

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

PRINTED: 05/31/2011  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>552586</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>02/18/2011</b>
NAME OF PROVIDER OR SUPPLIER  <b>CLEARLAKE DIALYSIS CENTER</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>14400 OLYMPIC DRIVE CLEARLAKE, CA 95422</b>	
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V 000	INITIAL COMMENTS  The following reflects the findings of the California Department of Public Health during a RECERTIFICATION SURVEY from 2/14/11 - 2/18/11.  Representing the California Department of Public Health: 27294 - Health Facilities Evaluator Nurse (HFEN), 14067- HFEN, 28786 -HFEN, 27136 - HFEN.	V 000		
V 110	494.30 CFC-INFECTION CONTROL  This CONDITION is not met as evidenced by: Based on observation, patient and staff interview, policy and procedure review, and document review, the facility failed to ensure that services were provided in a sanitary and safe environment.  Findings:  1. The facility failed to provide and monitor a sanitary environment to minimize the transmission of infectious agents within the facility (See V111).  2. The facility failed to ensure that staff used protective personal equipment (PPE) when caring for patients or touching the patients' equipment at the dialysis station (See V113).  3. The facility failed to ensure that the gowns that the visitors wore, were buttoned up to protect their clothing (See V115).  4. The facility failed to ensure that supplies that	V 110		

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 110	<p>Continued From page 1</p> <p>were taken into the dialysis station were dedicated for single patients (See V116).</p> <p>5. The facility failed to ensure that common supply carts that were used to store clean supplies were at a sufficient distance from patient stations to avoid contamination with blood (See V119).</p> <p>6. The facility failed to ensure that staff cleaned and disinfected contaminated surfaces, medical devices, and equipment in between patients (See V122).</p> <p>7. The facility failed to ensure that the staff used proper technique to clean the patients' access sites (See V132).</p> <p>8. The facility failed to ensure that aseptic technique was used when dispensing and administering medications and that medications were not expired and available for patient use (See V143).</p> <p>9. The facility failed to ensure that the patients faces were turned away from the catheter site during catheter care (See V147).</p> <p>10. The facility failed to ensure that the reprocessing room door was kept closed to prevent the germicide vapors from entering the patient care area (See V318).</p> <p>The cumulative effect of these systemic failures resulted in the facility's failure to maintain a functional, sanitary, safe, and comfortable setting for patients, staff, and the public.</p>	V 110			

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V 111	<p>494.30 IC-SANITARY ENVIRONMENT</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, staff interview, personnel file review, and policy and procedure review, the facility failed to ensure that the environment was kept clean and sanitary by monitoring the patient care area and all equipment used in the patient care area to minimize the potential transmission of infectious agents within the facility that would affect 44 patients.</p> <p>Findings:</p> <p>1. On 2/14/11 at 9:30 a.m., observation revealed that a large fan was sitting on the floor in the patient care area. Inspection of the fan revealed that the blade edges were covered with a layer of dust. During an interview on 2/15/11, Administrative Staff B stated that the fan should not be used in the patient care area, due to dust that got blown around in the air and that it was an infection control issue.</p> <p>2. On 2/15/11 at 9:30 a.m., observation revealed that a patient sitting at Station 1 was using a personal fan. The fan was blowing air directly on the patient. During an interview Administrative Staff B stated that there should be no fans in the patient care area because the fans blew dust all around and it was an infection control issue.</p> <p>3. During observations on 2/14/11, 2/15/11, and 2/16/11, oxygen concentrators (A device used to</p>	V 111			

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V 111	<p>Continued From page 3</p> <p>provide oxygen therapy to a patient at substantially higher concentrations than available at room air) were stored in the dialysis terminals (Including dialysis machine, dialysis chair, computer and stand). The concentrators were not cleaned after being used by the patient and during the terminal cleaning.</p> <p>4. Random observation on 2/14/11, revealed that a patient's family member moved the non-cleaned concentrator from Station 2 to Station 3 and turned it on for the patient to use during dialysis.</p> <p>5. Random observation on 2/14/11, revealed that the oxygen concentrator stored at Station 5 was not cleaned after patient use.</p> <p>6. During an inspection of the Laboratory room on 2/15/11, revealed that the formica counter top (A plastic laminate sheeting that was used as counter tops) adjacent to the sink was discolored and corroded (The gradual deterioration of material by chemical processes, such as oxidation or attack by acids). Inspection under the sink, revealed a container full of bleach, a 409 cleaning solution bottle, a bottle of glass cleaner, and five bleach containers. In addition, there was water damage to the floor.</p> <p>7. During an observation on 2/14/11 at 10 a.m., the Hoyer lift (An assistive device that allows patients to be transferred between a wheelchair and a chair) metal legs was dusty and dirty.</p> <p>8. During an observation on 2/14/11 at 10 a.m., the Intravenous (IV) pump (Used to electronically regulate and monitor the flow of IV fluid) stands were dusty and dirty.</p> <p>9. During an inspection of the blood pressure</p>	V 111			

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V 111	Continued From page 4 cuffs on 2/14/11 at 3:45 p.m., revealed that the blood pressure cuffs were frayed, and the Velcro (fabric of hook-and-loop fasteners) were entwined with lint, strings from blankets and clothing, and hair at the following stations: Stations 1, 2, 4, 5, 6, 8, 11, and 12.  10. During an observation on 2/14/11 at 9 a.m. and at 10:05 a.m., a used wadded-up paper towel was noted on the counter top by the ice machine.  11. During an inspection of the Emergency Crash Cart on 2/16/11 at 9 a.m., revealed that the top of the cart was dusty and dirty. A broken plastic lock and bits of torn paper were also observed on top of the cart.  During a concurrent interview on 2/16/11 at 9 a.m., Licensed Staff D stated that the licensed nurses that check the cart were to ensure that the cart was kept clean at all times.  12. Review of the Oxygen Concentrator Weekly Filter Cleaning log for Concentrators Number: 1, 2, 3, 4, and 5, indicated that the concentrator's external air intake gross particle filters had not been consistently cleaned on a weekly basis.  During a concurrent interview on 2/15/11 at 2 p.m., Staff F corroborated that the air intake gross particle filters had not been cleaned per the policy.  Review of the policy and procedure titled, "Oxygen Concentrator," dated August 2007, on 2/16/11, indicated that the external air intake gross particle filter should be cleaned on a weekly basis or more frequently depending on operation.	V 111			
V 113	494.30(a)(1) IC-WEAR GLOVES/HAND	V 113			

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V 113	<p>Continued From page 5</p> <p><b>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> <p>This STANDARD is not met as evidenced by: Based on observation and policy and procedure review, the facility failed to ensure that the staff implemented the policy and procedure titled, "Infection Control for Dialysis Facilities," for hand washing and the proper use of the Personal Protective Equipment (PPE). These failures had the potential of the transmission of contaminants (blood and body fluids) and cross-contamination between patients and out in the community.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. During an observation on 2/14/11 at 10:35 a.m., Patient Care Technician (PCT I) failed to wash her hands after picking up trash from the floor before she returned to draw up medications into syringes.</li> <li>2. During observation on 2/15/11 at 8:15 a.m., Patient Care Technician (PCT H) used a wadded-up glove wrapped around one finger when responding to the alarming dialysis machine at Station 11.</li> <li>3. During an observation on 2/14/11 at approximately 11 a.m., a patient was holding his access site using a gloved hand. The patient did not wash his hands prior to leaving the patient care area. Observation revealed that staff did not</li> </ol>	V 113			

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V 113	Continued From page 6 instruct the patient to wash his hands prior to leaving the patient care area.  Review of the policy and procedure titled, "Infection Control for Dialysis Facilities," dated December 2008, on 2/17/11, indicated that staff were to perform hand hygiene after contamination of infectious material and before touching clean areas such as supplies.  Review of the policy and procedure titled, "Infection Control for Dialysis Facilities", dated 2008, indicated that staff would wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station.	V 113			
V 115	494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK  Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory.  This STANDARD is not met as evidenced by: Based on observation, staff interview, and policy and procedure review, the facility failed to ensure that all visitors sitting with a patient receiving dialysis put on the Personal Protective Equipment ([PPE] - (including impervious gowns, face shields, eye wear, or masks) properly to protect from the soiling of their clothing from the potential blood droplets and/or spattering of blood.	V 115			

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V 115	<p>Continued From page 7</p> <p>Findings:</p> <p>1. During an observation on 2/15/11 at 9:30 a.m., a family member was sitting with a patient at Station 1. The family member was sitting adjacent to the access site. The family member had PPE (impervious gown) on, however the impervious gown was not buttoned up in front to protect the family member's clothing from potential splattering of blood.</p> <p>During a concurrent interview, Administrative Staff A stated that staff should ensure that family members properly put the impervious gowns on to protect their clothing from possible blood splattering.</p> <p>2. During an observation on 2/16/11 at 8:30 a.m., during a patient interview, a family member was sitting next to the patient and diagonally across from the dialysis machine. The family member was wearing an impervious gown. The gown was tucked behind the family member's waist, therefore was not buttoned up to protect the clothing. Observation revealed that the staff did not instruct the family member to button up the gown, per policy, to protect from the potential splattering of blood or body fluids.</p> <p>Review of the policies and procedures lacked documented evidence of a policy and procedure that addressed visitors wearing impervious gowns while sitting in the patient care area during dialysis. Administrative Staff A corroborated the above finding and stated that it was the standard of practice of the facility, that when visitors seated adjacent or next to a patient, they must have on an impervious gown and it was to be buttoned up to protect clothing from becoming soiled with</p>	V 115			

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V 115	Continued From page 8 blood or body fluids. Administrative Staff A stated that it was the staff's responsibility to be proactive to ensure that the gowns were properly worn and buttoned up for protection.	V 115			
V 116	494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT  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. -- 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. -- 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.  This STANDARD is not met as evidenced by: Based on observation, staff interview, and policy and procedure review, the facility failed to ensure: 1. That patient care items which could not be cleaned or disinfected, were dedicated for single patient use only; 2. That when patient's clothing became soiled with blood, the patient was given education on how to properly clean the soiled clothing to prevent cross-contamination; and 3. That a policy and procedure had been developed that would describe practices, objectives, and directions that staff was to implement for when blood gets on the patients clothing.	V 116			

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V 116	<p>Continued From page 9</p> <p>Findings:</p> <p>1. During an observation on 2/14/11 at 11:25 a.m., a Patient Care Technician (PCT) took adhesive tape to a patient's chairside, used it and returned the roll tape to a clean bin.</p> <p>Review of the policy and procedure titled, "Infection Control For Dialysis Facilities," dated December 2008 on 2/15/11, indicated that supplies taken into the dialysis station will be disposed of, dedicated or used only on a single patient, or cleaned and disinfected before taken to a common clean area or used on another patient. Non-disposable items that cannot be cleaned and disinfected (e.g., adhesive tape, gauze dressings (2 x 2), cloth-covered blood pressure cuffs) will be dedicated or use only on a single patient."</p> <p>2. Observation on 2/15/11 at 8:30 a.m., revealed that a patient sitting at Station 1 was cleaning his clothing (pant leg) with a disposal cloth and not wearing gloves. The disposal cloth appeared to be red tinged. The patient finished cleaning his clothing and tossed the disposal cloth into a trash container next to the chair. The patient then rubbed his hands together and wiped his hands on his pants. The patient was not offered any hand gel or a clean cloth with soap and water to clean his hands. The patient left the patient care area without washing his hands.</p> <p>During a concurrent interview, a Patient Care Technician (PCT) stated that he had dropped blood on the patient's clothing, during termination of dialysis. The PCT stated that he gave the patient an alcohol soaked disposal cloth to use to</p>	V 116			

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V 116	Continued From page 10 get the blood out of his clothing prior to leaving the facility. Upon inquiry as to why the patient had not been offered a glove to wear on his hands, the PCT did not respond. Upon inquiry regarding providing the patient with education on how to safely wash his clothing at home to prevent cross-contamination of other clothing, the PCT stated that he had not instructed the patient on washing his clothing at home. Administrative Staff A stated that the facility had P.A.W.S (Antimicrobial Disinfecting Towelette) available for everyone in the facility to use to clean their hands and staff should have offered this to the patient. Administrative Staff A stated that first of all, the staff should have had the patient wear gloves and also wash is hands prior to leaving the facility. A request was made for a policy and procedure regarding patients clothing getting soiled and how to properly launder the clothing at home, Administrative Staff A stated that they did not have a policy and procedure that covered this issue.	V 116			
V 119	494.30(a)(1)(i) IC-SUPPLY CART DISTANT/NO SUPPLIES IN POCKETS  If a common supply cart is used to store clean supplies in the patient treatment area, this cart should remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood. Such carts should not be moved between stations to distribute supplies.  Do not carry medication vials, syringes, alcohol swabs or supplies in pockets.  This STANDARD is not met as evidenced by: Based on observation, staff interview, and policy and procedure review, the facility failed to keep	V 119			

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V 119	<p>Continued From page 11</p> <p>clean storage containers in a designated area away from the patient care stations when multi-drawer plastic storage containers, containing clean supplies (clean gauze dressings (sizes: 2 x 2 and 4 x 4), paper tape, blood pressure cuffs, and stethoscopes), were stored under the computer terminals. This failure had the potential for clean supplies to be contaminated by blood from patients or pathogens (infection causing organisms).</p> <p>Findings:</p> <p>1. During an observation on 2/14/11 at 11:18 a.m., 12 of 12 patient care stations had a 5-drawer plastic storage container located underneath the computer terminal containing various clean supplies (blood pressure cuffs, stethoscopes, rolls of tape, dressing supplies, etc.).</p> <p>During an interview on 12/16/11, Administrative Staff A stated that he was told many years ago that it was okay to store clean supplies in closed plastic containers in the patient terminal area. He stated that the items that were stored in the 5-drawer plastic storage container located underneath the computer terminal really did not need to be stored there, because there were plenty of other places to store the supplies, which would ensure that there was no contamination of the supplies. Administrative Staff A corroborated that the current policy and procedure for infection control advocated the storage of the supplies in a covered container at the chairside (patient terminal area).</p> <p>Review of the policy and procedure titled,</p>	V 119			

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V 119	Continued From page 12 "Infection Control For Dialysis Facilities," dated December 2008, indicated that the clean patient supplies could be stored on the cart shelves in closed plastic containers at chairside.	V 119			
V 122	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL  [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.  This STANDARD is not met as evidenced by: Based on observation, staff interview, and policy and procedure review, the facility failed to ensure that staff cleaned and disinfected medical devices, equipment, and patient contact surfaces between patient treatments, when chairs were not cleaned completely. This failure had the potential to spread blood-borne pathogens for 44 of 44 patients.  Findings:  1. During observations on 2/14/11 at 10:57 a.m. and 11:24 a.m., and on 2/15/11 at 9:50 a.m. and 10:45 a.m., Patient Care Technician (PCT H), PCT F, PCT I, and PCT G did not completely open the patient chairs into a flat position while cleaning, and did not clean each chair's footrest between patients at the following stations: Station 2, 4, 6, and 7.	V 122			

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V 122	Continued From page 13 2. During an observation on 2/15/11 at 10:45 a.m., while cleaning Station 2 following the patient's termination from treatment, PCT H did not clean the oxygen concentrator that was placed between Station 1 and Station 2.  3. During an observation on 2/15/11 at 9:45 a.m., a PCT was cleaning a chair between patients. The PCT did not clean and disinfect between the seat cushion and the back of the chair or between the seat cushion and the armrest of the chair. The PCT did not completely open the chairs into a flat position to reach the above areas.  4. During an observation on 2/16/11 at 4:45 p.m., 12 of 12 footrests, that were attached underneath the dialysis chairs, were dirty with dust, debris, and were stained.  During a concurrent interview, Administrative Staff A and Administrative Staff B stated that it was the responsibility of the staff to make sure that the footrests were cleaned along with the rest of the chair.  Review of policy and procedure titled, "Infection Control for Dialysis Facilities," dated December 2008, on 2/16/11, indicated that equipment would be wiped down with a bleach solution between patient treatments and specifically the patient chairs would be opened for cleaning so as to reach crevices.	V 122			
V 132	494.30(a)(1)(i) IC-TRAINING & EDUCATION  Infection Control Training and Education  Infection control practices for hemodialysis units: intensive efforts must be made to educate new	V 132			

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V 132	<p>Continued From page 14</p> <p>staff members and reeducate existing staff members regarding these practices.</p> <p>This STANDARD is not met as evidenced by: Based on observation, staff interview, and policy and procedure review, the facility failed to ensure that staff practiced proper aseptic technique when: 1. Cleaning patient access sites using isopropyl alcohol and Betadine® (an iodine-based disinfectant) prior to cannulization (insertion of the intravenous catheter into the blood vessel); and 2. Palpating the prepped access sites for cannulization. These failure had the potential to expose patients to pathogens (disease-causing organisms) and subsequent infections.</p> <p>Findings:</p> <p>1. During observations on 2/14/11 at 10:41 a.m., and on 2/15/11 at 10:17 a.m., Patient Care Technician (PCT H) did not allow the Betadine® to dry for three (3) minutes (in order to allow for activation of the disinfectant) prior to cannulization.</p> <p>2. During an observation on 2/15/11 at 10:17 a.m., PCT H used a swiping motion (up and down) as opposed to a circular motion (moving from the center outward) when cleaning a patient's access site with alcohol.</p> <p>3. During an observation on 2/16/11 at 11:15 a.m., PCT K cleaned a patient's access site with alcohol for approximately ten (10) seconds as opposed to one (1) full minute.</p>	V 132			

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V 132	<p>Continued From page 15</p> <p>4. During observations on 2/14/11 at 10:44 a.m. and on 2/16/11 at 11:22 a.m., PCT H and PCT F palpated a patient's already prepped access sites while attempting cannulization.</p> <p>During concurrent interview on 2/17/11, Staff F stated that he was taught how to prep the patients' access site by a Registered Nurse (RN), the Facility Administrator and discussion at staff meetings. Staff F stated that he was aware of the policy and procedure for the disinfectant solution, the effective volume, the effective contact time, and the air drying time for the alcohol 70 percent (%) and the Betadine®.</p> <p>During a concurrent interview on 2/17/11, Staff K stated that she was taught to how to prep the patients' access site by a preceptor, who no longer was employed at the facility.</p> <p>5. During observation on 2/14/11 at 11:45 a.m., PCT H did not allow the Betadine® to dry for three (3) minutes (in order to allow for activation of the disinfectant) after cleansing a patient's access site before cannulation.</p> <p>6. During an observation on 2/14/11 at 11:40 a.m., a PCT was prepping the access site of the patient sitting at Station 12. The PCT did not allow the Betadine® to dry, per the manufacturer's recommendation, for three (3) minutes prior to the cannulation of the access.</p> <p>7. During an observation on 2/14/11 at 11:44 a.m., a PCT was prepping the access site of the patient sitting at Station 7. The PCT did not allow the Betadine® to dry, per the manufacturer's recommendation, for three (3) minutes prior to the cannulation of the access.</p>	V 132			

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V 132	Continued From page 16 Review of the policy and procedure titled, "AV Fistula or Graft Cannulation With Safety Fistula Needles (SFN) and Administration of Heparin," dated September 2009, on 2/14/11, indicated that staff would clean the patients' access sites with at least four (4) alcohol prep pads per site using a circular motion, center out for 60 seconds (1 minute). In addition, the staff would clean the patients' access sites using Betadine® in a circular motion, and would allow the Betadine® to air dry for 2 - 3 minutes. In addition, the policy and procedure indicated that staff were not to palpate the insertion access site once the access site had been prepped.	V 132			
V 143	494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS  [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  This STANDARD is not met as evidenced by: Based on observation and policy and procedure review, the facility failed to ensure: 1. That staff used aseptic (state of being free from disease-causing contaminants like bacteria, viruses, fungi, and parasites) technique in the dispensing of intravenous (IV) medications when staff touched the interior of the sterile syringe (the plunger) during the withdrawal of medication into ten (10) syringes for four (4) patients; 2. That staff dated vials of medication upon opening them; and 3. That staff cleaned the rubber stopper of the multi-dose medication vial with a new alcohol pad	V 143			

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V 143	<p>Continued From page 17</p> <p>using friction each time prior to drawing up medications. These failures had the potential to expose patients to possible infections.</p> <p>Findings:</p> <p>1. During an observation of a medication pass on 2/16/11 at 11:28 a.m., Licensed Staff E consistently touched the sterile plungers of ten (10) syringes with her cleanly-gloved hand (palm) and/or fingers during the dispensing of IV medications for four (4) patients.</p> <p>Review of the policy and procedure titled, "Medication Policy," dated March 2010, indicated that all staff members administering medications must use aseptic technique.</p> <p>According to Perry and Potter's 7th edition (Feb. 2009) of Clinical Nursing Skills and Techniques, section, "Preventing Infection During Injection," (p. 574), one should, "Avoid touching the length of the plunger or inner part of the barrel."</p> <p>2. During an observation on 2/14/11 at 10:35 a.m., Patient Care Technician (PCT) I was drawing up Heparin (Anticoagulant, used to stop the blood from clotting) from a multi-dose vial which had been previously accessed. The vial was not dated when opened.</p> <p>During a concurrent interview on 2/14/11 at 10:35 a.m., PCT I stated that she had opened the Heparin vial that morning but forgot to write the open date on the vial when it was opened and she proceeded to mark the label with today's date (2/14/11) during the interview.</p> <p>2a. During an observation on 2/14/11 at 10:50</p>	V 143			

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V 143	Continued From page 18 a.m. and 2/15/11 at 3 p.m., two (2) opened bottles of Lidocaine 1 percent (%) were not dated when opened.  During a concurrent interview on 2/14/11, Administrative Staff B stated that it was the standard of practice in the facility to date all medication vials upon opening. 3. During an observation on 2/17/11 at approximately 11:30 a.m., a PCT was sitting at the island stand that was in the middle of the patient care area on Side 1, filling syringes with Heparin. The PCT had stacked multiple alcohol pads; one on top of another making a pile. The PCT turned the Heparin bottle up side down and stamped the rubber stopper on the stacked alcohol pads and then inserted the needle into the rubber stopper and withdrew the Heparin into the syringe. The PCT repeated this action twelve times to fill twelve syringes. The standard of practice was to use one fresh alcohol pad using friction to clean the rubber stopper, prior to the needle being inserted into the rubber stopper.	V 143			
V 147	494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE  Recommendations for Placement of Intravascular Catheters in Adults and Children  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	V 147			

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V 147	<p>Continued From page 19</p> <p>A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site.</p> <p>Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.</p> <p>VI. Catheter and catheter-site care</p> <p>B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].</p> <p>This STANDARD is not met as evidenced by: Based on observation and policy and procedure review, the facility failed to ensure that licensed staff utilized proper aseptic technique during Central Venous Catheter (CVC) dressing change. This failure had the potential to expose patients to infections.</p> <p>Findings:</p> <p>1. During observations on 2/14/11 at 10:52 a.m., and on 2/15/11 at 11:12 a.m. and 11:45 a.m., Licensed Staff D accessed three (3) random patients' CVC (a catheter placed into a large vein in the upper chest, used to administer medication, fluids, and provide access for dialysis) sites while the patients were in upright sitting positions and without their faces being</p>	V 147			

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V 147	Continued From page 20 turned away from the catheter site.  2. During an observation on 2/17/11 at 8:00 a.m., Licensed Staff E accessed a random patient's CVC site while the patient was in an upright sitting position and without the patient's face being turned away from the catheter site. 3. During observation on 2/15/11 at 11:50 a.m., Licensed Staff Nurse D was accessing the Central Venous Catheter (CVC) for a random patient sitting at Station 6. Both patient and Licensed Staff B were wearing masks, however, they were having a conversation while facing each other during the access procedure. Licensed Staff Nurse D did not instruct the patient to keep his face turned in the opposite direction from the CVC exit site.  Review of facility policy and procedure titled, "Predialysis Central Venous Catheter (CVC) Care," dated 6/08, on 2/16/11, indicated that the patient's face should be turned to the opposite side of the CVC exit site and that the patient should be in a supine (lying on one's back) position.	V 147			
V 318	494.50(b)(1) REPROCESSING AREA & VENTILATION  ANSI/AAMI RD47:2002/A1:2003 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1) 8 Physical plant and environmental safety considerations 8.1 Reprocessing area and ventilation The reprocessing area should be designed to suit the operation carried out and maintain acceptable ambient concentrations of harmful substances (see Table 1). The area should be kept clean and sanitary. It may be part of the dialysis treatment	V 318			

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V 318	<p>Continued From page 21 area, as long as equipment used is properly designed and vented to meet the requirements for environmental safety (see [AAMI] 8.5).</p> <p>Table 1-OSHA environmental exposure limits (29 CFR 1910, 1 July 1998), except as indicated</p> <table border="1"> <thead> <tr> <th>Substance/material</th> <th>Limits (PEL)<sup>a</sup></th> </tr> </thead> <tbody> <tr> <td>Acetic acid</td> <td>10 ppm TWAb</td> </tr> <tr> <td>Chlorine dioxide (syn: chlorine oxide)</td> <td>0.1 ppm TWA</td> </tr> <tr> <td>Citric acid</td> <td>None developed</td> </tr> <tr> <td>Formaldehyde</td> <td>0.75 ppm TWA 2 ppm STELc(15 min) 0.5 ppm action level</td> </tr> <tr> <td>Glutaraldehyde</td> <td>0.2 ppm ceiling NIOSH/OSHA</td> </tr> <tr> <td>Hydrogen peroxide</td> <td>1 ppm TWA</td> </tr> <tr> <td>Peracetic acid</td> <td>None developed</td> </tr> <tr> <td>Phenol</td> <td>5 ppm TWA</td> </tr> </tbody> </table> <p>ppm = parts per million a) PEL (permissible exposure limit) represents the limit of what employees can be exposed to; PELs can be TWAs or STELs. b) TWA (time-weighted average) represents the limit of what an employee can be exposed to in an eight-hour period. c) STEL (short-term exposure limit) represents the limit of what an employee can be exposed to in any 15-minute time period.</p>	Substance/material	Limits (PEL) <sup>a</sup>	Acetic acid	10 ppm TWAb	Chlorine dioxide (syn: chlorine oxide)	0.1 ppm TWA	Citric acid	None developed	Formaldehyde	0.75 ppm TWA 2 ppm STELc(15 min) 0.5 ppm action level	Glutaraldehyde	0.2 ppm ceiling NIOSH/OSHA	Hydrogen peroxide	1 ppm TWA	Peracetic acid	None developed	Phenol	5 ppm TWA	V 318		
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V 318	Continued From page 22  This STANDARD is not met as evidenced by: Based on observation, staff interview, policy and procedure review, and log review, the facility failed to ensure: 1. That the door to the reuse room was closed door during the reprocessing of the dialyzers. This failure had the potential of exposing patients and staff to high and excessive vapor concentrations of peracetic acid and hydrogen peroxide (Renalin).  1. During an observation on 2/15/11 at 8:15 a.m., during the reprocessing of dialyzers, the door to the reuse room was open. Observation revealed that the door's automatic closing mechanism had been removed.  During a concurrent interview on 2/15/11 at 8:15 a.m., Reuse Technician L stated that she did not know when the door to the reuse room was disabled.  During an interview on 2/15/11 at 3 p.m., Administrative Staff A stated that the automatic closing device on the reuse room door was removed in 2007, for the convenience of the staff coming in and out of the the room.	V 318			
V 400	True 494.60 CFC-PHYSICAL ENVIRONMENT  This CONDITION is not met as evidenced by: Based on observation, staff interview, and policy and procedure review, the facility failed to ensure that the physical environment was clean and	V 400			

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V 400	Continued From page 23 sanitary.  Findings:  1. The facility failed to ensure that the clinic was maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment (See V401).  2. The facility failed to ensure implementation and maintenance of a program to ensure that all equipment was maintained and operated in accordance of the manufacture's recommendations (See V403).  3. The facility failed to ensure that there were accommodations to provide full visual separation to all patients when needed (See V406).  4. The facility failed to ensure that all vascular access site and bloodline connections were visible throughout the patients' dialysis treatments (See V407).  5. The facility failed to ensure that the emergency equipment was clean and complete (See V413).  6. The facility failed to provide regular training by conducting mock drills to ensure that all staff was trained and competent in emergency procedures (See V415).  7. The facility failed to contact and develop a communicative relationship with the local disaster management agency. This relationship would help expedite restoration of interrupted services due to an emergency or disaster (See V416).	V 400			

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V 400	Continued From page 24 8. The facility failed to ensure the privacy and confidentiality of the patients medical records (See V455)  9. The facility failed to conduct on each new patient an initial comprehensive assessment within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session (See V516).  10. The facility failed to ensure education and training for patients and family (See V562).  11. The facility failed to implement its policy and procedure to ensure that annual Tuberculosis (TB) screening for staff was completed timely (V715).  The cumulative effects of these systemic problems resulted in the failure of staff to provide care in a clean and sanitary environment and ensure the safety of the patients during dialysis.	V 400			
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, staff interview, and policy and procedure review, the facility failed to ensure: 1. That the fire door in the lobby was kept closed, when not in use; 2. That clean dialysis tubing was kept off the floor; 3. That the citric acetic acid and	V 401			

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V 401	<p>Continued From page 25</p> <p>bicarbonate containers were not stored in the patient care area. That the counter in lab area was kept in good condition; 4. That the medication refrigerator was kept locked when there was no surveillance by licensed staff, and that medication was stored per facility policy; 5. That syringes containing heparin were not left on the counter, available to unauthorized persons; and 6. That containers of bleach solution were labeled with the concentration of the bleach solution.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. During an observation on 2/14/11 at 9:30 a.m., the fire door which is used to enter the patient care area from the lobby was propped open with a table. On the door was a sign that indicated that the staff were keep the door closed at all times.</li> <li>2. During observation on 2/14/11 at 11:25 a.m., a PCT was setting up the dialysis machine at Station 12. During the set up, the PCT allowed the clean dialysis tubing to fall on the floor and then stepped on the tubing. The PCT continued the set up of the dialysis machine in preparation for the next patient without getting clean tubing.</li> <li>3. During observations on 2/14/11 and 2/15/11, citric acid jugs were stored in the patient care area adjacent to the Biomed room. In addition, jugs containing K-1 (potassium) bath were stored on a cart. Observations revealed that patients' using canes, walkers, and in wheelchair moved past these jugs to get to Stations 1, 2, 3, 4, 5, and 6.</li> </ol> <p>During a concurrent interview on 2/16/11, Administrative Staff A stated that the jugs were</p>	V 401			

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V 401	<p>Continued From page 26</p> <p>stored in the patient care area for the convenience of the staff, so that the staff did not have to walk to the back of the building to get the jugs each time they needed one.</p> <p>Review of the Material Safety Data Sheet (MSDS) for Citric Acid and bicarbonate dated 9/16/09, indicated that the hazards identification and potential health effects if spilled could cause irritation to the respiratory tract, irritation to the skin, and was highly irritating if it came in contact with the eyes.</p> <p>4. During observation on 2/14/11, 2/15/11, 2/16/11, and 2/17/11, at various times, the following medications were left out on the counter at the nurse's station without surveillance of licensed staff: Heparin (A anticoagulant), Calcitriol (A form of vitamin D), Epogen (Increases red blood cell levels), Hectorol (A treatment for hyperparathyroidism), and Venofer (A treatment for iron deficiency anemia).</p> <p>4a. During an observation on 2/14/11 at 9:30 a.m., the medication refrigerator at the nurse's station was left unlocked. The nurse's station did not have constant surveillance or supervision by a licensed staff. The unlocked medication refrigerator was accessible to unauthorized persons and posed the potential for the diversion of or tampering with the medications.</p> <p>During an observation on 2/14/11 at 10:25 a.m., licensed staff opened the medication refrigerator without the use of a key.</p> <p>During an observation on 2/14/11 at 11:17 a.m., the medication refrigerator at the nurse's station was unlocked. There was no surveillance or monitoring by licensed staff.</p>	V 401			

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V 401	<p>Continued From page 27</p> <p>Review of the policy and procedure titled, "Medication Policy," dated March 2010, on 2/15/11, indicated that all refrigerated medications were to be locked if not under the supervision by the licensed staff. Non-refrigerated medications were to be stored in cabinets and locked if not under the supervision by the licensed staff.</p> <p>4b. Observation on 2/16/11, revealed that a vial of Epogen had been taken out of the refrigerator by a licensed nurse and left on the counter at the nurse's station for approximately 1 hour prior to the administration of the medication. The ambient temperature of the patient care area was approximately 72 °F.</p> <p>Review of the manufacturer's recommendation insert dated 2/2010, on 2/16/11, for the storage of Epogen to maintain the stability of the medication, indicated that Epogen was to be stored in a refrigerator between 36 degrees (°) Farenheit (F) and 46 °F. Do not freeze. Do not use a vial of Epogen that had been frozen. Keep away from direct light.</p> <p>Spoke with Epogen representative on 3/4/11, the representative corroborated that above manufacturer's recommendation for the storage of Epogen to maintain the stability of the medication.</p> <p>5. During an observation on 2/15/11 at 10 a.m., twelve syringes filled with heparin were stored under a Chux (An absorbent pad) on the island cart in the middle of Side 1. The heparin filled syringes were accessible to unauthorized person.</p>	V 401			

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V 401	Continued From page 28 Observation revealed that patients, visitors, and transport staff walked past the island cart. This posed the potential for the diversion of or tampering with the medication.	V 401			
V 403	6. On 2/14/11 at 9:45 a.m., observation revealed that the containers (2) of a bleach solution sitting on a cart adjacent to the Biomed room were not labeled with the concentration of the bleach solution (e.g. 1:100 percent (%) or 1:1000 %). <b>494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU</b>  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, staff interview and record review, the facility failed to ensure that the staff operated and maintained equipment according to manufacturer's guidelines, when an oxygen concentrator's external air intake gross particle filter (Used to prevent dust particles and debris from entering into the internal motor) was missing. The surveyor observed the oxygen concentrator being used to deliver oxygen to patients during dialysis.  Findings:  1. During an observation on 2/14/11 at 4:20 p.m., oxygen concentrator Number 1 did not have an exterior air intake gross particle filter.	V 403			

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V 403	Continued From page 29  2. During observation on 2/15/11 at 2:20 p.m., Patient Care Technician (PCT) J was cleaning the oxygen concentrator Number 1. An inspection of the concentrator revealed that the exterior air intake gross particle filter was missing. During a concurrent interview, PCT J stated that the concentrator had been used by the patient at Station 1 that morning.  3. During an interview on 2/15/11 at 2:45 p.m., Administrative Staff B stated that according to policy and procedure, the external air intake gross particle filters were to be washed once a week and placed back on the machine when dry. Administrative Staff B stated the concentrator could be used without an external air intake gross particle filter, but since the filter kept out dust particles, the concentrator could be damaged.  Review of the manufacturer's guidelines for the oxygen concentrator indicated that, to prevent damage, operation of the unit without the external air intake gross particle filter should not be attempted.	V 403			
V 406	494.60(c)(3) PE-ACCOMMODATE PT PRIVACY  The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required.  This STANDARD is not met as evidenced by: Based on observation and staff interview, the facility failed to provide full privacy for a patient during incontinence care. This failure resulted in the patient's intimate body area being exposed and viewable by other patients, staff, and visitors.	V 406			

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V 406	Continued From page 30  Findings:  During an observation on 2/15/11 at 11:15 a.m., a personal care attendant was providing incontinence (involuntary leakage of urine or feces) care to the patient sitting at Station 7. The privacy screen which was provided to the personal care attendant did not provide complete privacy. There was a half wall behind Station 7. The patient's intimate body area was visible to other patients, staff, and visitors.  During a concurrent interview on 2/15/11 at 11:25 a.m., Licensed Staff E corroborated that the privacy screen did not provide full privacy for the patient during incontinence care. She stated that she liked to have patients that needed their personal care attendants, who come to the facility to provide personal care, sit at a station that had a full wall behind the station to ensure complete privacy during incontinence care.	V 406			
V 407	494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS  Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement).  This STANDARD is not met as evidenced by: Based on observation, staff interview, and policy and procedure review, the facility failed to ensure: 1. That staff implemented the policy and procedure titled, "AV Fistula or Graft Cannulation with Safety Fistula Needles (SFN) and Administration of Heparin," by keeping the patients vascular access sites and bloodline	V 407			

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V 407	<p>Continued From page 31</p> <p>connections (arterial and venous) visible throughout dialysis treatments. This failure had the potential for accidental needle dislodgement or line disconnection which may go undetected and result in exsanguination (bleeding out) and death.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. During an observation on 2/14/11 at 9:50 a.m., the access site and bloodline connection of the patient sitting at Station 12, was covered with a blue blanket and not visible to staff during dialysis.</li> <li>2. During observations on 2/17/11 at 8:05 a.m., the access site and bloodline connection of patients sitting at Station 6, 7, 9, and 12 were covered and not visible to staff during dialysis.</li> <li>3. During an observation on 2/14/11 at 9 a.m., the access site of the patient sitting at Station 10 was covered with a blue blanket and not visible to staff during dialysis.</li> <li>4. During an observation on 2/17/11 at 7:40 a.m., The access and bloodlines of the patient sitting at Station 7 was covered and not visible to staff during dialysis. The access and bloodlines of the patient sitting at Station 9 were covered with beige colored blanket.</li> </ol> <p>On 2/14/11 at 9:30 a.m., a sign in large red bold letters read, "Access Sites Must Be Uncovered At All Times," was posted in the patient care area in several places.</p> <p>Review of policy and procedure titled, "AV Fistula or Graft Cannulation with Safety Fistula Needles</p>	V 407			

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V 407	Continued From page 32 (SFN) and Administration of Heparin," dated September 2009, on 2/16/11, indicated that access sites were to remain visible at all times during treatment.  During an interview on 2/17/11, Administrative Staff A and Administrative Staff B stated that it was the policy of the facility that all access sites and blood tubing be visible to the staff during dialysis. Upon inquiry regarding why the staff were not implementing the policy for the safety and surveillance of the patients, Administrative Staff A corroborated that it was an unsafe practice that the staff were doing.	V 407			
V 413	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, staff interview, policy and procedure review, and document review, the facility failed to maintain a fully equipped, well-maintained emergency crash cart and emergency evacuation kit and failed to ensure that they were clean and ready for use. These failures had the potential of not being able to respond to patients' medical emergency timely for 44 patients.  Findings:  1. On 2/16/11 at 9 a.m., an inspection of the	V 413			

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V 413	<p>Continued From page 33</p> <p>emergency crash cart with Licensed Staff E, revealed that there was no contents list on top the the cart for review. In addition, the top of the emergency crash cart, which contained a suction machine (used to remove secretions from a patient's mouth and throat in an emergency) had an accumulation of dust and debris.</p> <p>Review of the contents list revealed that it did not match what was stored in the emergency crash cart as follows:</p> <p>A. Emergency Crash Cart</p> <p>Top of Cart:</p> <p>a. The Ambu bag (A valve mask--a hand-held device used to provide positive pressure ventilation to a patient who was not breathing or who was breathing inadequately) was not on top of the cart as indicated on the contents list.</p> <p>b. The AED (Automated External Defibrillator - gave the heart an electric shock if no heart beat was found) was not on top of the cart as indicated on the contents list.</p> <p>First Drawer:</p> <p>a. Solu Cortef 100 milligram (mg): Eight vials were listed. Only two were on the cart.</p> <p>b. Syringes: 30 millimeters (ml), 10 ml, 3 ml, and Needles 18 G, the quantities were not listed.</p> <p>c. ANA Kit # 1 and # 2: Syringes Three - 3 ml were in the kits and were not listed on the contents list.</p>	V 413			

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V 413	Continued From page 34  d. Oral airways: Sizes were not identified (e.g. 8 mm, 10 mm).  e. Atropine Sulfate mg/ml was not identified correctly (e.g. 0.5 mg and not .5 mg)  f. Heparin 5000 Unit/ml: Was listed on the contents list, however not in the drawer.  Second Drawer:  a. Oral Airways: Six listed on the contents list. Only three in the drawer.  b. Nasal Cannula: Two listed on the contents list. Five were in the drawer.  c. Flashlights/Batteries: Quantity not listed and the batteries in the flashlight and the extra batteries expiration dates were not listed on the contents list.  d. Three (3) Priming Sets and three (3) - Na Chloride 9%/1000 ml listed on contents list and were not in this drawer, but were stored in the fourth drawer.  Third Drawer:  a. Betadine® prep pads: Expiration date not listed on the contents list.  b. Tape: paper and Transpore: Quantity for each was not listed on the contents list.  Fourth Drawer:	V 413			

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V 413	<p>Continued From page 35</p> <p>a. Ambu bag listed on the contents list, and stored on the top of the cart.</p> <p>b. Two (2) Endotracheal (ET) tubes listed on the contents list. None were in the drawer.</p> <p>c. AED pads and manual listed on the contents list, not in the drawer, but were stored with the AED on top of cart.</p> <p>Sixth Drawer:</p> <p>a. Nasal suction catheters: Sizes not listed.</p> <p>b. E+Med IV strip (used to secure the intravenous catheter to prevent dislodgement) not listed on the contents list. Seven (7) had expiration dates of 7/2006.</p> <p>The inspection of each drawer revealed that they were dusty and had debris.</p> <p>During an interview on 2/16/11 at 9 a.m., Licensed Staff E stated that there was a code recently and the cart may not have been fully stocked after the code. The code was on 1/14/11.</p> <p>Review of the contents list revealed that the crash cart had been last checked by a licensed nurse on 2/9/11.</p> <p>Review of the policy and procedure titled, "Emergency Equipment Checks," dated December 2008, indicated that the staff were to ensure that the emergency crash cart was to be maintained in a ready-to-use condition. The emergency crash cart was to be kept clean, operational, and no supplies were expired. In the</p>	V 413			

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V 413	<p>Continued From page 36</p> <p>event supplies were used from the emergency cart, replacement supplies would be obtained and placed on the cart.</p> <p>2. During an inspection of the emergency evacuation kit on 2/14/11 at 3:30 p.m. with a Licensed Staff D, the following was identified:</p> <p><b>B. Emergency Evacuation Kit</b></p> <p>a. The contents list was not on the outside of the kit for review.</p> <p>b. The contents list did not include the quantity or expiration dates of each supply.</p> <p>c. The contents list did not have a place where the date of the monthly inspections done by staff could be documented.</p> <p>d. Fifty-six (56) Betadine® prep pads had expired on 10/08.</p> <p>e. Catheter port caps and 1-inch 22 gauge needles were checked off on the contents list as being contained in the evacuation kit for the month of February 2011, but none were present.</p> <p>f. Eight (8) pairs of gloves were in the evacuation kit to be used by all patients (12 per shift) and staff.</p> <p>g. No blank treatment flowsheets were in the evacuation kit as listed on the checklist.</p> <p>h. The patient Kardex Reports (demographic information and physician orders) and the list of patients were not current.</p>	V 413			

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V 413	<p>Continued From page 37</p> <p>i. The roster of all staff's home phone numbers and addresses was not current.</p> <p>j. There was no copy of the facility's disaster plan.</p> <p>The following supplies were listed on the contents list but were not currently being used in the facility: 1. Two (2) bite blocks (a plastic treatment device once used in the mouths of patients experiencing seizures) and 2. Five (5) 3-cubic centimeter (cc) medication syringes and five (5) 1-milliliter (ml) lidocaine syringes without needles. The facility had gone to safety needles.</p> <p>During a concurrent interview, Licensed Staff D corroborated that the emergency evacuation kit had the above missing, expired, and outdated contents. She also stated that the 3-cc and 1-ml syringes and bite blocks were no longer used at the facility and needed to be removed from the evacuation kit and/or replaced with currently used supplies. Licensed Staff D corroborated that eight (8) pairs of gloves were not sufficient to care for patients in the event of an emergency. When asked who was responsible for checking the evacuation kit, she stated that it was the job of non-licensed staff person (PCT K - who was the facility's designated safety officer). When asked how she knew when supplies became expired, she stated that she did not know, but relied on PCT K and the contents list.</p> <p>During an interview on 2/14/11 at 4:27 p.m., Administrative Staff A and Administrative Staff B corroborated that the facility disaster plan was not contained in the evacuation kit. Administrative A also stated that he had asked PCT K to check the evacuation kit at the beginning of each month, but</p>	V 413			

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V 413	Continued From page 38 acknowledged that no dates were listed on the contents list and, thus, he did not know the exact dates when the inspections were done. When asked about the patient Kardexes being dated the day of the inspection, he stated that the old ones (dated 1/11) had just been replaced. When asked about the expired supplies, Administrative Staff A stated it was his expectation that if an item was checked off the list as being present, it was not expired. Administrative Staff A stated that PCT K had been functioning as the facility's safety officer since 4/10.  Review of the evacuation kit contents list, revealed that PCT K had been consistently checking the evacuation kit on a monthly basis since 4/09.  Review of the policy and procedure titled, "Evacuation Kit," dated March 2010, indicated that the staff were to ensure that supplies needed for patient care in case of an emergency evacuation were available for the staff caring for the patients. In addition, staff were to ensure that the evacuation kit contained a copy of the facility disaster plan and that a designated person was to inspect the contents of the kit and replace missing or expired supplies at least monthly.	V 413			
V 415	494.60(d)(4)(ii) PE-ANNUAL EVAL-EMERGENCY/DISASTER PLANS  The facility must- Evaluate at least annually the effectiveness of the emergency and disaster plans and update them as necessary;	V 415			

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V 415	Continued From page 39 This STANDARD is not met as evidenced by: Based on staff interview and document review, the facility failed to conduct disaster drills and mock code drills at least annually to ensure the staff were trained properly and correctly to carry out emergency procedures in the event of a disaster and/or a cardiac or respiratory arrest.  Findings:  Review of the Disaster Manual on 2/14/11 at 3:15 p.m., revealed that Disaster Drills and mock code drills had not been conducted on an annual basis.  During an interview on 2/14/11 at 5 p.m., Administrator A stated the last Disaster Drill had been conducted in 2007. In addition, Administrator Staff A stated that no mock code drills had been conducted since 2007.	V 415			
V 416	494.60(d)(4)(iii) PE-CONTACT LOCAL EOC ANNUALLY  The facility must-  (iii) Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency.  This STANDARD is not met as evidenced by: Based on staff interview and document review, the facility failed to ensure that a relationship was developed and maintained with the local disaster management agency at least annually to ensure that the agency was aware of the needs of the dialysis clinic in the event of an emergency.	V 416			

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V 416	Continued From page 40 Findings:  Review of the Disaster binder on 2/14/11 at 4:30 p.m., lacked documented evidence that the facility had contacted the local disaster management agency on an annual basis. This was to ensure that in case of an interruption of services during an emergency, the local agency would help expedite restoration of services and also be aware of the facility's needs in the event of an emergency.  During an interview on 2/14/11 at 5 p.m., Administrative Staff A corroborated the above findings and stated that about a year ago he and one of the Registered Nurse (RNs) had spoken with the county's head of the disaster preparedness program. No other information was given.	V 416			
V 455	494.70(a)(4) PR-PRIVACY & CONFIDENTIALITY-RECORDS  The patient has the right to-  (4) Privacy and confidentiality in personal medical records;  This STANDARD is not met as evidenced by: Based on observation and staff interview, the facility failed to: 1. Ensure the computer screens containing patient information were not left on and unattended with patient specific information displayed. This had the potential for other patients, visitors, and unauthorized persons access to the patients' medical information and therefore not ensuring the privacy and confidentiality of the medical records for ten of 44	V 455			

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V 455	Continued From page 41 patients.  Findings:  1. During an observation of the patient care area on 2/14/11 at 10:15 a.m., (first shift) revealed that one patient sitting at Station 12 had his treatment record visible on the computer screen.  2. During an observation of the patient care area on 2/14/11 at 10:40 a.m., (first shift) revealed that five patients sitting at Stations 1, 4, 8, 9, and 11 had their electronic treatment records visible on the computer screens.  3. During an observation of the patient care area on 2/15/11 at 8 a.m., (first shift) revealed that four patients sitting at Stations 1, 2, 3, and 12 had their treatment record visible on the computer screen.  4. During an observation of the patient care area on 2/15/11 at 11:40 a.m., (second shift) revealed that one patient sitting at Station 2 had his treatment record visible on the computer screen.  During a concurrent interview on 2/15/11, Administrative Staff B stated that it was the standard of practice that the staff was to minimize the computer screen before they left the compute, to protect the patient's privacy and confidentiality of the medical information.	V 455			
V 516	494.80(b)(1) PA-FREQUENCY-INITIAL-30 DAYS/13 TX  An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter	V 516			

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V 516	<p>Continued From page 42</p> <p>of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to ensure that all new patients admitted to the facility had an initial comprehensive assessment conducted by the interdisciplinary team, which included the Nephrologists, a Registered Dietitian (RD), a Registered Nurse (RN), and a Medical Social Worker (MSW), within a period of 30 calendar days or 13 Hemodialysis sessions beginning with the first dialysis session for one of one patient (Resident 1). This failure had the potential to delay the identification of the patient's co-morbid conditions and the development of a plan of care to address co-morbid conditions.</p> <p>Findings:</p> <p>Review of Patient 1's medical record on 2/16/11, indicated that Patient 1 was admitted to the facility on 10/6/09, with diagnoses of End Stage Renal Disease secondary to glomerulonephritis (The inflammation of the small blood vessels in the kidneys) and hypertension (High Blood Pressure).</p> <p>Review of the initial interdisciplinary comprehensive assessments, included the following disciplines: Nephrologists, a Registered Dietitian (RD), a Registered Nurse (RN), and a Medical Social Worker (MSW). The RN's assessment was completed on 11/21/09 (17 days late). The RD's assessment was completed on 11/13/09 (nine days late). The MSW's</p>	V 516			

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V 516	Continued From page 43 assessment was completed on 11/17/09 (13 days late).	V 516			
V 562	During a concurrent interview, Administrative Staff A stated that the facility staff was to be in compliance with all of the CMS regulations. 494.90(d) POC-PT/FAMILY EDUCATION & TRAINING  The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types.  This STANDARD is not met as evidenced by: Based on observations, patient and staff interview, and policy and procedure review, the facility failed to ensure that all patients/designees received education regarding washing their access site prior to the cannulation of the needles. This failure had the potential for an increase in access site infections.  Findings:  1. During an observation on 2/14/11 at 10:30 a.m., a random patient entered the patient care area, and went directly to Station 9 to begin treatment without washing his access site. 2. During an observation on 2/14/11 at 10:25 a.m., a patient went directly from the bathroom in the treatment area to Station 3 without washing his access site with soap and water.	V 562			

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V 562	<p>Continued From page 44</p> <p>3. During an observation on 2/14/11 at 10:32 a.m., a patient went directly from the scale area to Station 5 without washing his access site with soap and water.</p> <p>4. During observations on 2/14/11 at 10:37 a.m., 10:41 a.m., and 11:24 a.m., Staff G and PCT H did not use soap and water to wash the access sites of patients sitting at Stations 3, 5, and 7 prior to cannulization.</p> <p>5. During interviews on 2/16/11, with patients sitting at Station 2, 3, 6, and 8, revealed that they did not wash their access sites prior to the initiation of dialysis. Upon inquiry regarding the staff washing their access sites for them, the patients stated that the staff did not wash their access sites for them.</p> <p>During a concurrent interview, Administrative Staff A stated that the facility had a box of P.A.W.S. (A Premoistened Antimicrobial Disinfecting Towelette that kills 99.9 percent (%) of the most common germs, while removing soil and debris from skin. Manufacturer represents effectiveness against human immunodeficiency virus (HIV), Avian Flu A, Vancomycin-resistant enterococcus (VRE)--a bacteria/bacterium, Methicillin-resistant Staphylococcus aureus (MRSA)--a bacteria/bacterium, and Escherichia coli (E. Coli) bacteria. 66.5% ethyl alcohol formulation helps you meet OSHA, CDC, and APIC hand washing recommendations) adjacent to the sink that was designated for the patients to use to wash their access sites. Administrative Staff A stated that staff should encourage the patients to wash their access sites, either using soap and water or the P.A.W.S. The staff were to</p>	V 562			

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V 562	Continued From page 45 educate the patients regarding prevention of infection to their access sites. If the patients did not wash their access sites, then the staff should wash the patients' access sites using either soap and water or the P.A.W.S prior to cannulation. In addition, Administrative Staff A stated that staff were to have the patients wash their hands prior to leaving the patient care area. Review of the policy and procedure titled, "Infection Control For Dialysis Facilities," dated December 2008, on 2/16/11, indicated that the staff were to encourage the patients' wash their access arm upon entering the treatment area prior to the initiation of dialysis and to wash their hands after holding their own sites post dialysis.	V 562			
V 715	Review of the facility policy and procedure titled, "AV Fistula or Graft Cannulation with Safety Fistula Needles and Administration of Heparin," dated September 2009, on 2/16/11, indicated that staff were to have the patients wash their access sites with appropriate antibacterial soap, if able. If the patient was unable to do this, the Patient care Technician would clean the access site with a cleansing agent and pat dry. 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:	V 715			

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V 715	Continued From page 46 Based on personnel file review, staff interview, and policy and procedure review, the facility failed to implement the policy and procedure titled, "Tuberculosis Monitoring and Follow-Up," to ensure that annual Tuberculosis (TB) screening for six (6) staff was completed timely.  Findings:  On 2/15/11, fourteen (14) personnel files were reviewed. Six (6) personnel files lacked documented evidence that the Tuberculosis ([TB] A highly contagious infection caused by the bacterium called Mycobacterium tuberculosis, which was spread through air droplets which were expelled when persons with infectious TB cough, sneeze, speak, or sing) annual screening was provided to the six (6) staff, who continued to provide patient care. During a concurrent interview, Administrative Staff A corroborated that they were behind in the screening of staff, and that the facility did not have a policy that prevented the staff from continuing to provide patient care during the time they were not screened for TB. Review of the policy and procedure titled, "Tuberculosis Monitoring and Follow-Up," dated September 2009, on 2/16/11, indicated that the TB screening using Purified Protein Derivative (PPD) Mantoux Tuberculin Skin Test (TST) method would occur on an annual basis, from the date of the last TST, using a one-step method based.	V 715			
V 750	494.180 CFC-GOVERNANCE  This CONDITION is not met as evidenced by: Based on observation, staff interview, policy and	V 750			

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V 750	<p>Continued From page 47</p> <p>procedure review, the governing body failed in its responsibility for the governance and operation of the facility.</p> <p>Findings:</p> <p>The governing body had full legal authority and responsibility for the governance and operation of the facility. The ability of the health care team to provide a safe level of care to patients could not be ensured as evidenced by the seriousness and pervasiveness of the deficiencies cited throughout this document as follows:</p> <ol style="list-style-type: none"> <li>1. The facility failed to provide and monitor a sanitary environment to minimize the transmission of infectious agents within the facility (See V111, V116, V119, and V318).</li> <li>2. The facility failed to ensure that staff used Personal Protective Equipment (PPE) when caring for patients or touching the patients' equipment at the dialysis station (See V113, V114, and V115).</li> <li>3. The facility failed to ensure that staff cleaned and disinfected contaminated surfaces, medical devices, and equipment in between patients (See V122).</li> <li>4. The facility failed to ensure that staff used proper technique to clean the patients' access sites (See V132).</li> <li>5. The facility failed to ensure that all medications and biologicals that were available for patient use are not expired (See V143).</li> </ol>	V 750			

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V 750	Continued From page 48 6. The facility failed to ensure that the staff used proper technique in catheter care (See V147).  7. The facility failed to ensure the maintenance and the readiness of emergency equipment. This included the requirements for emergency preparedness for medical and non-medical issues (See V400, V401, V403, V406, V407, V413, V415, V416, and V562).  8. The facility failed to maintain complete and accurate records and to protect them against loss and unauthorized use. The requirements apply to both hard copy and electronic health records (See V 455).  9. The facility failed to ensure that the initial comprehensive nursing, dietary, and social worker assessments were completed within 13 dialysis treatment or 30 calendar days (See V 516).  The cumulative effects of these systemic problems resulted in the dialysis facility's inability to ensure the provision of quality care in a clean and sanitary environment, that medications were not expired, and the protection of the patients' medical records.	V 750			
V 761	494.180(b)(4) GOV-STAFF HAVE ACCESS TO CONTINUING ED  The governing body or designated person responsible must ensure that- (4) All employees have an opportunity for continuing education and related development activities  This STANDARD is not met as evidenced by:	V 761			

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

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>552586</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>02/18/2011</b>
NAME OF PROVIDER OR SUPPLIER  <b>CLEARLAKE DIALYSIS CENTER</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>14400 OLYMPIC DRIVE CLEARLAKE, CA 95422</b>		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
V 761	Continued From page 49 Based on observation, policy and procedure review, document review and staff interview, the facility failed to ensure that all staff demonstrated knowledge of infection control policies and procedure and practices (by implementing the policy and procedure titled "AV Fistula or Graft Cannulation With Safety Fistula Needles (SFN) and Administration of Heparin,") using proper techniques in the cleaning of the access sites prior to the cannulation (The introduction of the needles into the access sites). This failure had the potential to result in infection of the patients access site if proper disinfection techniques were not followed.  Findings:  See V132.	V 761			