10, the pre-treatment weight was 188.2 Kg., the calculated weight gain was 1.4 Kg. and the total fluid removed was 1.2 Kg. The patient was discharged at 187.0 Kg., 7.0 Kg over his EDW.</p> <p>8b. Patient 8 had an ordered treatment time of two hours and 30 minutes. The patient's measurement for adequacy of treatment was a KT/V of 1.03 (minimum is KT/V of 1.2 or greater).</p> <p>8c. Patient 8 had an ordered BFR of 350 mL/min and a DFR of 600 mL/min. The treatment sheets for 5/25, 6/3, 6/10 and 6/24/10 showed the patient's BFR and DFR for these treatments were not to physician's orders. There was no documentation to show why the ordered BFR was not achieved or why the patient was ran on a DFR of 800 mL/min.</p> <p>9a. Review of 14 treatments for Patient 21 from 5/28 to 6/28/10 showed the patient had been discharged under his EDW of 64.0 Kg. The</p>	V 503			

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V 503	<p>Continued From page 31</p> <p>patient was discharged 3.0 Kg. to 4.2 Kg under his EDW. There was no documentation to show the patient's EDW had been assessed.</p> <p>9b. The weight gains calculated and the fluid removal were not to policy. For example: * On 6/7/10, the pre-treatment weight was 63.8 Kg. which was 0.2 Kg. under his EDW. The calculated weight gain was 2.2 Kg. and the total fluid removed was 4.4 Kg. The patient was discharged at 59.8 Kg., 4.2 Kg. under his EDW. * On 6/23/10, the pre-treatment weight was 64.0 Kg. (the patient's EDW). The calculated weight gain was 1.2 Kg. and the total fluid removed was 1.5 Kg. The patient was discharged 1.5 Kg. under his EDW.</p> <p>10a. Review of Patient 1's 14 treatments from 4/27 to 6/26/10 showed the patient had an EDW of 74.5 Kg. Review of the 14 treatments showed Patient 1 had been discharged below his EDW. The patient's post-weights were from 4.8 Kg. to 12.8 Kg. below his EDW. There was no documentation to show Patient 1's EDW had been assessed.</p> <p>10b. Review of the treatments showed the following weight gain calculations and fluid removed were not to policy. For example: * On 4/27/10, the pre-treatment weight was 74.9 Kg. (0.5 Kg. over his EDW) and the calculated weight gain was 5.3 Kg. The fluid volume removed was 5.2 Kg. The patient was discharged at 69.7 Kg., 4.8 Kg. under his EDW. * On 5/15/10, the pre-treatment weight was 70.8 Kg. (3.7 Kg. under his EDW) and the calculated weight gain was 1.3 Kg. The fluid volume removed was 2.9 Kg and the patient was discharged at 67.9 Kg, 6.6 Kg. under his EDW.</p>	V 503			

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V 503	<p>Continued From page 32</p> <p>* On 6/24/10, the pre-treatment weight was 65.8 Kg. (9.7 Kg. under his EDW) and the calculated weight gain was 1.1 Kg. The fluid volume removed was 4.1 Kg. and the patient was discharged at 61.7 Kg. (12.8 Kg. under his EDW).</p> <p>10c. Further review of the medical record for Patient 1 showed there were orders for a BP medication, Clonidine 0.10 mg as needed for BPs with a systolic (top number in the BP reading) greater than 190 and diastolic (lower number in the BP reading) greater than 100. The treatment sheet for 5/13/10 showed the patient had a pre-treatment BP of 212/131. During initiation of the treatment, his BP was 197/125. The next two measured BPs were 210/133 and 209/133. The next five BPs showed the systolic reading had dropped below 180, but the diastolic readings were from 108 to 121. There was no documentation the nurse had been notified of the increased BPs or if the patient was given a BP medication. On 5/26/10, the patient also had elevated BPs with no documentation if the nurse had been notified or if BP medications were given.</p> <p>Care plan nursing notes for 5/1/10 showed the primary goal was to control Patient 1's BP and reach dry weight with ultrafiltration and BP medications. The nursing notes for 5/4/10 showed the goal was to maintain the patient's standing systolic BP to 140-120 and diastolic 70-90 with prescribed medication within two months. The dry weight would be achieved within one month through fluid restriction and ultrafiltration (fluid removal on the dialysis machine).</p> <p>10d. Patient 1 had an ordered BFR of 400</p>	V 503			

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V 503	<p>Continued From page 33</p> <p>mL/min. and a DFR of 800 mL/min. The treatment sheets showed that on 5/8/10, the DFR was 600, and on 6/24 and 6/26/10, the BFR was 350. There was no documentation to show why the ordered BFR and DFR were not ran.</p> <p>11. Review of Policy 1-01-09 for Against Medical Advice (AMA)/Early Termination of Treatment dated 9/07, showed that the facility Medical Director would determine the time frames for early termination of treatment requiring completion of the AMA Form.</p> <p>On 7/1/10 at 1400 hours, during a review of items with the designated FA, it was observed that patients were not running their full prescribed treatment times. On some treatment sheets there was documentation showing that the patient had signed an AMA (Against Medical Advice) form showing the time the patient's treatment was terminated early. When asked what the facility's policy was regarding the time frame when an AMA Form should be completed to document patients' voluntarily terminating treatments, the designated FA stated the facility did not have a specific policy stating the time frame.</p> <p>The facility failed to develop a facility specific policy for the time frame for early termination and the signing of the AMA form.</p> <p>On 7/2/10 at 1030 hours, an interview was conducted with the facility's Medical Director. The Medical Director stated the physicians' should address the patients' EDW, and the nurses should also let the physician know when the patients' post-weights were under or over their EDWs. He was not aware that a policy had not been done to specify the time frame when the</p>	V 503			

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V 504	494.80(a)(2) PA-ASSESS B/P, FLUID MANAGEMENT NEEDS The patient's comprehensive assessment must include, but is not limited to, the following: Blood pressure, and fluid management needs. This STANDARD is not met as evidenced by: Based on record review, staff interview and facility policy review, the facility failed to ensure assessment of patients' blood pressures (BP), weight gains, weight gain calculations, fluid removal volumes and estimated dry weights (EDW) were done for 10 of 19 sampled in-center hemodialysis patients (Patients 1, 2, 3, 4, 5, 6, 7, 8, 10 and 21), and to determine the potential causes of increased BP, patients not meeting their ordered EDWs, and weight gains not calculated to facility policy, which could potentially cause fluid overload, cardiovascular problems, hypotension (low blood pressure) and cramping. Findings: High blood pressure was not treated, assessed or reported to the patient's physician. The weight gain calculations were not calculated according to policy or being supervised by the nurses. The fluid removal volumes were not assessed and patients were discharged above and below their EDWs. Additionally, patient EDWs were not assessed for appropriateness and for root causes. Cross-reference V503	V 504		10/23/10	
V 543	494.90(a)(1) POC-MANAGE VOLUME STATUS	V 543		10/23/10	

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V 543	Continued From page 35 The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; This STANDARD is not met as evidenced by: Based on record review, staff interview and facility policy review, the facility failed to ensure that care and services were provided to manage the volume status and to assess when the patients' EDW was not attained, to determine calculated weight gains were accurate, to check the inconsistencies between the calculated weight gains and the total fluid volume removed, and to determine the reason for not attaining the patients' EDW for 10 of 19 sampled in-center hemodialysis patients (Patients 1, 2, 3, 4, 5, 6, 7, 8, 10, and 21) to prevent possible hypertension, cardiovascular complications or hypotension and possible vascular access clotting. Findings: On 6/30,7/1, and 7/2/10, Patient Review Reports and electronic treatment sheets were reviewed and the identified issues were discussed with the designated FA . Patients were being discharged with post-treatment weights above or below their ordered EDWs. The EDWs were not being assessed to determine if they were appropriate for the patients' needs. The calculated weight gains and fluid volumes removed were not monitored for accuracy, and blood pressures were not assessed. Cross-reference V503	V 543			
V 625	494.110 CFC-QAPI	V 625		8/1/10	

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V 625	<p>Continued From page 36</p> <p>This CONDITION is not met as evidenced by: Based on observation, staff interview and record review, the facility failed to recognize and prioritize major problems that threatened the health and safety of dialysis patients, and staff as evidenced by:</p> <p>Findings:</p> <p>The facility failed to ensure the fluid removal and treatments were properly evaluated per policy to determine whether patient goals were met for 10 of 19 sampled in-center hemodialysis patients (Patients 1, 2, 3, 4, 5, 6, 7, 8, 10 and 21). The failures resulted in patients being discharged above or below their EDWs leading to hypertensive (high blood pressure) or hypotensive (low blood pressure) episodes. Cross-reference to V503.</p> <p>The facility failed to provide and continuously monitor a sanitary environment to minimize the transmission of infections within and between the units of the facility. The pervasive presence of gnats for a number of months from the treatment area to the conference room to the water treatment area could serve as carriers of diseases and/or indirectly cause infection from one patient to another, or from a patient to another staff. Cross-reference to V111.</p> <p>The facility failed to correct the lack of nocturnal staffing and staffing support, on the premises and immediately available, to meet the critical needs of the nocturnal dialysis patients and staff. Cross-reference to V640.</p>	V 625			

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V 625	Continued From page 37 The facility failed to maintain their program to ensure the emergency crash cart and its emergency equipment were functional and available ready for use at all times. Cross-reference to V403.	V 625			
V 640	The cumulative effect of these systemic failures resulted in the facility's inability to provide safe and quality care. 494.110(c) QAPI-QAPI-IMMEDIATELY CORRECT ANY IJ ISSUES The facility must immediately correct any identified problems that threaten the health and safety of patients. This STANDARD is not met as evidenced by: Based on observation and staff interview, the facility failed to correct the lack of nocturnal staffing to meet the critical needs of the dialysis patients on the nocturnal shift. The failure posed as threat to the health and safety of dialysis patients and staff. Findings: On 7/1/10 at 1800 hours, the facility's nocturnal shift, "providing dialysis treatment while patients sleep," was surveyed. Patients vital signs were to be assessed every 30 minutes before and after "lights out" which was scheduled at 2030 hours. The last patients to be taken off dialysis treatment would be at 0430 hours. Staffing consisted of RN 3 and PCT 3 to provide dialysis treatments for ten patients. This meant that only one staff, either a PCT or RN, would have to monitor and care for 10 patients while the other staff took a break. RN 3 pointed out the	V 640		8/1/10	

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V 640	Continued From page 38 break must be taken inside the same building. When asked about a relief nurse in the event of being ill at work and/or staff was on vacation, RN 3 stated those events had to be planned. When asked if they needed help during emergencies, RN 3 responded that the Facility Administrator would be informed to send extra staff at an unspecified length of time. On 7/1/10 at 1900 hours, dialysis patients for the nocturnal shift were noted knocking on the transparent glass doors on the side of the building to come in to the treatment area. RN 3 stated that the main doors were locked and nobody was in the lobby. No building security officer throughout the night shift was mentioned either. When asked to contact the biomedical staff in case of emergencies, PCT 3 paged the biomedical staff on call. There was no response after 15 minutes. The biomedical staff was paged again but 20 minutes had passed and still there was no response.	V 640			
V 710	494.150 CFC-RESPONSIBILITIES OF THE MEDICAL DIRECTOR This CONDITION is not met as evidenced by: Based on record review and staff interview, the Medical Director failed to execute his full and	V 710		8/1/10	

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V 710	<p>Continued From page 39</p> <p>complete oversight related to patient health outcomes and monitoring/evaluating the data on a continual basis to improve performance.</p> <p>Findings:</p> <p>Patient total fluid removal volumes and weight gain calculations were not according to policy. Patient post-treatment weights and patients' EDWs were not assessed and evaluated to ensure they were appropriate for the patients per policy. The facility failed to develop a specific policy regarding the time frame for the signing of AMA Forms. Cross-reference V503, V715.</p> <p>The facility failed to provide and continuously monitor a sanitary environment to minimize the transmission of infections within and between the units of the facility. The pervasive presence of gnats for a number of months from the treatment area to the conference room to the water treatment area could serve as carriers of diseases and/or indirectly cause infection from one patient to another, or from a patient to another staff. Cross-reference to V111.</p> <p>Non-adherence by the staff to the approved infection control P&P as evidenced by dressing changes for central venous catheters, positioning of patients for treatment initiation and changing of gloves from dirty to clean areas per P&P. Cross-reference V113, V715</p> <p>Items taken into a dialysis station were not disinfected per policy, disinfected medication area covered with blue chux pads. Cross-reference V116, V117</p> <p>Priming of reused dialyzers to remove the</p>	V 710			

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V 710	Continued From page 40 germicide prior to treatment initiation not done per policy. Cross reference V353 The facility failed to correct the lack of nocturnal staffing and staffing support, on the premises and immediately available, to meet the critical needs of the dialysis patients and staff. Cross reference to V640. The cumulative effect of these systemic failures resulted in the facility's inability to provide safe and quality care.	V 710			
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 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; This STANDARD is not met as evidenced by: Based on record review, staff interview and document review, the facility failed to ensure that policies and procedures for accurate weight gain calculations, fluid removal volumes, infection control, and safety practices were being adhered to by all individuals who treated patients in the facility. Findings: Review of the facility Procedure 1-04-02A for Predialysis Central Venous Catheter (CVC) Care last revised 6/08, showed that the catheter patient should be placed in a comfortable supine (lying	V 715		10/23/10	

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V 715	<p>Continued From page 41</p> <p>on their back with face upward) position. The patient was to be placed in the supine position to increase the blood flow through the catheter and diminish the risk of an air embolism (obstruction of a blood vessel caused by an air bubble). The dressing change could then be done or the patient prepared for the initiation of their dialysis treatment.</p> <p>The Patient Review Reports and electronic treatment sheets for the patients were reviewed with the designated FA on 6/30, 7/1 and 7/2/10, and the identified issues were discussed.</p> <p>1. On 6/29/10 at 0845 hours, 1010 hours, 1251 hours, and on 6/30/10 at 0904 hours and 1818 hours, RNs 1, 2 and 5 were observed preparing catheter patients, Patients 6, 8, 18, 22 and 23 for initiation of their dialysis treatments. All patients were observed sitting upright in their chairs with their feet down toward the floor.</p> <p>On 7/1/10 at 1345 hours, RNs 1 and 2 were asked how patients were to be positioned when doing dressing changes or preparing the catheters for initiation of the dialysis treatment. Both RNs stated the patient should be sitting up, and if the patients were lying back in their chairs they would set them up prior to changing dressings or preparing the catheters for initiation of treatment or discontinuing treatment.</p> <p>2. Changing of gloves was not done per policy when changing dressings of dialysis catheter sites. Dialyzers not primed for removal of germicide per policy. Disinfection of an item taken into a dialysis station was not done per policy. Cross reference V113, V116, V117, V353</p>	V 715			

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V 715	Continued From page 42 3. Patient dialysis access sites were not kept in view of staff at all times. Cross-reference V407 4. Review of treatment sheets showed that fluid removal goals had not been calculated per policy, patient treatments were not being reviewed to ensure patients' goals were achieved, and high blood pressures were being addressed. BFRs and DFRs were not to physician's orders, and the facility did not have a policy designating the time frames for when AMA Forms for early termination of treatments should be signed. Cross-reference V503	V 715			