

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: 052307	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 01/07/2011
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NAME OF PROVIDER OR SUPPLIER PACIFIC DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP CODE 2351 CLAY STREET, 4TH FLOOR SAN FRANCISCO, CA 94114
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(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
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V 000	<p>INITIAL COMMENTS</p> <p>The following reflects the findings of the California Department of Public Health during the recertification survey from 1/3/11 through 1/7/11.</p> <p>Representing the Department of Public Health: Artemis Tumaneng, Health Facilities Evaluator Nurse Stella Tannehill, Health Facilities Evaluator Nurse</p> <p>The facility's census at the time of the survey was 156.</p> <p>The Condition for Coverage: 494.30 Infection Control was not met:</p> <p>Definition of terms commonly used in the deficiencies:</p> <p>Arteriovenous fistula (AVF) is formed connecting the artery to the vein causing more blood to flow into the vein. As a result, the vein grows larger and stronger, making repeated needle insertions for hemodialysis treatments easier.</p> <p>AV graft (AVG) connects an artery to a vein using a synthetic tube, or graft, implanted under the skin The graft becomes an artificial vein that can be used repeatedly for needle placement and blood access during hemodialysis.</p> <p>Aseptic technique - task performed in a sterile environment to avoid contact with harmful bacteria</p> <p>Ascorbic acid - Vitamin C</p> <p>Bicarbonate or bicarbonate concentrate- a</p>	V 000		
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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V 000	<p>Continued From page 1</p> <p>substance that minimizes change in the acidity of a solution when an acid or base is added to the solution.</p> <p>Bicarbonate cartridge - bicarbonate powder in a plastic casing</p> <p>Bicarbonate Cartridge (primed) - bicarbonate cartridge was manually attached to the hemodialysis machine and the machine will mix the bicarbonate powder with dialysate to make-up bicarbonate concentrate.</p> <p>Bloodlines - set of tubings that is filled with saline or blood during hemodialysis.</p> <p>Central Venous Catheter or short peripheral catheter - a catheter with two lumens inserted under the skin into a large vein in the neck or groin used for hemodialysis treatment.</p> <p>Clean sinks - are handwashing sinks dedicated only for handwashing purposes and should remain clean.</p> <p>Cross-contamination is the physical movement or transfer of harmful bacteria from one person, object or place to another.</p> <p>Dirty sinks - sinks designated for handling contaminated items like used saline bags.</p> <p>Dialysate - fluid used during dialysis to remove waste products in the body that kidneys cannot excrete. It is composed of purified water, bicarbonate and electrolytes.</p> <p>1K, 2K and 3K are kinds of dialysate.</p>	V 000			

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V 000	Continued From page 2 Dialysate ports - outlet on walls used to access the dialysate. Dialysate Transfer Pumps - an equipment used to pump out dialysate from a drum to the storage tank. Dialysate Delivery Tubing - hoses connected to the dialysate ports used to deliver the dialysate to the hemodialysis machine. Dialyzer - an artificial kidney usually composed of hollow fiber which is used in hemodialysis to eliminate waste products from the blood and remove excess fluids from the bloodstream. Dialyzer connectors - tubings with inlet and outlet connectors attached to the dialyzer and the dialysis machine in order for the dialysate to flow in the dialyzer during hemodialysis. Dialysate Storage Area - an area where drums of dialysate were stored and big holding tanks for dialysate were located. Hemodialysis treatment - a therapy that uses hemodialysis machine and a dialyzer to remove extra fluids and waste products of the body that kidneys could not excrete. Hemodialysis access - three basic kinds of vascular access for hemodialysis are AVF, AVG and a central venous catheter. Heparin - medication used to prevent blood clots. Heparin chamber - part of hemodialysis machine	V 000			

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V 000	Continued From page 3 where Heparin syringe was connected to deliver the Heparin to the patient during hemodialysis. Intravenous medications - medications given through the veins. Medication vial septum - a rubber membrane that covers a medication vial (a small glass or bottle) where needle and syringe are inserted to aspirate the medication. Mucus membrane - a lining of bodily tracts and structures of the body, including the mouth, nose, eyelids, windpipe and lungs. Saline - a bag of sterile solution of sodium chloride or salt. Sharp Bins - container for used needles or any kinds of sharps. Stations - patient designated treatment area equipped with a chair and a table, a hemodialysis machine, tubings and other equipment. Standard precautions are a set of infection control practices used to prevent transmission of diseases which can be acquired through contact with blood, body fluids, non-intact skin, and mucous membranes. These practices include cleaning and disinfection of potentially contaminated objects or surfaces. Water Room was the area where water used for dialysis was processed for purity and where staff went to get water samples three times a day to monitor the water quality.	V 000			

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V 000	Continued From page 4	V 000			
V 110	<p>Water Drain Box - a pipe opening on the wall used for draining the waste water from the hemodialysis machine.</p> <p>494.30 CFC-INFECTON CONTROL</p> <p>This CONDITION is not met as evidenced by: Based on observation of care delivery, interview with staff, and record review, the facility failed to comply with the Condition for Coverage for Infection Control as evidenced by the facility's:</p> <ol style="list-style-type: none"> 1. Failure to maintain a sanitary environment when staff did not practice standard precautions during hemodialysis treatments; and did not maintain a clean environment within the unit and in areas like the water room and dialysate storage area. Failure to practice standard precautions and failure to maintain a clean and sanitary environment in the unit, and in areas frequently visited by staff during patient treatment had the potential for cross-contamination of microorganisms causing infections to all patients receiving dialysis (V111). 2. Failure to ensure staff wore disposable gloves when touching dialysis machines, and/or disinfected/washed hands after removing gloves, after touching their face, eyeglasses, or mouth, after coughing, or before touching clean supplies. These practices could potentially expose multiple patients in the facility to infectious agents (V113). 3. Failure to have designated clean sinks only for handwashing in the patient treatment areas (Room 1 and 2), when contaminated saline bags were emptied in the handwashing sinks. Failure 	V 110		2/28/11	

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V 110	Continued From page 5 to have a designated clean and dirty sinks had the potential for cross-contamination and spread of infections to all patients in the facility. (V114) 4. Failure to ensure that clean areas were clearly separated from dirty areas and not used for handling contaminated items. This practice had the potential of cross-contamination and exposure to infectious agents for all patients in the facility. (V117) 5. Failure to follow standard precautions in cleaning and disinfecting contaminated items and equipment in between patient treatment which increased the risks for cross-contamination and spread of infections for multiple patients in the facility. (V122) 6. Failure to ensure aseptic technique with use of intravenous medications which had the potential to expose multiple patients to infectious agents. (V143) 7. Failure to ensure standard precautions were observed during central venous catheter (CVC) dressing change which had the risks for cross-contamination causing catheter-related infections that could compromise patient's hemodialysis access. (V146). The cumulative effect of these failures constituted a severe infection control safety breach that limited the facility's ability to furnish adequate care and had the potential to cause harm to patients.	V 110			
V 111	494.30 IC-SANITARY ENVIRONMENT	V 111		2/28/11	

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V 111	<p>Continued From page 6</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, interview, and record review, the facility failed to maintain a sanitary environment when: * The staff did not clean and disinfect the supplies and equipment on fifteen of 30 dialysis Stations (Room 2 - Stations 16 to 30); *The staff did not maintain a clean and sanitary environment within two of 2 treatment areas (Room 1 &2) and in the water room and dialysate storage areas.</p> <p>Failure to practice standard precautions (cleaning and disinfecting) and failure to maintain a clean and sanitary environment in the unit, and in areas frequently visited by staff during patient treatment had the potential for cross-contamination of microorganisms causing infections to all patients receiving dialysis.</p> <p>Findings:</p> <p>Room 1 & 2: 1. During the initial tour on 1/3/11 at 11:30 AM, the suction machine on the emergency cart in Room 1 was dusty, eight sharps bins in Room 2 had white and brown marks and with dust build-up. The baseboards below the dialysate ports between Stations 18 &19, 20 & 21, 22 & 23, 24 & 25, 27 & 28 and 29 & 30 were all peeling off the wall. Fifteen of 15 dialysate ports in Room 2 were corroded/rusted and left yellow and brown</p>	V 111			

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V 111	<p>Continued From page 7</p> <p>marks on the wall below the ports. These conditions increased the amount of contaminants in the dialysis delivery areas.</p> <p>2. In an observation on 1/5/10 at 11:00 AM, PCT 3 did not disinfect the dialyzer connectors, blood pressure cuff and the bicarbonate cartridge connected to the machine after patient treatment in Station 16.</p> <p>3. In an observation from 1/4/11 to 1/6/11, the bicarbonate cartridges connected to the dialysis machines were not cleaned in between patient treatments for all patients in Room 2.</p> <p>In an interview on 1/6/11 at 9:30 AM, the Nurse Manager said the bicarbonate cartridges should stay on the dialysis machine in between patient treatments until it's all used up. She acknowledged the staff should include the cartridges in cleaning and disinfection between patient treatments.</p> <p>Review of the facility's 3/09 Infection Control policy and procedure indicated, "Staff-Related Precautions: ... 2. All patient supplies and equipment including tourniquet, blood pressure cuff, etc., will be cleaned after patient use..."</p> <p>4. In an observation on 1/7/11 at 11:00 AM, there were bicarbonate cartridges stored at the bottom of dialysis machines in Stations 17 and 18 during treatments for multiple patients.</p> <p>In an interview on 1/7/11 at 11:00 AM, the Nurse Manager said the bicarbonate stored at the bottom of the dialysis machine were used for the next patient or were placed there whenever the</p>	V 111			

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V 111	<p>Continued From page 8</p> <p>supply of bicarbonate from the source ran out. She said the cartridges were considered clean. She acknowledged that storing it under the dialysis machines could potentially be contaminated during patient treatment.</p> <p>Review of the bicarbonate manual booklet entitled 2010 Operator's Manual for Bicart, indicated, "Between treatments, the Bicarb cartridge shall be stored in room temperature... Aseptic handling is recommended."</p> <p>5. In an observation on 1/4/11 at 11:40 AM, the Housekeeper was observed collecting biohazard waste in Room 2. He had two big gray containers on a trolley and went around the room and emptied into the gray containers the three red biohazard bins located in between stations. He was doing this task while patients were having their hemodialysis treatments.</p> <p>In an interview on 1/4/11 at 11:45 AM, the Housekeeper said he went around the room with the big containers in the trolley to empty the biohazard bins into it because the red bags were heavy. He said he did the same in Room 1.</p> <p>In an interview on 1/7/11 at 9:00 AM, the Nurse Manager said the housekeeper should empty the biohazard bins after every shift. She acknowledged that going around the room from station to station during patient treatments with the big containers of biohazard waste was unsanitary.</p> <p>Water Room and Dialysate Area: 1. During the initial tour inspection of the Water Room on 1/3/11 at 12 noon, while accompanied</p>	V 111			

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V 111	<p>Continued From page 9</p> <p>by the Administrator and the Biomedical Technician, there was a storage chest with drawers that had a circular brown dried spill on top with dry brown drip marks down the front over the drawers, and was coated with dust.</p> <p>2. A desk-like table with two table-top levels was placed across from the entrance to the Water Room.</p> <p>When concurrently interviewed, the Biomedical Technician said it had no use in the Water Room and had been placed there for storage.</p> <p>3. There was an eye-level tall, shelved cart with water connection supplies that was coated with a thick layer of rusty colored dust on all the shelves.</p> <p>4. One deep window sill had a long, discolored and mottled card board box containing light bulbs. At one end of the sill not covered by the box, were thick clumps of dust and dirt. The other deep window sill was covered with dust, chipped paint and dirt.</p> <p>5. The Dialysate Area was outside of the building. Around the bases of the dialysate holding tanks and the dialysate transfer pumps were wadded paper, dirt, chipped paint and debris.</p> <p>During closer inspection of the dialysate transfer pumps on 1/4/11 at 12:30 PM, while accompanied by the Biomedical Technician and the Administrator, there was rusty corrosion around the pump hull housing connections on the 3K and 2K pumps. The left hand pump had rusty corrosion across its mid-housing. A bracket holding the dialysate tubing above the pumps on</p>	V 111			

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V 111	Continued From page 10 the outside building wall was rusted and the upper attachment was pulled off the wall.	V 111			
V 113	When concurrently interviewed on 1/4/11 at 12:30PM, the Administrator said the Water Room and the outside dialysate holding area had fallen off the environmental services cleaning schedule. 494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure eight of eight staff observed during care delivery (PCT 1, PCT 3, PCT 4, PCT 5, PCT 6, PCT 7, RN 2 & RN 4) used gloves, practiced hand hygiene after touching mouth, face and eyeglasses, and practiced hand hygiene when handling potentially contaminated hemodialysis equipment at six of 30 Stations, increasing the risk for cross-contamination and spread of infections. These practices could potentially expose all patients in the facility to infectious agents. Findings: 1. During the initial tour on 1/3/11 at 11:00 AM, PCT (Patient Care Technician) 3 touched dialysis machine screen in Station 16 without gloves. After prompted by another staff, he wore gloves and went to Station 19 and touched the dialysis	V 113		2/28/11	

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V 113	<p>Continued From page 11</p> <p>machine screen but did not do hand hygiene after removing the gloves & going to the next patient.</p> <p>In an interview on 1/3/10 at 11:10 AM, PCT 3 said he should be wearing gloves when touching the machines and disinfect hands after taking off gloves.</p> <p>2. In observation on 1/4/11, RN (Registered Nurse) 2 touched dialysis machine screen without gloves during the start of patient treatment on Station 14; and PCT 1 who was helping the nurse on same station touched the dialysis machine and the bloodlines without gloves.</p> <p>3. In an observation on 1/6/11 at 3:45 PM, RN 4 touched the dialysis machine in Station 14 with bare hands during patient treatment.</p> <p>4. During medication preparation observation on 1/6/11 at 3:45 PM, RN 2 touched her mouth and eyeglasses, and without disinfecting her hands opened the clean supply cart and took syringes and alcohol swab.</p> <p>In an interview on 1/6/11 at 3:52 PM, RN 2 said she forgot to disinfect her hands before touching the clean supplies.</p> <p>Review of the facility's 3/09 Infection Control policy and procedure indicated, "Staff-Related Precautions: 6. Gloves, masks, goggles or shields are to be worn at all times when there is potential exposure to blood and body fluids...7. Hand hygiene which includes antibacterial gels/foams will be done between patients, after removal of gloves..."</p>	V 113			

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V 113	<p>Continued From page 12</p> <p>5. During observation of care delivery to Patient 4 on 1/4/11 at 3:10 PM, PCT 4 touched the heparin chamber and pushed buttons on the dialysis machine with ungloved hands while it was in use.</p> <p>When concurrently interviewed, PCT 4 said her left hand was her clean hand and her right hand was her dirty hand. She said she used her right hand to chart.</p> <p>6. During observation of care delivery in Room 1 on 1/5/11 at 10:40 AM, in the walking area in front of Station 7, PCT 5 coughed and brought his right fist to his mouth. He then walked around in the walking space watching his patients with his hands held together behind his back. The surveyor stopped him and pointed out her observation. PCT 5 then washed his hands.</p> <p>When concurrently interviewed, PCT 5 said he was only clearing his throat.</p> <p>7. During observation of care delivery at Station 24 on 1/5/11 at 12 noon, PCT 7 connected the patient to dialysis, removed her gloves and washed her hands. She then touched the dialysis machine buttons without wearing gloves.</p> <p>When concurrently interviewed, PCT 7 said she had been taught not to touch the dialysis machine without wearing gloves, but she forgot.</p> <p>8. During observation of care delivery at Station 28 on 1/5/11 at 12:10 PM, PCT 6 rested his left forearm across the top portion of the dialysis machine while it was in use for a patient. He then walked around the room, but when he began to</p>	V 113			

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V 113	Continued From page 13 reach across a supply cart with both hands, the surveyor stopped him and pointed out her observation.	V 113			
V 114	PCT 6 said, " I will change my gown, " and did so. 494.30(a)(1)(i) IC-SINKS AVAILABLE A sufficient number of sinks with warm water and soap should be available to facilitate hand washing. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to have designated clean sinks used only for handwashing in one of 2 treatment areas (Room 2), when contaminated saline bags were emptied in 3 of 8 handwashing sinks. Failure to have a designated clean and dirty sinks had the potential for cross-contamination and spread of infections to patients in the facility. Findings: During the initial tour observation and interview on 1/3/10 at 11:00 AM, there were no distinctive "clean" and "dirty" sinks in the patient treatment areas (Room 2). When PCT 5 was asked where contaminated saline bags were emptied, he said, "We emptied the bags in the sinks (Sink 1, 2, & 3) where we wash our hands." In an observation on 1/3/11 at 2:00 PM, there was a saline bag draining in the handwashing sink 1 near Station 18; and on 1/4/11 at 10:30 AM, PCT 2 was emptying the contaminated saline bag in the handwashing sink 3 near Station 30.	V 114		2/28/11	

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V 114	Continued From page 14	V 114			
V 117	<p>494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS</p> <p>Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.</p> <p>When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.</p> <p>Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.</p> <p>This STANDARD is not met as evidenced by:</p>	V 117		2/28/11	

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V 117	<p>Continued From page 15</p> <p>Based on observation and interview, the facility failed to ensure that clean areas were clearly separated from dirty areas and not used for handling contaminated items when:</p> <ul style="list-style-type: none"> *Three of 8 handwashing sinks and one of 15 water drains were used to empty contaminated saline bags; *Two of 4 soiled linen hampers were adjacent to clean supplies storage; *Two of 2 medication carts in two treatment areas (Room 1&2) were brought from station to station during medication pass; *Clean items were stored in the two of 2 dirty utility rooms; *A funnel used for transferring bicarbonate was not disinfected; and *Dialysate delivery tubings (clean items) in two of 30 stations were draped over a sharps container (dirty items) between the wall outlet and the dialysis machine. <p>Failure to have a designated clean and dirty area increased the risks for cross-contamination and spread of infections.</p> <p>Findings:</p> <p>1. During the initial tour observation and interview on 1/3/10 at 11:00 AM, there were no distinctive "clean" and "dirty" sinks in the patient treatment areas (Room 2). When PCT 5 was asked where contaminated saline bags were emptied, he said, "We emptied the bags in the sinks (Sink 1, 2, & 3) where we wash our hands."</p> <p>In an observation on 1/3/11 at 2:00 PM, there was a saline bag draining in the handwashing sink 1 near Station 18; and on 1/4/11 at 10:30 AM, PCT</p>	V 117			

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V 117	<p>Continued From page 16</p> <p>2 was emptying the contaminated saline bag in the handwashing sink 3 near Station 30.</p> <p>During further observations in Room 2 on 1/4/11 at 10:30 AM, PCT 2 was emptying the contaminated saline bag in the handwashing sink 2 near Station 24. On 1/4/11 at 11:40 AM, there was a saline bag hanging in the water drain box between Station 26 and 27.</p> <p>In an interview on 1/4/11 at 11:30 AM, the Nurse Manager said staff used the handwashing sinks to empty saline bags because the dirty sink was inside the dirty utility room and it was far to walk to the dirty utility. She acknowledged that emptying contaminated saline bags in the handwashing sink increased the risks for cross-contamination within the unit. She added, there was no policy and procedure which specified the designated use of clean or dirty sinks or where contaminated saline bags should be emptied.</p> <p>2. During the initial tour observation on 1/3/11 at 11:45 AM, one soiled linen carts in Room 1 were adjacent to the dialyzer storage and the soiled linen carts in Room 2 were adjacent to clean and sterile supply cart.</p> <p>3. During the initial tour observation on 1/3/11 at 11:50 AM, there were no designated areas for medication preparation, handling and storage of medication in Room 1 & 2.</p> <p>During medication pass observation on 1/6/11 at 3:20 PM, RN 3 brought the medication cart to Station 1 and prepared the medication there. After administering the medication, she moved</p>	V 117			

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V 117	<p>Continued From page 17 the medication cart to Station 3.</p> <p>In an interview on 1/6/11 at 4:30 PM, the Nurse Manager said they didn't have a medication preparation area because of the limited space in the nursing station but there were medication carts which were brought from station to station. She added that there was no policy and procedure that covered the specified designated clean area where staff should prepare or handle medications.</p> <p>CDC (Center for Disease Control) published Infection Control Requirements for Dialysis Facilities and Clarification Regarding Guidance on Parenteral Medication Vials dated August 15, 2008 indicated, "All parenteral medications should be prepared in a clean area separate from potentially contaminated items and surfaces. In hemodialysis settings where environmental surfaces and medical supplies are subjected to frequent blood contamination, medication preparation should occur in a clean area removed from the patient treatment area."</p> <p>4. During the initial tour of Room 1 on 1/3/11 at approximately 10:30 AM, while accompanied by the Registered Nurse Clinical Coordinator (RNCC), there were clean items used in patient treatments stored in the designated dirty utility room, as follows: There was a basin of clean (already disinfected and ready for use with patients), white clamps used for applying pressure to the dialysis access sites of patients, in the window sill approximately four inches (splashing distance) from a the basin of dirty (used by patients and in process of disinfection), soaking white clamps on the</p>	V 117			

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V 117	<p>Continued From page 18</p> <p>counter. On an open shelf above the dirty utility room sink, and in reach of splash from use of the dirty sink, were clean plastic bottles and two plastic graduated containers.</p> <p>When concurrently interviewed the RNCC said the plastic bottles and graduated containers were used to disinfect the dialysis machines with bleach. She said there was no where else to put the clamps and bottles for disinfection.</p> <p>5. During inspection of the designated dirty utility room in Room 2 on 1/3/11 at 4:25 PM, while accompanied by the RNCC, there was a basin of clean, white clamps in the window sill approximately six inches (splashing distance) from a basin of soaking dirty clamps on the counter.</p> <p>6. In an observation on 1/6/10 at 10:00 AM, there was a red funnel in one of the handwashing sink in Room 1.</p> <p>In an interview on 1/6/10 at 10:00 AM, PCT 1 said the funnel was used for transferring bicarbonate concentrate in to another jug. When asked how the funnel was cleaned, she said, "We clean it with water only."</p> <p>In an interview on 1/7/10 at 9:00 AM, the Nurse Manager said there was no policy and procedure for cleaning the funnel. She said they got rid of the funnel and will not use any funnel in the facility.</p> <p>The funnel used in transferring the bicarbonate concentrate should be cleaned with a disinfectant like bleach and not water only.</p>	V 117			

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V 117	<p>Continued From page 19</p> <p>According to AAMI (Association for the Advancement of Medical Instrumentation): "Bacteria can multiply very rapidly in bicarbonate concentrate. Therefore, if disinfection is inadequate, one organism can grow into hundreds of thousands-literally overnight." (source Hemodialysis Horizon www.aami.org)</p> <p>7. In an observation on 1/4/11 at 2:50 PM, the dialysate hoses (clean items) were draped around the sharp bin (dirty item) in Station 14. The Nurse Manager acknowledged the hoses should not touched contaminated surfaces like the sharp bins to minimize cross -contamination.</p> <p>8. During dialysis observation on 1/5/11 at 11:45 AM, the dialysate delivery tubing was draped across the sharps bin between the wall connection and the dialysis machine at Station 30, while dialysis was in process. When pointed out to the PCT who was working with the patient, he removed the dialysate tubing from the sharps bin.</p> <p>Dialysate hoses deliver dialysate for direct intravenous (into the veins or arteries) treatment of a patient. During treatment, if dialysate tubing is in contact with sharps bins, which contain disposed contaminated needles and other sharps used for multiple patients, there is a potential for contamination of potentially infectious blood borne agents into the vascular system of a patient.</p> <p>Review of the facility's policy and procedure, Hazardous Materials and Waste Management: Medical Waste Management, indicated the</p>	V 117			

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V 117	Continued From page 20 definition of medical waste included waste generated as a result of, "1...treatment or immunization of human beings...2.a...articles contaminated with fluid blood...b. Sharps waste means anything that is capable of penetrating or puncturing the skin... contaminated with biohazardous waste..."	V 117			
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 record review, the facility failed to follow standard precautions in cleaning and disinfecting contaminated items and equipment in between patient treatment which increased the risks for cross-contamination and spread of infections. Findings: 1. In an observation on 1/5/10 at 11:00 AM, PCT 3 did not disinfect the dialyzer connectors, blood pressure cuff and the bicarbonate cartridge connected to the machine after patient treatment on Station 16. 2. In Room 2 observations from 1/4/11 to 1/6/11, the bicarbonate cartridges connected to the	V 122		2/28/11	

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V 122	Continued From page 21 dialysis machines were not cleaned in between patient treatments. In an interview on 1/6/11 at 9:30 AM, the Nurse Manager said the bicarbonate cartridges were attached to the dialysis machine in between patient treatments until the cartridge was all used up. She acknowledged the staff should include the cartridges in cleaning and disinfection between patient treatments. 3. In an observation on 1/6/10 at 10:00 AM, there was a red funnel in one of the handwashing sink in Room 1. In an interview on 1/6/10 at 10:00 AM, PCT 1 said the funnel was used for transferring bicarbonate concentrate to another jug. When asked how the funnel was cleaned, she said, "We clean it with water only." In an interview on 1/7/10 at 9:00 AM, the Nurse Manager said there was no policy and procedure for cleaning the funnel. She said they got rid of it and will not use it in the facility.	V 122			
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 interview, the facility	V 143		2/28/11	

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V 143	<p>Continued From page 22</p> <p>failed to ensure aseptic technique with use of intravenous medications when:</p> <ul style="list-style-type: none"> *Ascorbic acid packets were expired on 12/20/10 and were available for use in the unit; *Two boxes of Telfa pads had discolored packaging and expiration dates of 2006 were available for use in the supply cart; *A primed bicarbonate cartridge available for use was not dated when primed; *Staff did not clean the septums of medication vials after removing the caps; *Staff used one alcohol prep to clean the septum of three medication vials; and, <p>Findings:</p> <p>1a. During inspection of medication and supply storage in Room 1 on 1/3/11 at 11:45 AM, while accompanied by the Registered Nurse Clinical Coordinator (RNCC), there was a half filled box of ascorbic acid packets in a cupboard above the solutions counter in Room 1 that had the expiration date 12/20/2010.</p> <p>When concurrently interviewed, the RNCC said they were used for inpatients and that inpatients were no longer being treated in Room 1.</p> <p>b. In a cupboard under the supply storage counter of Room 1 were two boxes of Telfa pads that had discolored packaging and had expiration dates of 08/2006.</p> <p>When concurrently interviewed, the RNCC said she did not know why the Telfa pads were there. She said it was not the usual place they were stored.</p>	V 143			

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V 143	<p>Continued From page 23</p> <p>2. In an observation on 1/6/11 at 9:25 AM, there was an undated already primed bicarbonate cartridge at the bottom of the dialysis machine in Station 26.</p> <p>In an interview on 1/6/11 at 9:25 AM, PCT 4 said, "I would assume it was used and primed yesterday. I will throw it away."</p> <p>Review of the 2010 Operator's Manual for Bicarb indicated, "The concentrate in the Bicarb cartridge must be used within 24 hours after being primed."</p> <p>3. During medication pass observation on 1/6/11 at 3:20 PM, RN 3 took the medication cart to Station 1. She took one opened multidose vial (medication which can be punctured with needles multiple times to get the desired dosage of medication) and two unopened medication vials from the cart and put it on top of the cart. She cleaned the septum of the multidose vial and used the same alcohol wipe to clean the septum of the other two medications. After administering the medication, she moved the medication cart to Station 3.</p> <p>4. When observed on 1/6/11 at 3:45 PM, RN 4 took medication vials from the medication cart near Station 3 where RN 3 was preparing medications. After she took the medication vials from the cart, she put the medications on top of the clean supplies trolley. Before starting to prepare the medication, she touched the corner of her mouth and adjusted her eyeglasses with her fingers. Without washing or disinfecting her hands, she opened the clean supplies trolley and took syringes and alcohol wipe and continued to</p>	V 143			

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V 143	Continued From page 24 prepare the medications. She removed the caps off the two medication vials and without cleaning the septums with alcohol wipe, she entered the vial with the needle. She then proceeded to give the medications intravenously. In an interview on 1/6/11 at 3:50 PM, RN 4 said she forgot to disinfect her hands after she touched her mouth and eyeglasses. She said she did not clean the septum of the medication vials because it's sterile. Review of the facility's 3/09 Infection Control policy and procedure indicated, "Avoid hand to mouth, eyes or nose touching..." There was no policy and procedure provided by the facility on medication administration which covered the cleaning of medication vial septum before puncturing it with a needle.	V 143			
V 146	494.30(c)(2) IC-CATHETERS:GENERAL (2) The "Guidelines for the Prevention of Intravascular Catheter-Related Infections" entitled "Recommendations for Placement of Intravascular Catheters in Adults and Children" parts I - IV; and "Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients," Morbidity and Mortality Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection as the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained	V 146		2/28/11	

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V 146	<p>Continued From page 25</p> <p>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>This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to ensure standard precautions were observed during central venous catheter (CVC) dressing change of one of 15 sampled patients (Patient 12) when the nurse touched the dialysis machine with bare hands and without disinfecting hands proceeded to prepare the sterile supplies for dressing change on an uncleaned/undisinfected table. Failure to practice standard precautions during dressing change had the potential of cross-contamination causing catheter-related infections which could compromise Patient 12's hemodialysis access.</p> <p>CDC "Guidelines for the Prevention of Intravascular Catheter-Related Infections" August 9, 2002, indicated, "For short peripheral catheters, good hand hygiene before catheter insertion or maintenance, combined with proper aseptic technique during catheter manipulation, provides protection against infection."</p> <p>Findings:</p> <p>In an observation on 1/4/11 at 2:50 PM, RN 2 was initiating hemodialysis treatment of Patient 12. She aspirated the Heparin (medication to prevent blood clots) from the arterial and venous lines of the CVC and put the two syringes containing</p>	V 146			

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V 146	Continued From page 26 Heparin and blood on the table. She took the dressing off the CVC site and put it on the table together with the syringes. After the treatment was initiated, she threw away the dirty syringes and the old dressings. She went back to the dialysis machine to check the settings and touched it with her bare hands. Without disinfecting her hands, she proceeded to prepare the new dressing for the CVC site by placing the sterile supplies on the uncleaned/undisinfected table. After she changed the dressing, she threw away all the trash and then cleaned the table with alcohol wipes.	V 146			
V 184	In an interview on 1/4/11, at 3:00 PM, RN 2 said she forgot to wear gloves when touching the machine and disinfect her hands after touching it. She also said she should have disinfected or cleaned the table before using it and not after she did the dressing change. 494.40(a) ENVIRONMENT-SECURE & RESTRICTED 8 Environment: secure & restricted The water purification and storage system should be located in a secure area that is readily accessible to authorized users. The location should be chosen with a view to minimizing the length and complexity of the distribution system. Access to the purification system should be restricted to those individuals responsible for monitoring and maintenance of the system. This STANDARD is not met as evidenced by: Based on observation and interview, the access door to the facility's dialysate area was not secured and restricted to prevent access by visitors and staff who were not involved in	V 184		2/28/11	

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: 052307	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 01/07/2011
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V 184	Continued From page 27 dialysis. This practice provided a potential for tampering with the dialysate system and possible contamination. Findings: During the initial inspection of the dialysate area, while accompanied by the Biomedical Technician on 1/3/11 at approximately 12:30 PM, surveyors were taken down the main elevator to the ground floor and led down the hall and through an unsecured door to an outside area. Part of the outside area to the right had three large dialysis holding tanks behind gated fences with no locks, which were easily opened. Beyond these was a partially fenced section with open access walk-ways where sealed barrels of dialysate and empty dialysate barrels were stored. Also in the partially fenced section, across from the barrels were three transfer pumps and tubing used for transferring dialysate from the barrels into the holding tanks. The remainder of the outside area was used for other facility functions not related to dialysis. During concurrent interview with the Biomedical Technician, he said there was no access directly to the street. He said there was an exit door that could be used by staff, but it could not be entered from the street. He acknowledged the hall door was not secure, but said few visitors came down to that level.	V 184			
V 222	494.40(a) ACID BULK STORAGE TANKS-SAFETY CONTROLS 5.4 Concentrate preparation 5.4.3 Bulk storage tanks (acid concentrate): safety controls	V 222		2/1/11	

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V 222	<p>Continued From page 28</p> <p>Procedures should be in place to control the transfer of the acid concentrate from the delivery container to the storage tank to prevent the inadvertent mixing of different concentrate formulations. If possible, the tank and associated plumbing should form an integral system to prevent contamination of the acid concentrate. The storage tanks and inlet and outlet connections, if remote from the tank, should be secure and labeled clearly.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to implement safety procedures to ensure inadvertent mixing of dialysate when inventory technicians performed the transfer of dialysis, and the tubing at the transfer nozzles was not color-coded.</p> <p>Lack of safety procedures for the transfer of dialysate from delivery barrels into the appropriate holding tanks created a potential for the wrong dialysate prescription to be delivered to patients.</p> <p>Findings:</p> <p>During observation of the dialysate area on 1/4/11 at 12:30 PM, while accompanied by the Biomedical Technician and the Administrator, there were long hoses leading from the three dialysate pumps to long nozzles used to put down into barrels of dialysate. The hoses were bracketed to the wall above the pumps and were clearly labeled 1K, 2K, and 3K (potassium acid concentrates) at that point. They were not color coded, and the tubing at the point of the nozzles was not clearly labeled or color coded.</p>	V 222			

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V 222	Continued From page 29 During concurrent interview with the Biomedical Technician, he said the dialysate was transferred by inventory technicians from the barrels to the holding tanks. The surveyor asked to see the inventory technicians' training records for handling the transfer of dialysate, but these was not provided by the facility. Review of the facility's technical policy and procedure for acid concentrate found under Policy: " To ensure that the lot numbers of delivered acid concentrate is being recorded. This will allow the facility to remove from service any concentrate recalled by the manufacturer." Under Procedure: "1. The lot numbers of all concentrate delivered to the facility will be recorded. 2. The use of the acid concentrate lot number will be utilized to record all pertinent information." The facility's policy did not include verification by a licensed nurse that the correct acid concentrate was pumped into its designated holding tank to ensure the correct prescription was delivered to patients.	V 222			
V 245	494.40(a) ACID CONC DIST-CONC LABELED & COLOR-CODED RED 5.5.3 Acid concentrate distribution systems: labeled & color-coded red Acid concentrate delivery piping should be labeled and color-coded red at the point of use (at the jug filling station or the dialysis machine connection). All joints should be sealed to prevent leakage of concentrate. If the acid system remains intact, no	V 245		2/28/11	

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V 245	<p>Continued From page 30</p> <p>rinsing or disinfection is necessary.</p> <p>More than one type of acid concentrate may be delivered, and each line should clearly indicate the type of acid concentrate it contains.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to color-code the long hoses used for dialysate transfer and failed to clearly label or color code the acid concentrate tubing at the point of nozzle attachments used for pumping acid concentrate into the acid holding tanks.</p> <p>Failure to color code the acid transfer hoses and clearly label the tubing at the point of nozzle connections could contribute to mistakes in acid transfer from delivery barrels to the holding tanks.</p> <p>Findings:</p> <p>During observation of the dialysate area on 1/4/11 at 12:30 PM, while accompanied by the Biomedical Technician and the Administrator, there were long hoses leading from the three dialysate pumps to long nozzles used to put down into barrels of dialysate. The hoses were bracketed to the wall above the pumps and were clearly labeled 1K, 2K, and 3K (potassium acid concentrates) at that point. They were not color coded, and the tubing at the point of the nozzles was not clearly labeled or color coded.</p> <p>During concurrent interview with the Biomedical Technician, he offered no explanation for the lack of color coding for the acid concentrate hoses/tubing.</p>	V 245			

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V 245	Continued From page 31 Review of the facility's policy and procedure for acid concentrate found no reference to the color coding or labeling of dialysate transfer tubing.	V 245			
V 310	494.50(b)(1) PERSONNEL HEALTH MONITORING RECORDS 4 Records 4.4 Personnel health monitoring records A file must be kept of the results of medical examinations of personnel that are required by OSHA or other regulatory agencies. This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to have annual tuberculosis (TB) screening for two staff (Renal Dietitian & PCT 2). Failure to have a regular screening of staff for highly communicable diseases like tuberculosis had the potential of exposing patients to TB. Findings: During personnel record review on 1/7/11, the Renal Dietitian and PCT 2 did not have TB screening on file. In an interview on 1/7/11 at 10:15 AM, the Nurse Manager said she did the TB screening annually and keep a copy of the record in her office but if the screening was done in the Occupational Health, she did not get a copy of the screening. In an interview on 1/7/11 at 11:20 AM, the Human Resources Project Manager said the Occupational Health kept the screening record and filed it on employees personnel record. He was aware that copies of the screening for the two staff were not on their personnel record file.	V 310		2/7/11	

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V 403	<p>494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to implement a program that ensured weighing scales were maintained and calibrated according to manufacturer's instructions, failed to ensure intravenous pumps (IV pumps) were maintained as scheduled by the Biomedical Engineering Department, and failed to monitor the temperature of the peritoneal dialysis (PD) bag warmer.</p> <p>Failure to maintain and calibrate scales can lead to inaccurate measurement of patients' weight, an indicator of fluid gain or loss. Failure to maintain IV pumps can lead to electrical hazards or inaccurate delivery of IV fluids. Failure to monitor temperature of PD bags can lead to infusion of PD fluids that are too cold or too hot.</p> <p>In addition, the facility failed to ensure discolored and expired sterile Telfa pads (gauze dressings) and expired ascorbic acid (vitamin C) were not stored as available for use with patients. Discoloration of packaging may indicate contamination from external elements, expiration of a sterile product indicates its sterility is not certain, and expired medications may have lost potency and effectiveness.</p>	V 403		2/28/11	

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V 403	<p>Continued From page 33</p> <p>Findings:</p> <p>1. During the initial tour of Room 1 on 1/3/11 at 11:45 AM, while accompanied by the Registered Nurse Clinical Coordinator (RNCC), the Scale-Tronix wheelchair scales that was also used for ambulatory patients, had a sticker indicating maintenance was due 12/09.</p> <p>Room 2 inspection on 1/3/11 at 4:25 PM, while accompanied by the RNCC, found the B-TEK wheelchair scales that was also used for ambulatory patients, had a sticker indicating no maintenance was needed.</p> <p>On 1/3/11, review of the facility's Asset Inventory Details for both the Scale-Tronix and the B TEK scales indicated they were both on Tier 3 and no work order for preventative maintenance would be generated.</p> <p>On 1/3/11, the Biomedical Technician presented Scale-Tronix maintenance guidance printed from the Scale-Tronix online source for the scales in Room 1. Review of the Scale-Tronix information indicated under the section, "What about recalibration? ...just like any precision instrument one should check the calibration periodically- usually once every year or two ...This should be done with precision scale test weights ... "</p> <p>During an interview with the Manager of Biomed for several campuses within the associated medical system including the facility, on 1/5/11 at 3 PM, he said when a scale was inventoried into ISIS (a computer program to track maintenance due dates), it was automatically assigned a Tier 3</p>	V 403			

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V 403	<p>Continued From page 34</p> <p>level. Tier 3 would not generate preventative maintenance. The Manager of Biomed said the facility was in the process of contacting the original manufacturers of the scales used throughout the associated medical system to find out what the recommended maintenance requirements were. He did not know the recommended maintenance requirements for the scales in Rooms 1 and 2 of the facility.</p> <p>When interviewed by telephone on 1/6/11 at 11:10 AM, the B-TEK Distributor said recalibration requirements for scales depended on how heavy its traffic was. He said that quarterly calibrations were more in line for the facility traffic. He said what would be most equitable for the facility would be to purchase test weights and do verification on a daily basis. The B-TEK Distributor named several dialysis facilities that were using test weights.</p> <p>2. During inspection of Room 2 on 1/3/11 at 4:25 PM, while accompanied by the RNCC, there was a Lifecare IV pump with a maintenance due date of 5/10.</p> <p>When interviewed on 1/5/11 at 3 PM, the Manager of Biomed said IV pumps were on Tier 2 in the ISIS program and a maintenance due date would be generated for them. He said sometimes the data base will indicate maintenance due for an IV pump, but the pump will have been moved to another location for use on any of the associated three medical campuses, and could not be located. He said there was no tracking system for where IV pumps were moved and they were in high demand. He said they had to depend of facility staff to notice</p>	V 403			

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V 403	<p>Continued From page 35</p> <p>when maintenance was due for IV pumps.</p> <p>Review of the facility's policy and procedure, Preventative Maintenance Schedule, indicated under II. "Departments will be scheduled for maintenance on designated months. Preventative maintenance will be scheduled within the scheduled month ...plus 90 days for Tier 2 devices. Tier 3 devices will be PM'd (preventative maintenance) initially and when serviced thereafter."</p> <p>3. During the initial tour of Room 1 on 1/13/11 at 11:45 AM, while accompanied by the Registered Nurse Clinical Coordinator, a cupboard under the supply storage counter next to the nurses' station had two full boxes of Telfa pads that had discolored packaging with expiration dates of 08/2006.</p> <p>When concurrently interviewed, the RNCC said she did not know why the Telfa pads were there. She said it was not the usual place they were stored.</p> <p>4. During inspection of medication and supply storage in Room 1 on 1/3/11 at 11:45 AM, while accompanied by the Registered Nurse Clinical Coordinator (RNCC), there was a half filled box of ascorbic acid packets in a cupboard above the solutions counter in Room 1 that had the expiration date 12/20/2010.</p> <p>When concurrently interviewed, the RNCC said they were used for inpatients and that inpatients were no longer being treated in Room 1.</p> <p>5. During the initial tour observation on 1/3/11 at</p>	V 403			

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V 403	Continued From page 36 11:50 AM, there was a dialysate bag warming cabinet in the peritoneal dialysis training area with a temperature reading of 100 degrees Fahrenheit (37.7 degrees Celsius). In an interview on 1/3/11 at 11:50 AM, RN 1 said she did not have a log to monitor the temperature of the warming cabinet but often checked it to make sure it was between 96 degrees to 100 degrees Fahrenheit. Review of the facility's 8/10 Operational Procedures (Warming CAPD [Continuous Ambulatory Peritoneal dialysis] Dianeal and Extraneal Solution [bag of dialysate fluids used in CAPD] Using Steris Warming Cabinet) indicated, "Indication: To enhance patient comfort and tolerance of the CAPD fluid infusion. DIANEAL and EXTRANEAL solutions may be warmed in the overpouch to 37 degree Celsius (98.6 degree Fahrenheit) prior to use...." 4. In an observation on 1/6/11 at 9:25 AM, there was an undated already primed bicarbonate cartridge at the bottom of the dialysis machine in Station 26. In an interview on 1/6/11 at 9:25 AM, PCT 4 said, "I would assume it was used and primed yesterday. I will throw it away." Review of the bicarbonate manual booklet entitled 2010 Operator's Manual for Bicart, indicated, "The concentrate in the Bicart cartridge must be used within 24 hours after being primed."	V 403			
V 407	494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS	V 407		2/1/11	

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V 407	<p>Continued From page 37</p> <p>Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement).</p> <p>This STANDARD is not met as evidenced by: Based on observation, the facility failed to ensure the safety of patients on 9 of 30 Stations when their vascular access site during dialysis treatment was covered and were not in staff's view. This failure placed patients at risk for undetected needle dislodgement or line disconnection to go undetected which poses risks for extensive loss of blood due to bleeding.</p> <p>Findings:</p> <p>1. During observation on 1/4/11 at 11:00 AM, patients' vascular access and bloodlines were covered with blanket in Stations 5, 9, 14 20 &25. Another observation on the same day at 3:00 PM found patients' access and bloodlines were covered with blankets in Stations 14, 24 & 28. When this was brought to the attention of staffs, they approached the patients and uncovered their accesses and bloodlines.</p> <p>In an interview on 1/4/11 at 11:35 AM, PCT 3 said the patients were cold and staffs tried to keep their access visible.</p> <p>2. During patient care observation on 1/5/10 at 10:50 AM, while accompanied by the assigned administrative staff, the patients at Station 19 and Station 21 had their access sites covered and not in view. When pointed out to the PCTs taking care of these patients, the PCTs asked the patients to expose their access sites.</p>	V 407			

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V 412	<p>494.60(d)(2) PE-ER PREP-PTS ORIENTED/TRAINED</p> <p>The facility must provide appropriate orientation and training to patients, including the areas specified in paragraphs (d)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure patients were oriented and trained on how to handle emergencies (cut and clamp) when one of 15 sampled patients (Patient 6) did not know what to do if there is a fire in the facility during his treatment. Failure to provide orientation and training on how to handle emergencies like fire could threaten the health and safety of the patient.</p> <p>Cut and Clamp is a procedure used in emergency evacuation where patients, relatives or staffs will clamp the access line (fistula, graft or catheter) and bloodlines and then cut the bloodlines (not the access line) to remove the patient from the dialysis machine and safely evacuate.</p> <p>Findings:</p> <p>In an interview on 1/5/11 at 3:30 PM, Patient 6 said he did not know what to do if there's a fire in the unit while he's undergoing dialysis treatment; although he said he's capable of walking and could look after himself if there's an emergency. He said nobody taught him what to do.</p> <p>Review of the 2010 Annual Patient Education Calendar For Outpatient Dialysis indicated, "Emergency Procedures - Patient demonstrates: a) the clamp and cut procedure correctly..." The form indicated the education should be done</p>	V 412		2/7/11	

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V 412	Continued From page 39 every three months but section for the "Emergency Procedures" were left blank.	V 412			
V 503	<p>Review of the facility's 3/09 Administrative: Charting and Chart Organization policy and procedure indicated, "Patient Education Calendar. The RN should ...Identify learning deficits using the Patient Educational Needs Assessment Form"</p> <p>494.80(a)(2) PA-APPROPRIATENESS OF DIALYSIS RX</p> <p>The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>(2) Evaluation of the appropriateness of the dialysis prescription,</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, for 1 of 15 sampled patients (Patient 3), the facility failed to assess and monitor weight after dialysis treatment. Weight is one of the components of dialysis prescription and should be done post treatment to ensure the physician's ordered target weight is achieved.</p> <p>In addition, for 1 of 15 sampled patients (Patient 5), the facility failed to ensure the physician's order for the blood flow rate was implemented during treatment.</p> <p>Findings:</p> <p>1. Patient 3 was admitted to the facility on 8/30/10 with diagnoses including ESRD. His 12/2010</p>	V 503		2/28/11	

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V 503	<p>Continued From page 40</p> <p>hemodialysis prescription included Estimated Dry Weight of 55 kg. (kilograms).</p> <p>Review of the Patient 3's 12/30/10 Outpatient Hemodialysis record indicated the patient's weight before treatment was 57.3 kg. (2.3 more than the dry weight). He started the treatment at 7:05 AM and at 7:37 AM complained of dizziness and was given oxygen 2 liters/minute. The patient remained stable throughout the treatment. The post assessment was done by the Registered Nurse but there was no post weight recorded. The record did not indicate whether the target weight was achieved.</p> <p>Review of 3/09 Patient Assessment: Pre and Post Dialysis policy and procedure indicated, "...Vital signs will include pre and post weight, temperature, heart rate, and sitting blood pressure on all patients...Pre and post dialysis assessments will be done on each patient by a Registered Nurse"</p> <p>2. Record review on 1/5/11 indicated Patient 5 was admitted to the facility on 5/14/09. Patient 5's current printed summary of physician's orders (MD orders) dated 1/3/11, indicated Patient 5 had a left arm A-V (arterial-venous) fistula access. The 1/3/11 MD orders included a hemodialysis order dated 12/21/10 that indicated: "Change blood flow rate to: 400 ml (milliliters)/ min (minute)." A line had been drawn through the 400 by hand, and 350 was written by hand after min. There was no indication when this change in blood flow rate (BFR) was made or by whom the change was made.</p> <p>Review of physician progress notes for December</p>	V 503			

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V 503	<p>Continued From page 41</p> <p>2010 and January 2011, found no indication the physician intended to change the blood flow rate from 400 to 350. Review of Patient 5's hemodialysis treatment (HD) records for 12/21/10 indicated Patient 5 had a right chest catheter access (RCC), and the treatment plan was BFR 400. The BFR was consistently documented at 250 throughout the treatment.</p> <p>On 12/23 and 12/28/10 the HD records indicated a RCC and a treatment plan for BFR 400. The BFR delivered throughout the treatments was consistently documented at 350. On 12/28/10, a notation in the HD record indicated the arterial pressure alarm continued and the blood lines were reversed, but there was no indication of arterial pressure problems throughout the treatment.</p> <p>On 12/29/10, the HD record indicated a RCC, and a treatment plan for BFR 400. The BFR was consistently documented at 400 throughout the treatment.</p> <p>On 12/31/10 and 1/3/11, the hemodialysis treatment record indicated an RCC and a treatment plan for BFR 350. Documentation indicated the BFR was consistently 350 throughout the treatments.</p> <p>None of the HD treatment records reviewed from 12/21/10 through 1/3/11 indicated a problem with treatment delivery at BFRs of 250, 350, or 400. There was no notation to indicate the physician was contacted to notify him of the delivered BFR when it did not match the current order, or to verify the prescribed BFR.</p>	V 503			

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V 503	Continued From page 42 During interview with the Registered Nurse Clinical Coordinator (RNCC) on 1/6/11 at 3 PM, she said when using a catheter access, the facility's policy was a BFR of no more than 350. She said Patient 5 's initial BFR order was for 400 because he had a fistula , but on 11/22/10, he was treated for an abscess at the fistula site and a catheter was placed for dialysis access. The RNCC said for a number of years the catheter company has said there was no problem with delivering treatment at BFR 400, if the catheter was well- placed. On 1/6/11 at 3:22 PM, the RNCC printed out a physician's order dated 1/3/11 from the computer. It indicated a change of the BFR to 350. The surveyor requested a copy of the facility's policy and procedure for BFRs with catheter access, but the RNCC came back and said she did not have time to get it because she had to go to the emergency room. On 1/6/11, the surveyor requested the policy for BFRs with catheter access from the Nurse Manger, but it was not provided by the end of the survey.	V 503			
V 508	494.80(a)(5) PA-ASSESS RENAL BONE DISEASE The patient's comprehensive assessment must include, but is not limited to, the following: (5) Evaluation of factors associated with renal bone disease. This STANDARD is not met as evidenced by:	V 508		2/28/11	

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V 508	<p>Continued From page 43</p> <p>Based on record review and interview, the facility failed to assess a high alkaline phosphatase blood value for 1 of 15 sampled patients (Patient 7).</p> <p>Quest Diagnostics.com indicated: "An alkaline phosphatase (ALP) test measures the amount of the enzyme ALP in the blood. Normal values may vary from lab to lab. The adult reference range is 25 to 100 units per liter (U/L). Very high levels of ALP can be caused by liver problems, such as hepatitis, blockage of the bile ducts (obstructive jaundice), gallstones, cirrhosis, liver cancer, or cancer that has spread (metastasized) to the liver from another part of the body. High ALP levels can be caused by bone diseases, such as Paget's disease, osteomalacia, rickets, bone tumors, or tumors that have spread from another part of the body to the bone, or by overactive parathyroid glands (hyperparathyroidism). Normal healing of a bone fracture can also raise ALP levels. Heart failure, heart attack, mononucleosis, or kidney cancer can raise ALP levels. A serious infection that has spread through the body (sepsis) can also raise ALP levels." (Thompson, MD, E. Gregory, Internal Medicine, and Dalkin, MD, Alan C., Endocrinology. Healthwise Staff, July 9, 2010)</p> <p>Findings:</p> <p>Record review on 1/6/11 indicated Patient was admitted to the facility on 3/2/10 with diagnoses including end stage renal disease secondary to nephrosclerosis. Review of Patient 7's laboratory blood values obtained in 12/2010 indicated his ALP was elevated at 2111 U/L. This was a</p>	V 508			

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V 508	<p>Continued From page 44</p> <p>marked elevation from Patient 7's previous ALP levels, which ranged between 69 and 148 between 3/2010 and 11/2010.</p> <p>Review of Patient 7's "Dialysis Monthly Clinical Review (the review) for 12/2010 found the elevated ALP was not included in the laboratory blood levels in the review and the physician's note in the review dated 12/16/10, did not reference the elevated ALP. Review of the progress notes for December 2010 found no reference to the elevated ALP.</p> <p>When interviewed on 1/6/11 at 4 PM, the Registered Nurse Clinical Coordinator (RNCC) had not been aware Patient 7's ALP was elevated. She stated she did not know why it had not been addressed. She checked the medical record, but found no analysis of the cause of the elevated ALP.</p> <p>Review of the facility's policy and procedure (P&P), "Interdisciplinary Assessment and Progress Notes/Monthly Review Form," found under "Purpose:Progress Notes /Monthly Review are used to: a. Ensure documentation of the patient's assessment problems/needs, interventions/action plan, and response to the interventions. b. Communicate information among the various disciplines, further document information or problems noted in other parts of the medical record (e.g. consults, flowsheets, lab results, etc.)." Under "Policy," the P&P read, "...2...progress notes are documented on the Progress Notes/Monthly Clinical Review Form of the patient's record...5. Documentation related to medical necessity, such as the medical assessment of the patient and evaluation of all</p>	V 508			

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V 508	Continued From page 45 interventions...may be placed in the Progress Notes/Monthly Review Form. 6. Medical necessity is defined as "detailed narrative assessment and plan of care statements in the medical record that support current medical therapy and provide evidence of active patient monitoring. Medical necessity must include the evaluation and the results of actions taken..."	V 508			
V 509	494.80(a)(6) PA-RD-NUTRITIONAL STATUS The patient's comprehensive assessment must include, but is not limited to, the following: (6) Evaluation of nutritional status by a dietitian This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to provide documentation for 1 of 15 sampled patients (Patient 5) that his diet was evaluated by the dietician when he had low a albumin blood level. Albumin levels are indications of adequate protein required for the maintenance and repair of body tissue. Low albumin levels are associated with an inability to heal wounds, increased risk of infection and muscle wasting. Findings: Record review on 1/5/11 indicated Patient 5 was admitted to the facility on 5/14/09. Review of his laboratory values indicated on 12/8/10 his albumin level was 2.8 Normal levels of albumin are between 3.5 and 5.0. The albumin level goal for chronic kidney disease is greater than four	V 509		2/28/11	

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V 509	<p>Continued From page 46</p> <p>("Dialysis Lab Values at a Glance," Centers for Medicare and Medicaid Services - Version 1.0, revised July 2008) .</p> <p>Record review on 1/5/11, of Patient 5's "Monthly Clinical Review" for December, 2010 found the section designated for the Registered Dietician's (RD) evaluation was left blank.. Review of Patient 5's progress notes for December 2010 and January 2011, found no documentation by the RD.</p> <p>When interviewed on 1/6/11 at 3:40 PM, the RD acknowledged she had not documented her evaluation of the low albumin level, but said she had spoken with Patient 5 when he came back from the hospital at his first treatment on 12/8/10. She said Patient 5 took the protein supplement Nepro at home. The RD presented an undated, unsigned "Dialysis Nutrition Report" for Patient 5 which indicated his albumin level on 1/5/11 was 3.3. The RD said this report was given to Patient 5.</p> <p>Review of the "Dialysis Nutrition Report" indicated a goal range for albumin of 3.2 to 5.0, which was a lower range than the standard established by the Centers for Medicare and Medicaid Services. Under the column entitled, "What You Can Do," the printed form indicated: "Two low: eat enough high quality protein foods and protein supplements if necessary. " Above this was handwritten, "Increase protein intake." The section for comments at the bottom of the "Dialysis Nutrition Report" was left blank. There was no personalized analysis of Patient 5's actual intake of the Nepro, or of other sources of protein. There was no analysis of possible</p>	V 509			

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V 509	Continued From page 47 causes for the low albumin level. There was no individualized plan for increasing his protein intake. There was no notation to indicate the report was discussed with Patient 5, or his response to it. Review of the facility's policy and procedure (P&P), "Interdisciplinary Assessment and Progress Notes/Monthly Review Form," found under "Purpose:Progress Notes /Monthly Review are used to: a. Ensure documentation of the patient's assessment problems/needs, interventions/action plan, and response to the interventions. b. Communicate information among the various disciplines, further document information or problems noted in other parts of the medical record (e.g. consults, flowsheets, lab results, etc.)." Under "Policy," the P&P read, "...2...RD...progress notes are documented on the Progress Notes/Monthly Clinical Review Form of the patient's record...5. Documentation related to medical necessity, such as the medical assessment of the patient and evaluation of all interventions...may be placed in the Progress Notes/Monthly Review Form. 6. Medical necessity is defined as "detailed narrative assessment and plan of care statements in the medical record that support current medical therapy and provide evidence of active patient monitoring. Medical necessity must include the evaluation and the results of actions taken..."	V 509			
V 715	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and	V 715		2/28/11	

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V 715	<p>Continued From page 48</p> <p>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, interview and record review, the facility failed to ensure all staffs adhered to facility's medication policy and procedure when one licensed staff (RN 4) administered the Venofer injection to Patient 12 in less than 5 minutes as written in the facility's policy. Failure to adhere to an approved policy and procedure increased the potential for medication error which could compromise the patient's safety.</p> <p>Venofer is a medication used to replenish iron stores in the body to treat anemia.</p> <p>Findings:</p> <p>Patient 12 was admitted to facility on 12/21/10 with diagnoses including ESRD (End-Stage Renal Failure). Her 12/2010 hemodialysis treatment order included Venofer 100 mg. (milligrams)</p> <p>During medication pass observation on 1/6/10 at 3:45 PM, RN 4 administered the Venofer 100 mg. intravenously in approximately 1 minute.</p> <p>In an interview on 1/6/10 at 3:50 PM, RN 4 said she administered the Venofer 100 mg. in less than a minute because the medication gets diluted by the patient's blood before it reached the patient's vein.</p> <p>Review of the 3/09 Venofer Administration policy</p>	V 715			

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V 715	Continued From page 49 and procedure indicated, "Give 100 mg Venofer (5 ml. undiluted) slow IV [intravenous] push over 5 minutes..."	V 715			