

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

PRINTED: 05/27/2011
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 052641	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 01/10/2011
NAME OF PROVIDER OR SUPPLIER HUNTINGTON BEACH DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 16892 BOLSA CHICA AVENUE HUNTINGTON BEACH, CA 92649		
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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 at 0715 hours on 1/5/11. The facility census at the time of the survey was 33 in-center hemodialysis patients. The patient sample consisted of eight hemodialysis patients.</p> <p>The Clinical Manager and Clinical Services Specialist were the facility coordinators for this survey.</p> <p>Representing the Department of Public Health: 22781 HFEN; 21177 HFEN and 22779 HFEN.</p> <p>GLOSSARY:</p> <p>AA - Administrative Assistant BP - Blood Pressure BFR - Blood Flow Rate CHT - Certified Hemodialysis Technician CSS - Clinical Services Specialist DFR - Dialysate Flow Rate Diastolic - lower number of the blood pressure reading EDW - Estimated Dry Weight FA - Facility Administrator IV - Intravenous Kg. - kilograms (equal to 2.2 pounds) mL - milliliters PPE - Personal Protective Equipment PCT - Patient Care Technician QAPI - Quality Assurance and Performance Improvement</p>	V 000			
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE			TITLE		(X6) DATE

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

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V 000	Continued From page 1 RN - Registered Nurse Systolic - upper number of the blood pressure reading UFR - Ultrafiltration Rate (rate at which fluid is removed)	V 000			
V 110	494.30 CFC-INFECTION CONTROL This CONDITION is not met as evidenced by: During observation, policy review and staff interview, the facility failed to ensure infection control practices and policies were implemented to decrease the possible transmission of infectious agents as evidenced by: The facility failed to ensure follow-up with regard to a grievance filed about a patient being sprayed with blood when the patient in the seat next to them pulled out their dialysis needles. There was no documented evidence the risk of blood exposure to the patient was investigated and action taken if needed to protect the patient. No action plans were developed and implemented to prevent this from recurring. Cross reference V112. The facility failed to ensure hand cleaning was done between glove changes and bare hands were cleaned after touching contaminated equipment or after patient contact. Cross reference V113. The facility failed to ensure personal protective equipment was removed prior to leaving the treatment area and entering the patient waiting area. Cross reference V115.	V 110		1/18/11	

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V 110	Continued From page 2 The facility failed to ensure non-disposable equipment and supplies taken into patient stations were disinfected after use, and supplies for the next patient were not stored on the dialysis machines. Cross reference V116. The facility failed to ensure contaminated or non-disposable equipment such as thermometers, IV pumps, and dialysis machines were disinfected per policy. Cross reference V122. The facility failed to ensure medication vial septums (rubber stopper) were disinfected and the opening of medication syringes was per policy. The facility failed to ensure medications were stored per manufacturer's recommendations. Cross reference V143. The facility failed to ensure a safe and sanitary environment as evidenced by: blood spots observed on the wall in the treatment area. A rusty base on the eyewash station in the reuse room, and rusty areas on the bottom shelves on the computer carts made the areas porous and disinfection of the areas could not be ensured. The bottom shelves on the computer carts also had a build up of a black substance. Cross reference V401 #2, #3 and #6.	V 110			
V 112	494.30(a) IC-CDC MMWR 2001 The cumulative effect of these deficient practices limited the facility's ability to provide quality patient care in a safe environment. The facility must demonstrate that it follows standard infection control precautions by implementing-	V 112		2/21/11	

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V 112	<p>Continued From page 3</p> <p>(1)(i) The recommendations (with the exception of screening for hepatitis C), found in "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html.</p> <p>The recommendation found under section header "HBV-Infected Patients", found on pages 27 and 28 of RR05 ("Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients"), concerning isolation rooms, must be complied with by February 9, 2009.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to ensure a grievance reported to the facility involving a blood exposure for Patient 2 was investigated, actions were taken to protect the exposed patient and actions were taken to ensure a similar event did not occur in the future.</p>	V 112			

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V 112	Continued From page 4 Findings: "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001 shows, in part, that infection control practices recommended for hemodialysis units will reduce opportunities for patient-to-patient transmission. These practices should be carried out routinely for all patients in the chronic hemodialysis setting because of the increased potential for blood contamination during hemodialysis and because many patients are colonized or infected with pathogenic bacteria. Chronic hemodialysis patients are at high risk for infection because the process of hemodialysis requires vascular access for prolonged periods. In an environment where multiple patients receive dialysis concurrently, repeated opportunities exist for person-to-person transmission of infectious agents, directly or indirectly. Furthermore, hemodialysis patients are immunosuppressed. Hepatitis B can be transmitted by direct contact with mucous membranes from exposure to infectious blood or to body fluids that contain blood. Hepatitis C is also transmitted by exposure to infectious blood. The CDC recommends the following if exposure to blood occurs: * Wash needlesticks and cuts with soap and water. * Flush splashes to nose, mouth, or skin with	V 112			

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V 112	Continued From page 5 water. * Irrigate eyes with clean water, saline, or sterile wash. * Report all exposures promptly to ensure that you receive appropriate followup care. During review of the facility's grievance log with the CSS and FA on 1/6/11, it was observed a grievance had been filed on 4/6/10 by a family member concerning a patient who had been sprayed with another patient's blood. The patient seated next to Patient 2 had pulled out their dialysis needles. The complaint showed the blood had sprayed in the patient's hair. There was no documentation provided to show this complaint had been investigated or to show an assessment of the patient had been done by the registered nurse to determine the extent of the blood exposure to ensure the blood did not come into contact with any of the patient's mucous membranes or dialysis access site. There was no documentation provided to show: * That staff had reported this incident to administration. * The patient's physician had been contacted and made aware of the incident. * The status of the other patient with regard to any possible blood infections was investigated. * Any actions were taken to ensure all the blood was removed from the patient or their clothing. * A plan had been developed and implemented for any needed changes to prevent recurrence of this incident.	V 112			
V 113	Cross reference V637. 494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE	V 113		1/18/11	

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V 113	<p>Continued From page 6</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 facility policy review, the facility failed to ensure gloves were worn by staff members or hands were cleaned after touching dialysis machines and other equipment. The facility failed to ensure hands were cleaned after removing gloves or prior to putting on a new pair of gloves, for two of two staff members, to prevent the possible transmission of infection.</p> <p>Findings:</p> <p>Review of the facility's policies and procedures was initiated on 1/6/11.</p> <p>Policy 1-05-01, Infection Control for Dialysis Facilities, revised 9/10, showed hand hygiene was to be performed upon entering the facility, prior to putting on gloves, after removing gloves, after patient and dialysis delivery system contact, between patients, even if the contact was casual, before touching clean areas such as supplies and before leaving the patient care area. Physicians, allied health professionals, social workers and dietitians were to follow these same requirements for glove use and hand hygiene. Non-disposable items, such as stethoscopes, were not to be shared unless disinfected between patients.</p> <p>1. During observation of the treatment area on</p>	V 113			

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V 113	<p>Continued From page 7</p> <p>1/5/11 from 0730 to 1700 hours, glove changes were being performed between tasks and patients, but hands were not being cleaned after gloves were removed or prior to putting on a new pair of gloves. The staff members were observed removing gloves, and getting supplies from the clean supply area without cleaning their hands. Staff members were also observed removing gloves after performing a task or patient care and using the computer keyboards to make entries for patient treatments without cleaning their hands before or after touching the keyboard.</p> <p>* On 1/5/11 at 0830 hours, CHT 1 was observed doing patient care. CHT 1 removed their gloves and went to use the computer keyboard at another station. CHT 1 did not clean their hands after removing their gloves and prior to using the keyboard.</p> <p>* On 1/5/11 at 0843 hours, CHT 1 was observed holding a pair of gloves in their hand and touching the dialysis machine to reset a machine alarm. After resetting the alarm, CHT 1 put on the gloves, and made more adjustments to the dialysis machine. After finishing the adjustments, CHT 1 removed the gloves, went to the computer cart at another station and used the computer keyboard. CHT 1 did not clean their hands prior to putting on the gloves, after removing the gloves or prior to using the computer keyboard.</p> <p>* On 1/5/11 from 0730 hours to 1700 hours, PCT 2 was observed setting up machines at Stations 1 to 3. After the machine was cleaned, PCT 2 would change gloves before setting up the machine for the next patient. Gloves were changed, but hands were not cleaned after gloves were removed or before putting on a clean pair of gloves. After the machines had been</p>	V 113			

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V 113	<p>Continued From page 8</p> <p>readied, PCT 2 would remove the gloves and go to the clean supply counter to get the equipment used to test the pH and conductivity, and replace it on the counter after the testing was completed. PCT 2's hands were not cleaned after removing the gloves or prior to putting on a new pair of gloves before going to another machine to get it ready for the next patient.</p> <p>2. At 0820 hours on 1/5/11, a patient's physician was observed touching the patient's dialysis machine. The physician was not wearing gloves and was holding the patient's medical record in his other hand. After looking at the medical record, the physician went to the nurses' station and placed the patient's medical record on the counter, and returned to the patient. He removed the stethoscope from around his neck, that he had previously used on another patient and had not disinfected. He listened to the patient's heart and lung sounds and replaced the stethoscope around his neck. The physician went and used a computer keyboard on a computer cart near the patient. The physician went back to the nurses' station and picked up the patient's medical record. After looking through the medical record, the physician returned it to a cart containing the medical records for all the patients. After returning the medical record, the physician went to the sink and washed his hands. The stethoscope was not disinfected after being used on the patient.</p> <p>3. Each computer cart in the facility had an opened box of gloves on the top shelf for use by staff members. Because of the limited floor space in the facility, there was a small clearance space (less than approximately 7 inches on either</p>	V 113			

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V 113	Continued From page 9 side) between the machines and the computer cart. In some areas the computer carts were sitting between the dialyzers at two patient stations which increased the the potential for contamination of the computer cart and supplies on the cart with blood. During observation of the treatment area on 1/5/11 from 0730 to 1200 hours, staff members were observed using a small black machine on the counter at the nurses' station to print labels. The labels were then placed on the outside of the plastic bags containing contaminated dialyzers being taken back to the reuse room. Staff members were observed touching the machine with contaminated gloves and with bare hands. RN 1 was told about the observations. RN 1 disinfected the machine and removed it from the counter at the nurses' 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 and facility policy review, the facility failed to ensure visitors were not leaving the treatment area to enter non-treatment areas (patient waiting area and offices) while wearing personal protective equipment (PPE)	V 115		5/13/11	

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V 115	<p>Continued From page 10 such as gowns, which had the potential to spread infections.</p> <p>Findings:</p> <p>Review of the facility's policies and procedures was initiated on 1/6/11.</p> <p>Facility Policy 1-05-01, Infection Control for Dialysis Facilities, revised 9/10, showed that personal protective equipment was not to be worn in non-treatment areas.</p> <p>1. During entry into the facility on 1/5/11 at 0715 hours, a family member was observed seated in the patient waiting area wearing a yellow gown. Off the waiting area was a short hallway leading to the treatment area. On one side of the hallway was a sink, red biohazard trash container and a clear plastic container on the counter next to the sink containing yellow gowns for visitors. Across from this area were two offices, one for the Administrative Assistant and one for the Social Worker.</p> <p>During observations on 1/5/11 from 0730 hours to 1700 hours, family members who came into the facility with the patients or to pick up patients, would stop and put on a yellow gown before entering the treatment area. Not all visitors removed the gowns when leaving the treatment area, and would leave the gowns on and make trips back into the treatment area to check on the family member, and then back out into the patient waiting area. Visitors were observed seated in the waiting area wearing the yellow gowns or would remove them and place them over the back of the chair next to them. There was no sign</p>	V 115			

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V 115	Continued From page 11 posted prior to entering the patient waiting area to show visitors the gowns could not be worn into the patient waiting area from the treatment floor, and no one was observed reminding the patients not to wear the gowns into the waiting area. Upon removal of the gowns, visitors were observed opening the red biohazard trash can with their bare hands, or using their bare hands to push the gowns down into the container to make more room. A lack of hand hygiene was observed after gowns were removed.	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	V 116		1/18/11	

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V 116	<p>Continued From page 12 on other patients.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview and facility policy review, the facility failed to ensure items taken into patients' dialysis stations were disinfected after use or before being returned to a common supply area. Supplies for the next dialysis patient were also observed hanging on the IV (intravenous) poles of the dialysis machines. These practices could possibly lead to the spread of infection.</p> <p>Findings:</p> <p>Review of the facility's policies and procedures was initiated on 1/6/11.</p> <p>Policy 1-05-01 Infection Control for Dialysis Facilities, showed if electronic thermometers and/or blood glucose meters were used, measures would be taken to prevent cross contamination between patients. For example, the thermometer should not be placed on potentially contaminated equipment such as the dialysis delivery system. If the potential for contamination existed, the device should be wiped with an appropriate disinfectant before being returned to a clean area or used on another patient. The outside surfaces of all equipment would be wiped with a bleach solution prior to removal from the treatment area. Items taken into the dialysis station would be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before taken to a common clean area, or used on another patient.</p>	V 116			

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V 116	<p>Continued From page 13</p> <p>1. On 1/5/11, the electronic thermometers were being removed from clean supply areas, or from a computer cart where they had been placed after use, by staff members who had removed their gloves, but had not performed hand hygiene after glove removal. Electronic thermometers and blood glucose meters were being taken into patient stations and placed on chairside tables and returned to the clean supply storage areas without being disinfected:</p> <p>* At 1310 hours an IV pump used to deliver medications to a patient was taken off the treatment floor and returned to the laboratory room without being disinfected.</p> <p>* At 1510 hours, a blood glucose machine was removed from a patient's chairside table after being used, and returned to a drawer in the laboratory room without being disinfected.</p> <p>2. On 1/5/11 during observation of the treatment floor from 0730 hours to 1200 hours, staff members were observed using a small black machine on the counter at the nurses' station to print labels containing the time and date. The labels were placed on the bags of contaminated dialyzers being taken back to the reuse room. During this observation, staff members were using the machine with contaminated gloves and bare hands. Hands were not being cleaned after contact with the machine.</p> <p>3. On 1/5/11 at 0945 hours, a paper bag was observed hanging on the IV pole of a dialysis machine at Station 7 while a patient was receiving treatment. During an interview with RN 1, the RN stated the bag on the IV pole contained treatment supplies for the next patient. RN 1 removed the bag from the pole to show the surveyor what</p>	V 116			

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V 116	Continued From page 14 supplies were in the bag (dialysis needles, heparin syringe, etc). RN 1 replaced the paper bag on the IV pole and stated having the supplies for the next patient on the IV pole made set up for the next patient faster. A paper bag containing supplies for the next patient was also observed on the IV pole of the dialysis machine at Station 6. At 1335 hours on 1/5/11, a paper bag containing dialysis supplies for the next patient was observed on the IV pole of the dialysis machine at Station 6 during a patient's treatment. During the observation, PCT 1 removed the contaminated paper bag from the IV pole and placed it on the clean supply counter.	V 116			
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, interview and policy review, the facility failed to ensure the cleaning and disinfection of patient dialysis machines were performed per policy which could possibly lead to cross-contamination and patient infections. Findings:	V 122		2/21/11	

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V 122	<p>Continued From page 15</p> <p>Review of the facility's policies and procedures was initiated on 1/6/11.</p> <p>Review of facility Policy 1-05-01, revised 9/10, showed equipment including the dialysis delivery system, the interior and exterior of the prime container, the dialysis chair and side tables including opening the chair to reach crevices, outside of sharps containers, IV poles, as well as all work surfaces would be wiped clean with a bleach solution after completion of procedures, before being used on another patient, after spills of blood, throughout the work day, and after each treatment. The outside surfaces of all equipment would be wiped with a bleach solution prior to removal from the treatment area.</p> <p>1. During observation of the treatment area on 1/5/11 from 0730 to 1700 hours, staff members were observed disinfecting dialysis machines between patients. The IV poles, items on the poles such as clamps, the non-disposable dialysate lines and prime containers (where the dialyzer disinfectant was drained during initial rinsing of the dialyzers), sharps containers and the crevices of the chairs were not being disinfected between patient treatments. On 1/5/11 at 1345 hours, one staff member (RN 1) was observed disinfecting the IV pole on a dialysis machine. RN 1 removed the blue clamps on the pole and disinfected the IV pole, and placed the contaminated clamps back on the disinfected IV pole. When asked about the disinfection of the dialysis machines, RN 1 stated the entire dialysis machine including the IV poles needed to be disinfected.</p> <p>2. On 1/5/11 at 0829 hours, PCT 2 was observed</p>	V 122			

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V 122	Continued From page 16 disinfecting the dialysis machine at Station 1. The intravenous (IV) pole, the lower part and the two sides of the machine were not disinfected. On 1/5/11 at 0846 hours, PCT 2 was observed disinfecting the dialysis machine at Station 6. The IV pole and the sides of the machine were not disinfected. 3. On 1/5/11 at 0838 hours, CHT 1 was observed disinfecting the dialysis chair at Station 8. CHT 1 wiped the blood pressure cuff and the TV remote control without cleaning the connecting tubing and wires. The blood pressure cuff tubing and remote control wires were observed to be in contact with the patient or the dialysis chair during the dialysis process. CHT 1 was observed disinfecting the dialysis chair without cleaning the two exterior sides of the chair. On 1/5/11 at 0850 hours, CHT 1 was observed disinfecting the dialysis chair at Station 6. The right side and the foot rest of the chair and the wire of the TV remote control. were not disinfected. 4. On 1/5/11 at 0915 hours, RN 2 was observed disinfecting the dialysis chair at Station 9. The right chairside table and the side of the chair were not disinfected.	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 staff members and reeducate existing staff members regarding these practices.	V 132		1/10/11	

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V 132	Continued From page 17 This STANDARD is not met as evidenced by: Based on interview and review of the facility documentation, the facility failed to ensure three of nine direct care staff members completed the annual mandatory infection control training. This would affect the staffs' practice in the control of infection or cross contamination in the work place with a high risk of blood exposure. Findings: On 1/6/11, review of nine personnel files was conducted. Three of nine files reviewed showed the staff members did not complete the facility annual infection control training as follows: - PCT 2's last mandatory infection control training was completed on 12/11/08. - RN 1's last mandatory infection control training was completed on 9/22/09. - RN 2 had not completed the mandatory infection control since being rehired in 2009. On 1/6/11 at 1635 hours, during an interview, the CSS stated per the facility policy, the staff member has to attend the class and pass the test for the mandatory infection control training. On 1/6/11 at 1640 hours, an interview with review of the personnel files for the above three staff members: CHT 2, RN 1 and RN 2 was conducted with the CSS and the FA. The concern that the three staff members had not completed the mandatory infection control training was addressed. There was no further information received.	V 132			

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V 143	<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, policy review and interview, the facility failed to ensure 44 expired disinfectant pads were not available for use, the rubber stoppers of medication vials were being disinfected prior to inserting the needles, the medication area was disinfected prior to each medication preparation per policy, and storage for four of ten medication syringes was per manufacturer's recommendations. These failures could possibly cause infections or use of a medication that may not be effective.</p> <p>Findings:</p> <p>1. On 1/5/11 at 0720 hours, during observation of the medication refrigerator with RN 2, which was maintained at a temperature of 36 to 46 degrees Fahrenheit (2-8 degrees Centigrade), 10 filled medication syringes were found in a small plastic container. Review of the syringes showed that four of the syringes were filled with Hectorol, a medication that was to be kept at room temperature. The manufacturer's storage instructions for the medication showed it was to be stored at 77 degrees Fahrenheit, but for a short time, a temperature from 59 to 86 degrees Fahrenheit (15-30 degrees Centigrade) could be</p>	V 143		5/13/11	

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V 143	<p>Continued From page 19 permitted.</p> <p>2. During observation of the crash cart at 0730 hours on 1/5/11, 44 expired disinfectant pads were found on the crash cart. The expiration date of the pads was 8/09.</p> <p>3. On 1/6/11 the facility procedure 1-06-01A for Preparation and Administration of Parenteral Medications (Non-EPO), revised 3/10, showed prior to each medication preparation, the medication preparation surface area was to be disinfected with a 1:100 bleach solution, and the required supplies were to be placed in the disinfected medication preparation area. Only one medication syringe should be removed from the protective packaging at a time. If the medication was in a vial, the vial cap was to be removed and the vial's rubber stopper was to be cleaned with an alcohol pad. A new alcohol pad was to be used prior to each time the vial was entered.</p> <p>During observation of the treatment area on 1/10/11 at 0725 hours, CHT 1 was observed at the counter used as the medication preparation area. CHT 1 was preparing to fill syringes with heparin for the next shift of patients. CHT 1 opened and removed approximately ten syringes from their packages and placed them on top of a blue pad which had been placed on the counter. CHT 1 then placed labels on each syringe and started filling the syringes with heparin. The rubber vial stopper was not cleaned with an alcohol pad prior to the insertion of each needle.</p> <p>When asked how the counter had been prepared prior to the filling of the syringes, CHT 1 stated</p>	V 143			

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V 143	Continued From page 20 the RN had previously drawn medications in the same area and the counter had been disinfected at that time. She added, because she used the same area, she did not have to bleach it, she just put down a blue pad over the area while she prepared the medications. CHT 1 stated she was preparing heparin for the next shift of patients, and the vial top should be cleaned with an alcohol pad.	V 143			
V 331	494.50(b)(1) REPROCESSING-TRANSPORTATION & HANDLING 11 Reprocessing 11.1 Transportation and handling Persons handling used dialyzers during transportation shall do so in a clean and sanitary manner maintaining Standard Precautions until the dialyzer is disinfected both internally and externally. To inhibit bacterial growth, dialyzers that cannot be reprocessed within 2 hours should be refrigerated and not allowed to freeze. Other transportation and handling issues (such as prolonged delays in reprocessing) not described in this recommended practice shall be validated and documented by the responsible party. This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to ensure the refrigerator temperatures for the storage of used dialyzers prior to processing was within the accepted limits which could cause possible freezing of the dialyzers. Findings: On 1/10/11 at 0900 hours, observation of the reuse room and review of the reuse daily log	V 331		2/9/11	

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V 331	Continued From page 21 sheets was done with Biomedical Technician 1. Review of the refrigerator temperature logs showed the temperature of the reuse refrigerator should be 36 to 50 degrees Fahrenheit (2 to 10 degrees Centigrade). The facility operated only three days a week so only three temperatures were recorded per week. For the 21 days of recorded temperatures from 10/25 to 12/10/10, the temperatures recorded for 14 of the 21 days showed the refrigerator temperature ranged from 30 to 34 degrees Fahrenheit. For the 9 recorded days from 11/12 to 12/1/10 the temperature ranged from 30 to 33 degrees Fahrenheit. There was no documentation on the records to show if adjustments had been made to bring the temperature into range or reported to the Biomedical Department so they could check the refrigerator to see if it was functioning properly.	V 331			
V 353	494.50(b)(1) TEST FOR RESID GERM/MAX TIME RINSE TO USE 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 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. A written policy should establish the maximum allowable time between rinsing the germicide from the dialyzer and beginning dialysis. The	V 353		1/18/11	

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V 353	<p>Continued From page 22</p> <p>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 policy review the facility failed to ensure the rinsing procedure was performed for eight of 19 dialyzers on 1/5/11 per policy and AAMI guidelines. The correct rinsing procedure was necessary to remove any air and germicide trapped in portions of the dialyzer that could possibly be infused into the patients. This could cause pain at the access site or possible rupture of the patient's red blood cells.</p> <p>Findings:</p> <p>Review of the facility's policies and procedures was initiated on 1/6/11.</p> <p>Procedure 1-03-04A for Priming a Reprocessed Dialyzer, revised 1/10, showed that after the dialysate lines had been attached to the dialyzer, the dialyzer should be rotated by hand to ensure it was filled with dialysate and then placed in the dialyzer holder with the venous (blue) end up. Recirculation was then started for 15 minutes.</p>	V 353			

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V 353	<p>Continued From page 23</p> <p>Approximately halfway through the recirculation procedure, the dialyzer was to be rotated so the arterial (red) end was up and the venous (blue) end down. This was done to reduce the possibility of any air being retained in a dead space of the dialysate compartment.</p> <p>Per AAMI (Association for the Advancement of Medical Instrumentation) Rationale for the Development and Provisions of this Recommended Practice, A.12.4.1 Testing for residual germicide: procedural steps to follow have been identified by AAMI to ensure no residual germicide remains in the dialyzer following rinsing. One step showed air trapped in the dialysate side of the dialyzer may cause germicide to also remain trapped in portions of the dialyzer and the dialyzer should be rotated during the rinsing process. This action should normally release the trapped air and allow the germicide to be fully rinsed.</p> <p>During observation of the treatment area on 1/5/11 from 0730 hours to 1700 hours, the priming of reprocessed dialyzers showed the venous (blue) end of the dialyzer was in the up position after completion or near completion of the 15 minute recirculation (rinsing) cycle to remove the disinfectant prior to patient use at the following stations:</p> <ul style="list-style-type: none"> * 0800 hours at Station 8 * 0845 hours at Station 5 * 0831 hours at Station 4 * 0940 hours at Station 7 * 0945 hours at Station 5 - dialyzer still in this position since 0845 hours * 1344 hours at Station 7 (different patient) * 1358 hours at Station 9 	V 353			

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V 353	Continued From page 24 * 1452 hours Station 5 (different patient) * 1506 hours Station 3.	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, equipment was noted with rusty areas which could affect the disinfection of the items and blood spots were found on the wall which could potentially cause the spread of infection. The facility's room for mixing bicarbonate for use in the dialysis treatments had water on the floor which could possibly cause a staff member to slip and fall. Findings: 1. At 0810 hours on 1/5/11, it was observed the base of the eyewash station in the reuse room was rusty. The two containers of dialyzer disinfectant attached to the two reprocessing machines were sitting in a large plastic container. The container had been placed on top of its lid and a pallet to keep it off the floor. The lid and the pallet had a build up of a black substance around the edges. 2. On 1/6/11 at 0730 hours, on a day the facility does not do any patient treatments, blood spots were observed on the wall behind the computer cart between Stations 5 and 6.	V 401		1/28/11	

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V 401	Continued From page 25 3. Observation of the janitor closet on 1/5/11 at 1002 hours, showed the floor around the base of the floor sink was rusty, the metal rack over the side of the sink and the sides of the sink were rusty with a build up of a black substance. There was also a build up of a black substance on the outside of the rolling yellow container used to hold the floor cleaning solution. 5. During observation of the bicarbonate mixing room at 1050 hours on 1/5/11, water was found on the floor around the bottom of the mixing tank and inside the entry door near a pallet containing bags of powdered bicarbonate mixture. 6. During observation of the treatment area on 1/6/11 at 0730 hours, the bottom racks on all the computer carts in the treatment area had a build up of a black substance. The bottom racks also had areas of missing paint exposing the metal underneath. The exposed areas were rusty which caused the surface to become porous and disinfection of these areas could not be ensured.	V 401			
V 403	494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. This STANDARD is not met as evidenced by: Based on observation, and interview, the upper part of the emergency crash cart was found	V 403		3/2/11	

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V 403	Continued From page 26 unlocked exposing the contents to public tampering. Findings: On 1/5/11 at 0730 hours, inspection of the facility's emergency crash cart revealed the upper part of the crash cart where the medications and syringes were stored was not locked. The bottom part where other supplies were stored was locked. There was no check list on the cart to show the frequency of the emergency cart supply checks. The FA stated she was not aware the crash cart was unlocked, and review of the check list showed the list for the new year had not been started. The FA stated the crash cart was checked on a weekly basis.	V 403			
V 408	494.60(d) PE-EMERGENCY PREPAREDNESS-PROCEDURES The dialysis facility must implement processes and procedures to manage medical and non medical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to have developed an disaster/emergency plan that was specific to their dialysis facility and natural disasters that occur in California. Findings:	V 408		1/10/11	

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V 408	Continued From page 27	V 408			
V 409	<p>Review of the facility's evacuation plan with the FA and CSS showed the facility had a basic plan with some items that were specific to the facility but did not include other items for the facility (i.e., the location of the water and gas shutoff valves, location of their emergency supplies, and an alternate evacuation area).</p> <p>494.60(d)(1) PE-ER PREP STAFF-INITIAL/ANNUAL/INFORM PTS</p> <p>The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following:</p> <ul style="list-style-type: none"> (i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of- <ul style="list-style-type: none"> (A) What to do; (B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated; (C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and (D) How to disconnect themselves from the dialysis machine if an emergency occurs. <p>This STANDARD is not met as evidenced by: Based on interview and review of the facility's documentation, the facility failed to ensure three</p>	V 409		1/10/11	

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V 409	Continued From page 28 of nine staff members (PCT 2, RN 1 and RN 2) completed the annual mandatory emergency preparedness test. This may affect the competency of staff in an emergency situation and in patient education about how to handle emergencies. Findings: On 1/6/11 at 1500 hours, review of nine personnel files was conducted. Three direct care staff members did not complete the facility's annual emergency preparedness training as the follows: - PCT 2's last mandatory emergency preparedness training was completed on 12/11/08. - RN 1's last mandatory emergency preparedness training was completed on 9/22/09. - RN 2 had not completed the mandatory emergency preparedness training since being rehired in 2009. On 1/6/11 at 1635 hours, during an interview, CSS stated per the facility policy, the staff member has to attend the class and pass the test for the mandatory emergency preparedness training. On 1/6/11 at 1640 hours, an interview with review of the personnel files for the above three staff members was conducted with CSS and the FA. There was no further information provided.	V 409			
V 412	494.60(d)(2) PE-ER PREP-PTS ORIENTED/TRAINED The facility must provide appropriate orientation and training to patients, including the areas	V 412		1/21/11	

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V 412	Continued From page 29 specified in paragraphs (d)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on interview, the facility failed to ensure two of eight sampled patients (Patients 6 and 8) were trained how to contact and who to contact to receive instructions for treatments if a disaster prevented them from getting to the facility for treatment. Findings: On 1/5/11 at 1405 hours, Patient 6 was interviewed regarding any training received for emergencies and disasters. The patient stated he was fully aware of his part when an in-center disaster or emergency arose. When asked about training in case a disaster should happen that would prevent the patient from getting to the dialysis center for treatment, Patient 6 stated that he was never instructed on what he should do or who to contact.	V 412			
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, the facility failed to ensure five of five oral airways (equipment used to assist in opening the patient's airway) were clean to be ready for emergency use.	V 413		2/9/11	

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

PRINTED: 05/27/2011
FORM APPROVED
OMB NO. 0938-0391

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V 413	Continued From page 30 Findings: On 1/5/11 at 0722 hours, during inspection of the the crash cart, a white tray containing five oral airways was found on the bottom shelf of the crash cart. Observation showed the tray was not covered. A grayish-brown powder was noted inside the tray and on the oral airways. The bottom of the tray was sticky when touched.	V 413			
V 503	494.80(a)(2) PA-APPROPRIATENESS OF DIALYSIS RX The patient's comprehensive assessment must include, but is not limited to, the following: (2) Evaluation of the appropriateness of the dialysis prescription, 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 related components (weight gains, fluid removal, hypertension and low blood pressures) were evaluated to determine patient goals for four of eight sampled patients (Patients 1, 2, 3 and 4). The failure resulted in low blood pressures not being monitored, patients being discharged above their estimated dry weights and high blood pressures that could lead to possible strokes not being evaluated. Findings: Facility policy review was initiated on 1/6/11.	V 503		2/9/11	

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V 503	<p>Continued From page 31</p> <p>Facility Policy 1-02-09, Intradialytic Treatment Monitoring showed any interventions and patient response would be documented in the patient's medical record. Significant changes were to be reported to the licensed nurse and documented, and treatment checks should be completed at least every 30 minutes.</p> <p>Facility Policy 1-04-05, Blood Flow Problems dated 9/07, showed the purpose was to achieve and maintain prescribed blood flow, and if blood flow problems remain unresolved, the licensed nurse should be notified. The licensed nurse would assess the patient, their vascular access, and the blood line circuit for possible causes. If interventions were done the licensed nurse was to assess the effectiveness of the interventions and determine the need to reduce blood flow and extend treatment time. The licensed nurse was to notify the nephrologist (kidney physician) for further evaluation and/or interventions.</p> <p>On 1/6/11, review of the patient treatment sheets was done with the CSS and FA.</p> <p>1. Patient 1 had an ordered blood flow rate (BFR) of 300, a dialysate flow rate (DFR) of 500 and an estimated dry weight (EDW) of 58.5 Kg (1 kilogram is equal to 2.2 pounds). Review of the patient's treatment sheets showed the following: * On 9/13/10, the patient had a pre-treatment weight of 57.4 Kg, which was 1.1 Kg. below her EDW. The patient was discharged at 60.6 Kg., 2.1 Kg. above her EDW. The patient was given normal saline when the treatment was started and ended, for a total of 450 mL (0.45 Kg.). The fluid removal goal for the patient was set at 0.5 Kg., and 0.5 Kg. of fluid was removed during the</p>	V 503			

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V 503	<p>Continued From page 32</p> <p>treatment. No other fluid was given to the patient during the treatment. There was no evaluation of the patient's fluid gain of 3.2 Kg. during treatment.</p> <p>* On 9/15/10, Patient 1 had a pre-treatment weight of 57.4 Kg., 1.1 Kg. below her EDW. The total fluid removed was 1.0 Kg and the patient was discharged at 60.0 Kg., 1.5 Kg. over her EDW, and 2.6 Kg. over her pre-treatment weight. The patient was given no extra fluids during the treatment. There was no evaluation of the patient's fluid gain during treatment.</p> <p>* On 9/13/10 the patient's BFR for the treatment was 250.</p> <p>On 9/24/10 the patient's BFR was 250 and the DFR was 600 for the treatment.</p> <p>On 9/27/10, Patient 1's BFR was 260 for the treatment.</p> <p>On 10/6/10, the patient's BFR was 260 and the DFR was 800 for the treatment.</p> <p>There was no documentation on the treatment sheets to show why the physician's ordered BFR and DFR were not met.</p> <p>2. On 1/6/11 at 0800 hours, review of the physician's orders for Patient 2 showed for a blood pressure (BP) with a systolic greater than 180 (the top number in a blood pressure reading) or a diastolic greater than 110 (lower number in a blood pressure reading), the patient was to be given blood pressure medication until the BP became stable.</p> <p>* On 12/6/10, Patient 2's pre-treatment BP was 216/81. At 0700 hours, the patient's BP was measured as 106/86 from a BP of 201/89 at 0630 hours (a drop of 95). Another BP was not taken for 30 minutes and was 196/91. The BP remained in the high 190's until the end of the treatment. The patient was given a BP</p>	V 503			

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V 503	<p>Continued From page 33</p> <p>medication 20 minutes before the end of their treatment and was discharged with a BP of 198/88. No further BP follow up was done with regard to response to the medication. There was no documentation on the treatment sheet to show when the RN had been notified of the increased BP during the patient's treatment or documentation to show the physician had been notified.</p> <p>* On 12/10/10, the patient's pre-treatment BP at 0545 hours was 230/92 and decreased during treatment to 172/88 at 0832 hours. Twenty minutes later at 0850 hours the BP had increased to 205/110. There was no documentation during the treatment to show the RN had been notified of the patient's BP. At 0850 hours, Patient 2's blood was returned and the treatment was completed. At 0906 hours, the patient was given a BP medication. There was no patient response to the medication documented or documentation to show the physician had been notified.</p> <p>* On 12/24/10, the patient had a pre-treatment BP of 188/124. During treatment the patient's BPs varied from 216/81 to a low of 166/82 at 0800 hours. At 0833 hours the patient's BP increased to 194/84. The patient's post-treatment BP was 208/80. There was no documentation on the treatment sheet to show the RN had been notified of the increased BP, and the patient was not given any BP medications.</p> <p>3a. On 1/6/11 at 0800 hours, review of the treatment sheet for Patient 3 dated 11/24/10, showed the patient had an EDW of 62.5 Kg. and a pre-treatment weight of 64.0 Kg. The fluid removal goal set for the patient was 2.0 Kg. (the weight gain of 1.5 Kg. plus the 0.5 Kg. of total fluids given to a patient at the start and end of the</p>	V 503			

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V 503	<p>Continued From page 34</p> <p>treatment). The total fluid removed from the patient was 2.9 Kg. The post-treatment weight was entered at 53.0 Kg., 11.0 Kg. under the patient's EDW. Review of the treatment sheet showed the following:</p> <ul style="list-style-type: none"> * Start of treatment at 0925 hours, the fluid removal rate (UFR) was set for 0.5 Kg. and the volume removed was 0.0 Kg. * At 1000 hours, the UFR was 0.5 and volume removed was 0.4 Kg. * At 1100 hours, the UFR was 0.5 and volume removed was 1.0 Kg. * At 1200 hours, the treatment notes showed the UFR had been turned off because the patient was cramping. At 1200 hours, the UFR recorded by the machine showed it had increased to 0.58 and the volume removed was 1.5 Kg. * At 1230 hours, the treatment notes showed the fluid removal was still turned off, but the volume removed was 0.5 Kg. The volume should have remained at 1.5 Kg. as shown at 1200 hours. * At 1235 hours, the treatment notes showed the fluid removal was still off, but the fluid removed rate was recorded by the dialysis machine as 1.1, and the volume removed was 2.9 Kg., an increase in total volume removed. * At 1258 hours, the UFR was 0.3 and the volume removed was 1.5 Kg. The patient's blood was returned and the treatment was completed. <p>The fluid removal volume for the treatment and volume removed were inconsistent. The fluid removal volume set for the treatment should remain consistent unless the fluid removal goal is increased or decreased. The machine has a controlled volume removal function, and only the amount of fluid removal programmed into the machine should be removed. When the fluid</p>	V 503			

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V 503	<p>Continued From page 35</p> <p>removal is turned off the volume of fluid removed should remain the same until the fluid removal is turned back on. There was no documentation to show the changes in the fluid removal rate and the total fluid volume were addressed or if the machine had been removed from service to determine if there was a problem with the fluid removal function. There was no documentation to show if the patient's discharge weight was evaluated.</p> <p>3b. Review of Patient 3's treatment sheet dated 12/1/10, showed at the beginning of her treatment, the patient had a BP of 161/71. At 1030 hours, the BP was 143/69 and at 1101 hours, had decreased to 91/77, a drop of 52 points. A follow up BP was not taken until 30 minutes later.</p> <p>3c. Patient 3 had a physician's order for a DFR of 600. Review of the treatment sheet dated 12/29/10, showed the patient had a DFR of 800 for the treatment. There was no documentation to show why the DFR was not to the physician's order.</p> <p>4. Review of Patient 4's treatment sheet dated 6/18/10 showed at 2029 hours, his BP had decreased by 26 points to 105/81. Another BP was not taken for one hour.</p> <p>On 1/6/11 at 1320 hours, an interview was done with RN 1. RN 1 stated blood pressure medications were to be administered per patient specific orders. For low blood pressures the PCT/CHT were to notify the nurse when a patient had a low blood pressure. The blood pressure cuff should be adjusted and another blood</p>	V 503			

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V 503	Continued From page 36 pressure done to make sure the low reading was correct. The RN also stated the RN should go to the patient station with the PCT/CHT and recheck the information together.	V 503			
V 504	Review of the Mayo Clinic website on 1/11/11, showed a sudden fall in blood pressure can be dangerous. A change of just 20 points (i.e., a drop from 130 systolic to 110 systolic) can cause dizziness and fainting when the brain fails to receive an adequate supply of blood, and big plunges in blood pressure can be life-threatening. 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' high and low blood pressures (BP), patient response to actions taken, and weight gain evaluations were done for three of eight sampled patients (Patients 1, 2 and 3) which could have resulted in fluid overload, possible strokes, cardiovascular problems, hypotension and cramping. Findings: High blood pressures were not treated, assessed or reported to the patient's physician, low blood pressures were not re-evaluated, patients were	V 504		5/13/11	

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V 504	Continued From page 37	V 504			
V 637	<p>discharged above their EDWs and were not evaluated for possible causes, fluid removal totals and fluid removal rates were not evaluated for a possible problem. Responses to actions taken were not documented. Cross reference V503.</p> <p>494.110(a)(2)(ix) QAPI-INDICATOR-INF CONT-TREND/PLAN/ACT</p> <p>The program must include, but not be limited to, the following: (ix) Infection control; with respect to this component the facility must-</p> <p>(A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence; (B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and (C) Take actions to reduce future incidents.</p> <p>This STANDARD is not met as evidenced by: Based on interview and review of the facility documentation, the facility's quality assessment and performance improvement (QAPI) program failed to develop an action plan to address the increased infection rate in September, 2010.</p> <p>Findings:</p> <p>On 1/10/11, review of the facility Quality Improvement & Facility Meeting Minutes dated 1/1/11, showed the infection rate had a significant increase from August, 2010 to September, 2010 as follows:</p> <ul style="list-style-type: none"> - For vascular access, the infection rate increased from zero to 7.7 percent. - For central venous catheters, the infection rate 	V 637		1/28/11	

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V 637	Continued From page 38 increased from zero to 8.3 percent. - For total infections, the infection rate increased from zero to 12.8 percent.	V 637			
V 710	On 1/10/11 at 1430 hours, during a QAPI interview, the FA could not show any documented evidence the QAPI program analyzed the data presented to address the increased infection rates. 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 complete oversight related to patient health outcomes and monitoring/evaluating these data on a continual basis to improve performance. He did not ensure data was analyzed and actions taken if needed for increased prevalence of infection. Findings: Data regarding increased infection rates for vascular access and central venous catheters had not been analyzed to address the increased infection rates. Cross reference V637 Patient post-treatment weights were not assessed and evaluated to ensure they were appropriate for the patients. High blood pressures were not treated per physician's orders and BP medication responses were not documented. BFRs and DFRs were not per physician's order, hypotensive patients were not re-assessed per policy. Cross-reference V503,	V 710		3/2/11	

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V 710	Continued From page 39 V715. Central venous catheter patients were not positioned for treatment initiation per policy, medication labels were not completed per policy. Cross reference V715. Reprocessed dialyzers were not primed for patient use per policy. Cross reference V353 Gloves were not worn or hands not cleaned during patient care per policy. Cross reference V113. Gowns were not removed when leaving the treatment area prior to entering a non-treatment area per policy Cross reference V115. Items taken into a patient's dialysis station were not being disinfected prior to removing them from the treatment area and supplies for other patients were placed on dialysis machines while the current patient was being dialyzed. Cross reference V116. Storage of medications was not to manufacturer's recommendations, medication syringes were not removed from the packages and medication vial stoppers were not disinfected per policy. Cross reference V143.	V 710			
V 715	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must-	V 715		1/18/11	

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V 715	<p>Continued From page 40</p> <p>(2) Ensure that-</p> <p>(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;</p> <p>This STANDARD is not met as evidenced by: Based on observation, facility policy review, and interview, the medical director failed to ensure that policies and procedures related to positioning of patients with catheters for one of seven sampled patients (Patient 6). The medical director failed to ensure infection control, medication storage, syringe labeling, glove changes, and handwashing policies and procedures were adhered to by all staff members that care for the patients to prevent the possible transmission of infection and possible air embolisms (obstruction of a blood vessel caused by an air bubble).</p> <p>Findings:</p> <p>Facility policy review was initiated on 1/6/11.</p> <p>1. Facility Procedure 1-06-01A, revised 9/10, showed a medication syringe should be labeled with the patient's name, name of the prescribed medication, dose, date, time and initials of the licensed teammate preparing the dose.</p> <p>On 1/5/11 at 0720 hours, observation of the medication refrigerator was done with RN 2. Of the 10 syringes observed, there was no time on the labels for four syringes and no initials on three of the syringe labels to show who had drawn the</p>	V 715			

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V 715	Continued From page 41 medication. 2. Procedure 1-04-02A for Predialysis Central Venous Catheter Care, revised 6/08, showed the patient was to be placed in a comfortable, supine position (lying on the back with face upward to increase blood flow through the catheter and diminish the risk of an air embolism). If the dressing change is not done at this time, the exit site should be covered with a sterile 4 x 4, secured with tape, and then start the patient's treatment. On 1/5/11 at 1346 hours, RN 2 was observed preparing to start a catheter patient's dialysis treatment. Patient 6 was seated upright in the dialysis chair while the catheter end caps were removed. Syringes were attached to remove the heparin packing, the catheter lines were flushed with normal saline, the heparin bolus was instilled and the dialysis blood lines were attached. The patient's treatment was started with the patient in the upright position in the dialysis chair. At 1405 hours, an interview was done with Patient 6. The patient stated he was always seated upright in the dialysis chair when the dressing change was done, and treatments were started and stopped.	V 715			
V 726	494.170 MR-COMPLETE, ACCURATE, ACCESSIBLE The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.	V 726		2/9/11	

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V 726	<p>Continued From page 42</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the facility failed to ensure the medical record for one of seven patients (Patient 2) was complete and accurate.</p> <p>Findings:</p> <p>Procedure 1-04-08A, Utilizing Vascular Access Clamps, revised 3/10, showed that clamps must be checked after 10 minutes to see if the bleeding has stopped and this can be repeated for up to 30 minutes. Prolonged bleeding may indicate access dysfunction and required additional intervention. If the bleeding has not stopped, the RN should be notified and the policy for Prolonged Bleeding of Cannulation Sites should be referred to.</p> <p>1. On 1/5/11 at 0922 hours, Patient 2 was observed to be placed in a wheelchair by a family member. The patient had access clamps placed over their needle sites. The patient was taken to the scale and then pushed out into the lobby. The family member was getting ready to push the patient out of the facility. When asked by the surveyor why Patient 2 still had the access clamps in place over the needle sites, the family member stated the patient's physician had written an order the clamps could be left in place until the patient reached her home. The clamps were to prevent bleeding while the patient was being driven home.</p> <p>During review of Patient 2's medical records with the FA and CSS, a physician's order allowing the patient to be taken out of the unit and driven home with the access clamps in place could not</p>	V 726			

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V 726	Continued From page 43 be provided. 2. During review of Patient 2's medical record on 1/6/11, it showed the patient's consents were all in English, and the patient had signed some of the consents and others were signed by someone else. Review of the form, Permission to Discuss Health Information with Other Individuals signed by the patient on 2/20/08, showed the patient had granted permission to have her health information discussed with persons listed on the form. There were no names listed on the form. An initial nursing form showed English was not the patient's primary language and the patient had limited reading ability and language difficulty. At 0735 hours on 1/10/11, the surveyor attempted to interview Patient 2. Patient 2 indicated she was having difficulty understanding the questions. A follow up interview was done with the patient's family member who stated she translated consents for her mother, and her mother would sign the forms if she was able. If the mother was unable to sign, the family member stated she signed the forms for her mother. There was no documentation on the signed consents a translator was used or the signature on some of the forms was done by a family member.	V 726			
V 765	494.180(e) GOV-INTERNAL GRIEVANCE SYS ID/IMPLEMENTED The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services.	V 765		5/13/11	

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V 765	<p>Continued From page 44</p> <p>The grievance process must include-</p> <p>(1) A clearly explained procedure for the submission of grievances.</p> <p>(2) Timeframes for reviewing the grievance.</p> <p>(3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to use or complete patient grievance investigations in order to identify any possible changes needed in how code situations (i.e., emergency situation such as a cardiac arrest or breathing problems) and blood borne infection exposures were handled, to document any actions taken, and to use the findings to improve patient care.</p> <p>Findings:</p> <p>1. On 1/6/11 at 1630 hours, a review of the grievance log with FA and CSS showed in January 2010, a patient had coded in the facility. The staff response during the code showed a need for staff re-education in handling of medical emergencies.</p> <p>Another grievance submitted in January 2010 was from a patient who had witnessed the code being performed, and had questioned the training and ability of the staff performing the code. The patient had questioned her safety and that of the other patients. The patient felt the staff did not know what to do, were inexperienced and not trained for emergencies. The paperwork showed the Social Worker and FA had talked to the</p>	V 765			

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V 765	<p>Continued From page 45</p> <p>patient to assure the patient the staff had previously been trained on how to handle emergencies. There was no documentation provided to show any needed changes were identified to address this issue, that any actions had been taken, and a plan developed and implemented.</p> <p>The FA stated since the code, an assignment sheet had been done to show who was responsible for certain tasks during a code, and an inservice had been given. No documentation could be provided regarding the conducted inservice.</p> <p>On 1/10/11 at 0845 hours, an interview was conducted with the patient who had filed the grievance. The patient stated they felt nothing had changed regarding the ability of the staff to perform during a code situation.</p> <p>2. A grievance was filed on 4/6/10 by a family member concerning a patient who had been sprayed with blood during their treatment when the patient seated next to them pulled out their dialysis needles.</p> <p>There was no documentation to show the complaint had been addressed, actions taken with regard to the care given to the patient after the blood spray, if a plan was developed and implemented for any needed changes that were identified during investigation of the grievance.</p>	V 765			