

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

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>052627</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>03/09/2011</b>
NAME OF PROVIDER OR SUPPLIER  <b>LA PALMA DIALYSIS CENTER</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>5451 LA PALMA AVENUE, SUITE 35 LA PALMA, CA 90623</b>		
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V 000	<p><b>INITIAL COMMENTS</b></p> <p>The following reflects the findings of the California Department of Public Health during a RECERTIFICATION survey.</p> <p>The surveyors entered the facility on 3/7/11 at 0800 hours. The census at the time of the survey was 92 in-center hemodialysis patients and 9 home peritoneal dialysis patients. The patient sample consisted of 8 home peritoneal dialysis patients and 7 in-center hemodialysis patients.</p> <p>The Facility Administrator was the facility coordinator for the survey.</p> <p>Representing the Department of Public Health: Surveyors 22781, HFEN; 21262, HFEN and 22779, HFEN.</p> <p><b>GLOSSARY</b></p> <p>Biomed - Biomedical engineering is the application of engineering principles and techniques to the medical field. BP - Blood Pressure BFR - Blood Flow Rate CHT - Certified Hemodialysis Technician EDW - Estimated Dry Weight FA - Facility Administrator IV - Intravenous Kg - Kilogram (equal to 2.2 pounds) mL - milliliters PD - Peritoneal Dialysis PPE - Personal Protective Equipment P&amp;P - Policy and Procedure Reverse Osmosis - a filtration method that removes many types of large molecules and ions from solutions by applying pressure to the</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 solution RN - Registered Nurse	V 000			
V 111	494.30 IC-SANITARY ENVIRONMENT  The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.  This STANDARD is not met as evidenced by: Based on observation and facility policy review, the facility failed to monitor the treatment area and provide a sanitary environment in order to reduce the potential for infection.  Findings:  The facility policy, "Environmental Control", dated 12/09/08, showed that dialysis machines, patient chairs, and counter tops were to be clean to sight and touch. Floors were to be free of dirt and debris. Machines, chairs and accessory equipment were to be cleaned after each patient.  Findings:  During observation of the treatment area from 3/7 to 3/9/11, the following was found: * Missing areas of laminate on the counters at the nursing station, at the sink areas and behind the patient chairs exposing the porous wood underneath. The lack of intact surfaces does not allow for effective disinfection of the areas. * Open areas in the vinyl coverings on all the dialysis chairs exposing the porous stuffing. * The corner of the laminate counter behind the sink by the scale was splitting apart at the seams	V 111			

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V 111	Continued From page 2 from water damage. The screws in the mountings holding the glass partition on the counter behind the sink, and the hinges on the cabinet under the sink were rusty from water damage. * There was water damage to the area around the sink at the nurses' station. * On the wall of the counter area behind the dialysis machine at Station 9 there was a hole through the entire thickness of the wall with a large cracked area next to the hole. * There was black dirt on top of the plastic housings in the counter area where the water and drainage pipes for the dialysis machines was located. * The separate small counter area between Stations 11 and 12 had chipped areas in the laminate exposing the porous wood underneath. * The side of the square pillar next to the dialysis machine at Station 11, facing the nurses' station, had an area of missing paint approximately 12 inches above the baseboard. At the corner of the pillar above the baseboard was a rusted area approximately 2 inches by 3 inches. There were areas of exposed metal at the corner of the pillar. * There were areas of the flooring in the treatment area where the top protective coating was missing making the areas porous. The areas with the missing coating looked dark gray/black.  On 3/9/11, an interview was conducted with the facility Medical Director. During the interview, the Medical Director acknowledged the conditions that were observed by the surveyors.	V 111			
V 113	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE	V 113			

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V 113	Continued From page 3 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 and facility policy review, the facility failed to ensure gloves were being worn and hands washed, when one staff member was caring for patients or exposed to potentially contaminated tasks or items that could possibly cause the spread of infection.  Findings:  On 3/8/11 at 1610 hours, RN 2 was observed removing a glove from a patient's hand. The patient had used the glove to hold his access site after the dialysis treatment. RN 2 was not wearing gloves. After discarding the patient's glove, RN 2 walked through the unit touching other items, such as patient chairs and tables, prior to cleaning her hands.	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.	V 115			

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V 115	<p>Continued From page 4</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the facility failed to ensure staff wore PPE when performing procedures where exposure to blood might occur. The facility failed to ensure staff members were not wearing their PPE into non-treatment areas, such as the patient waiting area and the staff lounge. These failures could result in the spread of infection.</p> <p>Findings:</p> <p>1. On 3/7/11 from 1415 to 1510 hours, RN 1 had drawn up 11 medication syringes and was observed administering the medications into patients' blood lines. RN 1 was not wearing a face shield. RN 1 did have on a surgical mask that had been pulled down under her chin and offered no protection to her nose and mouth area.</p> <p>On 3/8/11 at 1615 hours, RN 2 was observed at Station 5 injecting medications into the patient's blood line. RN 2 was not wearing a face shield or mask. RN 2 removed the gloves and returned to the medication station. No hand hygiene was observed. RN 2, put on new gloves and prepared more medication syringes. RN 2 took the medications to Station 8 and injected the medications into the patient's blood line. RN 2 was not wearing a face shield or mask.</p> <p>During an interview with the FA on 3/9/11 at 0920 hours, she stated that a face shield was required when giving patient medications because of possible blood spurts.</p> <p>2. On 3/7/11 at 0800 hours, CHT 5 was observed in the patient waiting area wearing a gown, gloves</p>	V 115			

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V 115	Continued From page 5 and mask.  On 3/9/11 at 1310 hours, CHT 2 was observed entering the patient waiting area wearing their gown and mask. 3. On 3/7/11, signage by the door before entering the staff lounge showed "No PPE Beyond This Point."	V 115			
V 116	On 3/9/11 at 1330 hours, the Dietitian was noted in the staff lounge sitting at a table eating her lunch. The Dietitian was wearing a PPE gown and a mask pulled underneath her chin. The FA was asked regarding the PPE boundary. It was stated, "...the PPE was to be removed before entering the lunch room, bathrooms and offices."  494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT  Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient. -- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient. -- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.  This STANDARD is not met as evidenced by: Based on observation and interview, the facility	V 116			

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V 116	<p>Continued From page 6</p> <p>failed to ensure electronic thermometers and glucose testing equipment taken into patient stations were disinfected between patients. The facility failed to ensure carts containing medical supplies were not moved between patient stations without being disinfected. These failures could possibly lead to the spread of infection.</p> <p>Findings:</p> <p>The facility policy, "Infection Control Precautions for All Patients," dated 12/9/08, showed items taken into patient stations should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.</p> <p>The facility policy, "Infection Control Surveillance/Monitoring and Infection Prevention Program," dated 12/8/09, showed if a common supply cart was used to store clean supplies in the patient treatment area, this cart should remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood.</p> <p>The facility policy, "Infection Control Surveillance/Monitoring and Infection Prevention Program," dated 12/9/08, showed items taken into the dialysis station [(including those items placed on the top or sides (baskets)] of the dialysis machine and dialysis chair, should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common area or used on another patient.</p>	V 116			

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V 116	<p>Continued From page 7</p> <p>The above P&amp;Ps were not implemented as follows:</p> <ol style="list-style-type: none"> <li>1. All dialysis machines in the facility had a bottle of test strips (used to test for the presence of disinfectant in the dialyzers) stored in the blood pressure cuff holder mounted on the side of the machine. Each shift the CHTs would remove the test strip container from the holder wearing contaminated gloves to remove a test strip. During observation of the treatment area on 3/7, 3/8 and 3/9/11, the containers and the blood pressure cuff holders were not being disinfected between patient treatments.</li> <li>2. During observation of the treatment area on 3/7/11 at 1000 hours, two small white wooden carts on rollers were observed sitting in the treatment area behind Stations 11 and 12. Staff members were observed moving the carts between patient dialysis stations. Further observation of the carts showed they contained diabetic blood sugar testing supplies and a blood sugar testing machine.</li> </ol> <p>On 3/7/11 at 1021 hours, CHT 1 was observed rolling one of the carts over to the patient at Station 4. After completing the blood sugar test, CHT 1 took the cart back to the area behind Stations 11 and 12. After returning the cart CHT 1, wearing the same contaminated gloves, went to the clean supply cart next to the nurses' station and got an electronic thermometer and returned to Station 4 to take the patient's temperature. The electronic thermometer was returned to the clean supply cart and CHT 1 was still wearing the same gloves. The cart and the blood sugar testing machine were not disinfected before or</p>	V 116			

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V 116	<p>Continued From page 8</p> <p>after being returned to their storage location. The electronic thermometer was not disinfected after use or before being returned to the clean supply cart.</p> <p>At 1023 hours on 3/7/11, RN 2 took the same blood glucose cart used by CHT 1 to Station 3. After taking the patient's blood sugar, RN 2 returned the cart back to the area by Stations 11 and 12. The cart or the blood sugar testing machine were not disinfected before taking the cart to Station 3 or after returning the cart to the storage area.</p> <p>3. On 3/7/11 at 1330 hours, CHT 5 removed an electronic thermometer from the clean supply cart next to the nurses' station and took it to Station 6. After taking the patient's temperature, the thermometer was returned to the clean supply cart. The thermometer was not disinfected after use or before being returned to the clean supply cart.</p> <p>4. On 3/7/11 at 1457 hours, CHT 6 removed an electronic thermometer from the clean storage cart and took it to Station 11. After taking the patient's temperature, the thermometer was returned to the clean storage cart. The thermometer was not disinfected after use or before being returned to the clean supply cart.</p> <p>5. On 3/9/11 at 0847 hours, CHT 3 was observed removing an electronic thermometer from the clean supply cart. After taking the patient's temperature, the thermometer was returned to the clean supply cart. The thermometer was not disinfected after use or before being returned to the clean supply cart.</p>	V 116			

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V 122	<p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL</p> <p>[The facility must demonstrate that it follows standard infection control precautions by implementing-</p> <p>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]</p> <p>(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.</p> <p>This STANDARD is not met as evidenced by: Based on observation and facility policy review, the facility failed to ensure the cleaning and disinfection of contaminated treatment equipment was done per policy which could possibly cause cross-contamination and patient infections.</p> <p>Findings:</p> <p>Facility policy review was initiated on 3/8/11.</p> <p>The facility policy, "Infection Control/Safety for Environmental Control" dated 12/9/08, showed after each patient the machines, chairs and accessory equipment were to be cleaned with a 1:100 dilution of household bleach.</p> <p>The facility policy, "Infection Control Precautions for All Patients" dated 12/9/08, showed chairs, tables and machines should be cleaned and disinfected between patients. Special attention should be given to cleaning the control panels on the dialysis machines and other surfaces that were frequently touched and potentially contaminated with patient blood. All fluids should be discarded. Surfaces associated with the prime</p>	V 122			

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V 122	<p>Continued From page 10</p> <p>waste (including containers attached to the machines) were to be cleaned and disinfected</p> <p>The facility policy, "Infection Control Surveillance/Monitoring and Infection Prevention Program" dated 12/9/08, showed that items taken into the dialysis station (including those items placed on the top or sides (baskets) of the dialysis machine and dialysis chair, should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common area or used on another patient.</p> <p>The facility P&amp;Ps were not implemented as follows:</p> <ol style="list-style-type: none"> <li>1. All dialysis machines in the facility had a bottle of test strips (used to test for the presence of disinfectant in the dialyzers) in the blood pressure cuff holder mounted on the side of the machine. Each shift the CHTs would reach into the holder wearing contaminated gloves to remove a test strip from the container. During intermittent observations of the treatment area from 0800 to 1700 hours on 3/7, 3/8 and from 0800 to 1100 hours on 3/9/11, these containers or the blood pressure cuff holders were not being disinfected between patient treatments.</li> <li>2. At all dialysis stations was a separate table on which was placed a plastic clipboard that contained the patient's treatment sheet. Staff were observed doing patient care and going to the table wearing their contaminated gloves to chart on the treatment sheet. Observation of the treatment area on 3/7, 3/8 and 3/9/11, showed the tables and clipboards were not consistently</li> </ol>	V 122			

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V 122	Continued From page 11 being disinfected between patients. Some staff members were observed removing their gloves, cleaning their hands and documenting on the contaminated treatment sheet area without gloves, and then putting on a clean pair of gloves without cleaning their hands.  3. On 3/7/11 at 1317 hours, after the patient treatments were started, patient medical records were observed being placed on the contaminated tables while the patients' physicians made rounds and documented in the records. After the rounds were finished, the records were removed from the contaminated tables and, without disinfection, placed back in a cart next to the nurses' station.  4. On 3/7 and 3/9/11 observation of the disinfection of the dialysis machines showed the IV poles, the clamps on the poles and the prime waste containers were not disinfected as follows: *On 3/7/11 at 0855 hours, CHT 5 at Station 12. *On 3/9/11 at 0847 hours, CHT 2 at Station 8. *On 3/9/11 at 0856 hours, RN 2 at Station 11. *On 3/9/11 at 0857 hours, CHT 3 at Station 12.  On 3/9/11 at 0906 hours, an interview was done with CHT 4. CHT 4 stated between treatments the machines were to be disinfected. They were to disinfect the screen, the front and sides of the machines, and the acid and bicarbonate containers on the machines.	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	V 143			

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V 143	<p>Continued From page 12</p> <p>medications from vials and ampules; and</p> <p>This STANDARD is not met as evidenced by: Based on observation, policy review and staff interview, the facility failed to ensure staff members demonstrated compliance with current aseptic techniques when dispensing and administering medications which could possibly spread infections.</p> <p>Findings:</p> <p>The facility policy, "Infection Control Surveillance/Monitoring and Infection Program" dated 12/9/08, showed staff should wear appropriate PPE for anticipated potential exposure such as when administering medications through the dialysis bloodlines. The rubber stopper of multi-use vials should be cleaned with an alcohol pad before inserting the needle. The P&amp;P was not implemented as follows:</p> <p>1. On 3/7/11 at 1455 to 1510 hours, RN 1 was observed preparing patient medications. RN 1 used the same single use alcohol prep pad to disinfect the rubber stoppers on the different medication vials used while preparing 11 medication syringes. When preparing two of the syringes, the alcohol pad was left lying on the counter, the medication vials were turned upside down and the stopper was moved back and forth over the alcohol pad to disinfect it. One medication vial disinfected in this manner did not have a flat rubber stopper. The rubber stopper on the vial was indented so the rubber stopper</p>	V 143			

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V 143	Continued From page 13 could not come in contact with the alcohol pad as it was passed over. RN 1 was observed administering the medications into the patients' blood lines not wearing a face shield. RN 1 did have on a surgical mask that had been pulled down under her chin and offered no protection to her nose and mouth area.  2. On 3/8/11 at 1615 hours, RN 2 was observed at Station 5 injecting medications into the patient's blood line. RN 2 was not wearing a face shield or mask. RN 2 removed the gloves and returned to the medication station. No hand hygiene was observed. RN 2, put on new gloves and prepared more medication syringes. RN 2 took the medications to Station 8 and injected the medications into the patient's blood line. RN 2 was not wearing a face shield or mask.  On 3/9/11 at 0910 hours an interview was done with Charge RN 2. Charge RN 2 stated a new alcohol prep pad should be used each time the rubber stopper on a medication vial was disinfected.  During an interview with the FA on 3/9/11 at 0920 hours, she stated a face shield was required when RNs were giving medications because of possible blood spurts.	V 143			
V 184	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.	V 184			

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V 184	<p>Continued From page 14</p> <p>Access to the purification system should be restricted to those individuals responsible for monitoring and maintenance of the system.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the facility failed to have a secured water purification and storage system. Being unable to secure the water purification area exposed the entire system, including the processed (disinfected) dialyzers for reuse and medical supplies to potential tampering.</p> <p>Findings:</p> <p>On 3/7/11 at 0830 hours, the initial tour of the water purification system was conducted with the Reuse Technician.</p> <p>The water purification system was located on the same third floor of the dialysis treatment area past the reception/lobby area, the nurses' station, the Biomed office and the laboratory room. The room, approximately 15-foot wide and 20-foot long, was combined with the reuse processing area and storage for medical supplies, such as boxes of protective gowns, masks, urinals and intravenous (IV) fluids. A rusty metal shelf containing medical supplies marked the division between the reuse section from the storage area while the water system occupied the full length of the backwall. Upon entry to the room, the reuse section occupied approximately a 6 X 12 foot area on the left hand side with a work table in the middle. Processed patient dialyzers were labeled and displayed in the respective pigeonholes attached to the wall before the exit door. Behind the work table were eight drums of mixed acid</p>	V 184			

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V 184	Continued From page 15 solutions. The right side, next to the medical supplies, contained carts of empty jugs of bicarbonate and acids for distribution to patients' stations. Two standby hemodialysis machines stood between the two rusty metal shelves and beside a housekeeping mop and bucket.  On 3/9/11 at 0830 hours, a pallet of intravenous fluids was noted stacked next to the reverse osmosis housing. In an interview with the Reuse Technician, the IV fluids (48 boxes) were delivered the afternoon before, using a pull cart requiring several trips, coming through the exit door. When the Reuse Technician was asked who supervised the incoming and outgoing of the delivery crew, he made no comment.  On 3/9/11 at 1030 hours, a package delivery crew was observed to walk directly inside the water purification system area; bypassing the reception area, nurses' station and the reuse area. The Reuse Technician and Biomed 1 both acknowledged the water purification area should be restricted to authorized personnel only. It was added that the cleanliness of the deliveries was unknown, which exposed the clean reuse and dialyzer processing area to possible dirt contamination.	V 184			
V 211	494.40(a) H2O DIST SYS-CONSTANT FLOW/NO DEAD ENDS  5.3.3 Water distribution systems: continuous flow rates/no dead ends Water distribution systems should be configured as a continuous loop and designed to minimize bacterial proliferation and biofilm formation. A centrifugal pump made of inert materials is necessary to distribute the purified water and aid	V 211			

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V 211	<p>Continued From page 16 in effective disinfection.</p> <p>7 Strategies for bacterial control 7.1 General To minimize biofilm formation, there should always be flow in a piping system. A minimum velocity of 3 ft/sec in the distal portion of the loop of an indirect feed system and a minimum velocity of 1.5 ft/s in the distal portion of a direct feed system are recommended when the system is operating under conditions of peak demand.</p> <p>Dead-end pipes and unused branches and taps that can trap fluid must be eliminated because they act as reservoirs of bacteria and are capable of continuously inoculating the entire volume of the system. These measures also minimize the possibility that pockets of residual disinfectant could remain in the piping system after disinfection.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the water purification system was found with two 4 foot clear plastic tubes attached to the sample ports with the tips of the tubes resting inside a common sink. The tubing contributed to prevention of accidental water drips wetting the floor, however, the tubing also served as reservoirs of bacteria related to trapped fluid with infrequent downward water flow.</p> <p>Findings:  On 3/7/11 at 0830 hours, during the initial tour of the water purification system, accompanied by the Reuse Technician, the sample port of the</p>	V 211			

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V 211	Continued From page 17 primary carbon tank had a 4-foot clear plastic tube with the tip of the tube laying down in a common sink. Another 4-foot clear plastic tube was found after the secondary carbon tank, also with the tip of the tube resting in the common sink. Both end tips did not have a protective cap.  At 0900 hours, the Reuse Technician was asked the purpose of the extended tubes. It was demonstrated how fluid content was allowed to flow down to the common sink for a few seconds using the extended tubing to prevent possible drips on the floor. The Reuse Technician verbalized the technique was time-saving when collecting processed fluid into a clean container for monitoring the performance of the tank.  On 3/7/11 at 1330 hours, Biomed 1 had taken the two clear plastic tubes out of the common sink and strapped the tubes to their respective carbon tanks. He stated that it was okay to keep the plastic tubing there because the downward flow of the fluid from the carbon tanks flushed possible bacteria away from the tank.  On 3/8/11 at 0800 hours, the tips of both plastic tubes coming from the sample ports were back in the common sink. The PD nurse, who also worked in the hemodialysis treatment area, stated the common sink was considered "dirty," contaminating the connected tubing.	V 211			
V 232	494.40(a) BICARB MIX SYS-EMPTY/DISINFECT/PREV CORROSION  5.4.4.3 Bicarbonate concentrate mixing systems: empty/ disinfect/prevent corrosion Bicarbonate concentrate mixing tanks should be designed to drain completely.	V 232			

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V 232	Continued From page 18  Mixing tanks should have a tight-fitting lid and should be designed to allow all internal surfaces to be disinfected and rinsed.  Because concentrate solutions are highly corrosive, mixing systems should be designed and maintained to prevent corrosion.  This STANDARD is not met as evidenced by: Based on observation and staff interview, the bicarbonate tank area was not maintained clean and free of spills to prevent corrosion of the container. Corrosion on metal parts prevent effective cleaning of the affected areas.  Findings:  On 3/7/11 at 0830 hours, initial tour of the water purification system, accompanied by the Reuse Technician, revealed bicarbonate powder on the floor and on the legs and braces of the bicarbonate mixing tank. There was rusty corrosion on the metal frames touching the floor which was pointed out to the Reuse Technician. He acknowledged the corrosive effects of bicarbonate and stated the facility had to keep up painting the corroded parts to allow effective cleaning of the area.	V 232			
V 300	494.50 CFC-REUSE OF HEMODIALYZERS & BLOODLINES  This CONDITION is not met as evidenced by: Based on observation, record review and staff interview, the facility failed to ensure their scheduled air-level testing for the reuse room and	V 300			

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V 300	<p>Continued From page 19</p> <p>treatment area was completed to make sure harmful germicidal vapors were within exposure limits. The facility failed to maintain a dialyzer reprocessing area that was restricted to authorized personnel and controlled contamination of reprocessed dialyzers.</p> <p>Findings:</p> <p>1. On 3/7/11 at 0950 hours, an interview was done with Biomed 1 regarding the air testing of the dialyzer reprocessing area, clean supply storage area and the treatment room. These areas were in one room. Biomed 1 stated the reuse room was to be tested on a monthly basis, and the treatment room was to be tested every three months. The germicide used by the facility to disinfect reused dialyzers between patient treatments is composed of acetic acid and hydrogen peroxide.</p> <p>Review of the air/vapor testing record showed it was for 2010. However, the last test taken for the treatment area was 10/28/10, and the last testing performed in the reuse area was for 1/26/11. See V318.</p> <p>2. On 3/7/11 at 1600 hours the facility's dialyzer reprocessing area and the medical supply storage areas were observed combined in one room. On 3/7/11 at 1600 hours, during an interview with the Reuse Technician, five empty pizza boxes were observed in the reuse processing area. An electric fan with accumulated dust and dirt recirculated the air in the room. The Reuse Technician stated the empty boxes of pizza had been sitting there since lunch waiting for disposal by the housekeeper. The</p>	V 300			

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V 300	<p>Continued From page 20</p> <p>housekeeper was expected to clean the facility at 2130 hours.</p> <p>On 3/7/11 at 1600 hours the Reuse Technician was asked which route the housekeepers take to dispose of biohazard materials, such as bloody dialysis tubing and sponges. The Reuse Technician stated the housekeeper walks through the reprocessing and clean storage areas to the exit door. This route exposed the clean, reprocessed dialyzers and clean supplies to potential blood contamination.</p> <p>On 3/9/11 at 1430 hours, within the same room as the water treatment, reprocessing and storage of medical supplies, were drums of potassium and multiple empty jugs for distribution of bicarbonate occupying the middle of the floor. The processed dialyzers were exposed to chemical (acids and bicarbonate) splashes during refills of the distributing jugs. Biomed 1 admitted to chemical spills twice when it was decided to manually refill the individual jugs.</p> <p>3. On 3/9/11 at 1100 hours, a pallet of IV fluids (48 boxes) was stacked beside the reverse osmosis tank. Reverse osmosis is a process for purification of the water used in hemodialysis and disinfection of used hemodialyzers (reprocessing). The Reuse Technician stated the exit door was unlocked the afternoon before to facilitate the delivery via a dolly. When asked who supervised the delivery personnel to ensure nothing was disturbed, the Reuse Technician did not make any comment.</p> <p>While speaking to Biomed 1 and the Reuse Technician, a delivery person bypassed the</p>	V 300			

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V 300	Continued From page 21 reception area and the nurses' station, and walked directly inside the water treatment area to deliver a small box. The box was placed on the clean work table in the reuse processing area. When Biomed 1 and the Reuse Technician were asked how the facility limited entry to the hemodialyzer reuse processing area, no comment was made. See V321.	V 300			
V 318	494.50(b)(1) REPROCESSING AREA & VENTILATION  ANSI/AAMI RD47:2002/A1:2003 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1) 8 Physical plant and environmental safety considerations 8.1 Reprocessing area and ventilation The reprocessing area should be designed to suit the operation carried out and maintain acceptable ambient concentrations of harmful substances (see Table 1). The area should be kept clean and sanitary. It may be part of the dialysis treatment area, as long as equipment used is properly designed and vented to meet the requirements for environmental safety (see [AAMI] 8.5).  Table 1-OSHA environmental exposure limits (29 CFR 1910, 1 July 1998), except as indicated Substance/material Limits (PEL)a Acetic acid 10 ppm TWAb  Chlorine dioxide (syn: chlorine oxide) 0.1 ppm TWA  Citric acid None developed	V 318			

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V 318	Continued From page 22  Formaldehyde            0.75 ppm TWA 2 ppm STELc(15 min)  0.5 ppm action level  Glutaraldehyde            0.2 ppm ceiling NIOSH/OSHA  Hydrogen peroxide        1 ppm TWA  Peracetic acid              None developed  Phenol                        5 ppm TWA ppm = parts per million a) PEL (permissible exposure limit) represents the limit of what employees can be exposed to; PELs can be TWAs or STELs. b) TWA (time-weighted average) represents the limit of what an employee can be exposed to in an eight-hour period. c) STEL (short-term exposure limit) represents the limit of what an employee can be exposed to in any 15-minute time period.  This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to ensure their scheduled air-level testing for the reuse room and treatment area were completed to make sure the ventilation system was functioning and harmful substance vapors were within exposure limits.  Findings:  The germicide used by the facility to disinfect	V 318			

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V 318	Continued From page 23 reused dialyzers between patient treatments is composed of acetic acid and hydrogen peroxide. The Occupational Safety and Health Administration (OSHA) has indicated certain exposure limits for these items. Testing should be performed on a scheduled basis to ensure the exposure limits of these chemicals did not exceed the levels set by OSHA.  On 3/7/11 at 0950 hours, an interview was done with Biomed 1 regarding the air testing of the dialyzer reprocessing area, clean supply storage area and the treatment room. These areas were in one room. Biomed 1 stated the reuse room was to be tested on a monthly basis, and the treatment room was to be tested every three months.  Review of the air/vapor testing record showed it was for 2010. The record provided showed the test results were within the set limits. However, the last test taken for the treatment area was 10/28/10, and the last testing performed in the reuse area was for 1/26/11.	V 318			
V 321	494.50(b)(1) STORAGE AREA/SEGREGATE DIALYZERS  8.2 Storage area: segregation of dialyzers in process Reprocessing materials, hemodialyzers awaiting reprocessing, and reprocessed hemodialyzers should be stored so as to minimize deterioration, contamination, or breakage. New, used, and reprocessed dialyzers should be segregated to make clear the status of each group of dialyzers. Environmental contamination of the storage area should be controlled and monitored, if the personnel determine those actions to be	V 321			

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V 321	<p>Continued From page 24</p> <p>necessary. Storage areas for new dialyzers and reprocessing materials should be designed to facilitate rotation of stock and cleaning. Storage arrangements should also take into account fire safety considerations, OSHA regulations, and other appropriate regulations.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the facility failed to maintain a dialyzer processing area that was restricted to authorized personnel, controlled contamination of reprocessed dialyzers/supplies and maintained patient confidentiality. This created the potential for cross contamination of dialyzers and clean dialysis supplies and patient information displayed to the public.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. The facility's water treatment system, the dialyzer processing area for reuse, and the medical supply storage areas were combined in one room. On 3/7/11 at 1600 hours, during an interview with the Reuse Technician, five empty pizza boxes were observed in the reuse processing area on top of bicarbonate bags while an electric fan with accumulated dust and dirt recirculated the air in the room. The Reuse Technician stated the empty boxes of pizza had been sitting there since after lunch waiting for disposal by the housekeeper. The housekeeper was expected to clean the facility at 2130 hours.</li> <li>2. On 3/7/11 at 1600 hours the Reuse Technician was asked which route the housekeepers take to dispose of biohazard materials, such as bloody dialysis tubing and</li> </ol>	V 321			

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V 321	<p>Continued From page 25</p> <p>sponges, The Reuse Technician stated the housekeeper goes through the reprocessing and clean storage areas to the exit door. This route exposed the clean, reprocessed dialyzers and clean supplies to potential blood contamination.</p> <p>On 3/9/11 at 0910 hours, the FA was asked regarding the housekeepers' infection control training. The FA stated the housekeepers were provided by the building management. The dialysis facility did not provide oversight of the cleaning practices of the housekeepers.</p> <p>3. On 3/8/11 at 1430 hours, within the same room as the water treatment, reprocessing and storage of medical supplies, were drums of potassium and multiple empty jugs for bicarbonate occupying the middle of the floor. In-between two permanent shelves of medical supplies were two standby hemodialysis machines. The housekeeper's bucket and mop were next to the dialysis machines and clean medical supplies.</p> <p>At 1430 hours on 3/8/11, dusty metal spare parts were noted on the floor underneath the shelves where clean supplies were stored. Biomed 1 and the Reuse Technicians were asked how the heavy equipment would allow effective cleaning of the floor. It was stated the Reuse Technician had to move the acid drums around to wipe the middle of the floor, but they could not clean under the fixed shelving.</p> <p>Biomed 1 added the dirty utility room was combined with the area for laboratory specimens. The small biomed office was also converted to store other supplies such as bleach and soap. When asked how the hemodialysis machines</p>	V 321			

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V 321	Continued From page 26 were being repaired and tested for performance, he stated he had to make space in the crowded water treatment room where water and a sink were available. The repair of the hemodialysis machines and the processing of the used dialyzers exposed clean and sterile supplies to blood and chemical splashes. The processed dialyzers were exposed to chemical (acids and bicarbonate) splashes during refills of the distributing jugs and repair of the hemodialysis machines. Biomed 1 admitted to chemical spills twice when it was decided to manually refill the individual jugs.  4. On 3/9/11 at 1100 hours, a pallet of IV fluids (48 boxes) was stacked beside the reverse osmosis tank. Reverse osmosis is a process for purification of the water used in hemodialysis and disinfection of used hemodialyzers (reprocessing). The Reuse Technician stated the exit door was unlocked the afternoon before to facilitate the delivery via a dolly. When asked who supervised the delivery personnel to ensure nothing was disturbed, the Reuse Technician did not make any comment.  While speaking to Biomed 1 and the Reuse Technician, a delivery person bypassed the reception area and the nurses' station, and walked directly inside the water treatment area to deliver a small box. The box was placed on the clean work table in the reuse processing area. When Biomed 1 and the Reuse Technician were asked how the facility limited entry to the hemodialyzer reuse processing area, no comment was made.	V 321			
V 401	494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE	V 401			

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V 401	<p>Continued From page 27</p> <p><b>ENVIRONMENT</b></p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the facility failed to maintain a safe and comfortable environment for the patients and staff posing infection control and safety risks and the possible use of potentially ineffective testing strips.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. On 3/7/11 at 0900 hours the facility was noted to have a clean sink by the nurses' station across from Stations 1-5, where medications were being prepared. At the nurses' station across from Stations 11 and 12 was another clean sink for hand washing. A staff member from Station 1 had to walk to the end of the treatment area by station 10, bypassing stations 11 and 12, to drain or place used or contaminated items in the "dirty" sink. This posed a risk of blood spatters and contamination throughout the facility.</li> <li>2. On 3/7/11 at 0830 hours, the PD training area was found cluttered upon entry to the room. A three foot by four foot television and an empty cardboard box were on the floor by the dialysis chair. Two overbed tables, a portable blood pressure machine, and an IV pole surrounded the dialysis chair. A peritoneal dialysis cycler machine sat on a metal table. A bag of dialysate used for</li> </ol>	V 401			

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V 401	Continued From page 28 demonstration was hanging on the table. A Styrofoam box, with its lid on the counter, contained two more dialysate bags and a small thermal blanket serving as a warmer was on top of the box.  On 3/7/11 at 1100 hours, the clutter in the PD room was shown to the PD nurse. There was no comment made; but, by 1330 hours the PD room was rearranged to eliminate the obstacles.	V 401			
V 402	494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY  The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public.  This STANDARD is not met as evidenced by: Based on observation, staff interview and record review, the facility's treatment area and water purification system were not maintained in good repair. Broken surfaces of the floor, countertops, under the sink cabinets and the wall prevented effective disinfection due to exposed porous surfaces. An electrical outlet by the emergency supply cart was not maintained. The water purification system and hemodialyzer reprocessing areas were not secured by limiting access to only authorized individuals. This exposed the water system and the processed	V 402			

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V 402	<p>Continued From page 29</p> <p>dialyzers to potential tampering, contamination and public viewing of patient information.</p> <p>Findings:</p> <p>1. On 3/9/11, review of the facility's P&amp;P on Environmental Control/Safety, #5 showed, "Keep doors closed at all times except during deliveries to prevent entrance of insects."</p> <p>On 3/9/11 at 1100 hours, a pallet of IV fluids (48 boxes) was stacked beside the reverse osmosis tank. Reverse osmosis is a process for purification of the water used in hemodialysis and disinfection of used hemodialyzers. The Reuse Technician stated the exit door was unlocked the afternoon before to facilitate the delivery via a dolly. When asked who supervised the delivery personnel, the Reuse Technician did not make any comment.</p> <p>While speaking to Biomed 1 and the Reuse Technician, a delivery person bypassed the reception area and the nurses' station, and walked directly inside the water treatment area to deliver a small box. The box was placed on the clean work table in the reuse processing area. The delivery person then approached Biomed 1 and the Reuse Technician for a signature to acknowledge the delivery. When Biomed 1 and the Reuse Technician were asked how the facility limited the entry to the water treatment and reuse processing area, no comment was made.</p> <p>Processed dialyzers with patient names displayed were exposed to viewing by people delivering supplies.</p>	V 402			

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V 402	<p>Continued From page 30</p> <p>2. On 3/9/11 at 1100 hours, the linoleum flooring in the water treatment area had black and gray stains. The linoleum had cracks, cuts and aged degradation. Biomed 1 and the Reuse Technician stated they were out of ideas on how to maintain the area clean.</p> <p>3. On 3/8/11 at 1000 hours the shelves in the storage area were observed to prohibit effective cleaning of the floor necessary to maintain a sanitary reuse processing area. In addition, spare metal parts were found underneath the shelves creating an additional difficulty to cleaning of the floor. Biomed 1 attributed the limited cleanliness of the area to the limited space available in the facility.</p> <p>4. On 3/8/11 at 1500 hours, the cabinet under the dirty sink was shown to Biomed 1. Underneath was a dry disposable blue pad covering the wet and warped platform. Inspection of the next cabinet showed the platform was also damp from water. There was no obvious leak detected from the pipe or under the sink, however, signs of a whitish substance, possibly mold, were present on each side of the platform. Biomed 1 acknowledged the need to inspect further for possible leaks and the need to replace the platforms.</p> <p>5. The facility policy, "Environmental Control" dated 12/9/08, showed that dialysis machines, patient chairs, and counter tops were to be clean to sight and touch. Floors were to be free of dirt and debris. Machines, chairs and accessory equipment were to be cleaned after each patient.</p> <p>During observation of the treatment area from</p>	V 402			

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V 402	Continued From page 31 0800 hours to 1700 hours on 3/7/11 and 3/8/11 and from 0800 hours to 1100 hours on 3/9/11, the following was found: * There were missing areas of laminate on the counters and cabinets at the nursing station, at the sink areas and behind the patient chairs which exposed the porous wood underneath. *There were splits or missing areas in the vinyl covering on the foot rests and the corners of all the dialysis chairs which exposed the porous stuffing underneath. *The "dirty" sink was rusty. There was water damage to the cabinet door under the dirty sink with a large area of missing paint exposing the porous wood on the door. There was a black substance in the exposed porous wood. The shelf under the sink had been replaced. There was an open space between the new shelf and the sides of the cabinet of approximately 1/2 inch. There was a black substance in the open spaces along both sides of the shelf. The top of the backsplash was rusty near the paper towel dispenser. *There was water damage to the counter at the sink behind the reception desk. The corner of the laminate counter behind the sink by the scale was splitting apart at the seams from water damage, the screws in the mountings holding the glass partition on the counter behind the sink and the hinges on the cabinet under the sink were rusty from water damage. *There was water damage to the area around the sink at the nurses' station. *The faceplate around the electrical plug on the wall behind the crash cart was broken exposing the side of the plug. *The floor area behind the crash cart and the emergency supply kits had balls of black dust and	V 402			

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V 402	Continued From page 32 paper. *In the counter area behind the dialysis machine at Station 9 was a hole through the entire thickness of the counter wall and a large cracked area next to the hole. *There was black dirt on top of the plastic housings in the counter containing the water and drainage pipes for the dialysis machines. *The separate small counter area between Stations 11 and 12 had chipped areas in the laminate exposing the porous wood underneath. *At Stations 1 and 10 there was a crack in the flooring that ran the length of the wall at the sides of the chairs. The crack was through the entire thickness of the flooring. *The baseboard at the corner of the wall next to Station 1 and the hallway back to the reuse room was pulling away from the wall exposing the porous material underneath. *The side of the square pillar next to the dialysis machine at Station 11, facing the nurses' station, had an area of missing paint approximately 12 inches above the baseboard. At the corner of the pillar above the baseboard was a rusted area approximately 2 inches by 3 inches. There were areas of exposed metal at the corner of the pillar. *There were areas of the flooring in the treatment area where the top protective coating was missing making the areas look gray and dirty.	V 402			
V 413	494.60(d)(3) PE-ER EQUIP ON PREMISES-02, AED, SUCTION  On 3/9/11 at 1030 hours, an interview was conducted with the facility Medical Director. During the interview, the Medical Director acknowledged the conditions that were observed by the surveyors.	V 413			

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V 413	Continued From page 33 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 expired items were not available in the emergency evacuation kits which could possibly affect the quality of the product.  Findings:  On 3/7/11 at 0755 hours, the emergency evacuation kits were checked. In one emergency evacuation kit, 48 Betadine pads, with expiration dates of 10/08 and 2/09 were found. This finding was shared with the FA.	V 413			
V 502	494.80(a)(1) PA-ASSESS CURRENT HEALTH STATUS/COMORBIDS  The patient's comprehensive assessment must include, but is not limited to, the following:  (1) Evaluation of current health status and medical condition, including co-morbid conditions.  This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure all members of the interdisciplinary team were aware of the patient's current health status for four of 15 sampled patients (Patients 1, 5, 11 and 15). This could potentially result in the failure to incorporate new	V 502			

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V 502	<p>Continued From page 34</p> <p>patient information into the patient's treatment plan.</p> <p>Findings:</p> <p>1. On 3/8/11, a review of Patient 1's medical record showed the patient had been hospitalized twice in the past month, on 2/15/11 and 3/3/11. During an interview on 3/8/11 with Charge RN 1 at 0845 hours, she stated she was unaware of what the findings were for the patient's hospitalizations.</p> <p>On 3/8/11, a review of Patient's 1's physician's progress notes for 3/3/11, showed the patient had recently been hospitalized. However, the rest of the progress note was illegible. When the notes were reviewed with Charge RN 1 on 3/8/11 at 0846 hours, she was also unable to read the note.</p> <p>2. On 3/8/11, a review of Patient 5's medical record showed the patient had multiple episodes of low blood pressure (hypotension). On 2/1/11 at 0720, the patient's blood pressure was 83/44, on 2/5/11 at 0755 it was 84/42, on 2/11/11 at 0835 it was 77/38, on 2/12/11 it was 80/44, on 2/17/11 it was 83/44 and on 3/5/11 at 0655 it was 83/45. The patient's pretreatment blood pressure was in the 130's systolic (upper number in the reading). The hypotensive events were not addressed in the patient's care plan or in the physician's progress notes.</p> <p>3. On 3/8/11, a review of Patient 11's medical record showed the most recent physician's history and physical was dated 6/22/08, which was verified by the PD nurse.</p>	V 502			

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V 502	Continued From page 35  On 3/9/11 at 1030 hours, the facility's medical director stated the physician should update the patient's history and physical every 12 months.  4. Review of Patient 15's Interdisciplinary Team plan of care showed the patient's post systolic blood pressure goals were not met. The interventions were to review fluid restrictions with the patient and to evaluate and achieve the target weight. The fluid management area showed the goals were met as the patient's post treatment weight was within 1.0 Kg. post dialysis. There were no documented interventions to address the fluid gains between treatments and or the patient's decreased blood pressures during treatment that required interventions. The patient's dialysis prescription was not evaluated to determine if the prescription met their dialysis needs.	V 502			
V 504	494.80(a)(2) PA-ASSESS B/P, FLUID MANAGEMENT NEEDS  The patient's comprehensive assessment must include, but is not limited to, the following:  Blood pressure, and fluid management needs.  This STANDARD is not met as evidenced by: Based on medical record review, staff interview and facility policy review, the facility failed to ensure estimated dry weights, low blood pressures and interventions were monitored, documented and evaluated to determine patient goals for five of 15 sampled patients (Patients 1, 5, 13, 14 and 15). The failure resulted in patients	V 504			

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V 504	<p>Continued From page 36</p> <p>being discharged with low blood pressures which could result in possible falls or clotted dialysis accesses.</p> <p>Findings:</p> <p>Review of the facility's policies and procedures was initiated on 3/8/11.</p> <p>The facility policy, "Charting in Dialysis," dated 12/9/08, showed that extremes in blood pressure readings must be reported to the charge nurse. If the patient's blood pressure went down, follow up must be done. Medications could take 15 to 20 minutes to work so patient responses to medications should be charted after 15 minutes. Normal saline would raise the blood pressure immediately so the blood pressure could be taken as the saline entered the body.</p> <p>The facility policy, "Blood Pressure" dated 12/9/08, showed the Interdisciplinary Team evaluated each patient for hypotension and hypertension (low or high blood pressures) before, during ,and after dialysis to evaluate for possible causes.</p> <p>The undated facility policy, "Medical Complications That May Occur During Dialysis" showed signs and symptoms for shock included a systolic blood pressure of less than 100 and a feeling of warmth. One of the causes listed was depletion of intravascular (inside the blood vessel) fluid volume.</p> <p>Part of the standing orders included in all patient orders were medications for hypotension, and showed for a systolic (upper number of the blood</p>	V 504			

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V 504	<p>Continued From page 37</p> <p>pressure reading) blood pressure less than 100, the patient was to receive normal saline.</p> <p>Per the Core Curriculum for Nephrology Nursing, Fifth Edition, it showed that by impairing tissue perfusion, low blood pressure could compromise dialysis adequacy, contribute to a loss of residual kidney function and predispose patients to lack of blood flow to the heart and brain potentially causing damage to these organs.</p> <p>The above facility P&amp;Ps and physicians' orders for blood pressure and fluid maintenance were not implemented as follows:</p> <p>Review of patient medical records was initiated on 3/7/11.</p> <p>1. Patient 13's record review showed for January and February 2011, the patient had an ordered estimated dry weight (EDW) of 60.0 Kg. Review of Patient 13's treatment sheets showed the following: *For 20 treatments from 1/4 to 2/26/11, the patient had a pre-treatment average blood pressure of 155/70. During treatment, the patient experienced extreme blood pressure decreases which required interventions such as normal saline and having the fluid removal stopped on the hemodialysis machine. The patient complained of cramping and feeling dizzy. At other times, when the blood pressure decreased, no interventions were done. Follow up on the interventions taken was not done per policy.</p> <p>For example: * On 2/15/11, Patient 13's starting blood pressure was 147/70. One hour and 45 minutes after</p>	V 504			

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V 504	<p>Continued From page 38</p> <p>treatment was started, the patient's blood pressure decreased to 112/46. The patient complained of dizziness and the fluid removal on the machine was turned to minimum, but another blood pressure was not taken for 30 minutes after the intervention was done. Twenty-five minutes later the patient's blood pressure had decreased to 103/50 and the patient complained of cramping.</p> <p>* On 2/19/11, Patient 13's starting blood pressure was 153/77. At 1930 hours, the patient's blood pressure was 82/49, the patient complained of feeling hot. An intervention was not documented as done and another blood pressure was not taken for 30 minutes.</p> <p>* On 2/26/11, the starting blood pressure for Patient 13 was 141/73. Treatment was started at 1600 hours and at 1830 hours, the blood pressure decreased to 112/58, and at 1845 hours, was 91/48. No intervention was documented as done until 1845 hours. The fluid removal on the machine was stopped. At 1900 hours, the blood pressure was 108/40, and the patient complained of dizziness and was given 100 mL of normal saline. Another blood pressure was not taken for 30 minutes after the intervention was done.</p> <p>There was no documentation to show the patient's EDW or the low blood pressures experienced during the latter part of the treatments had been evaluated to determine if the dialysis prescription was appropriate for the patient until the end of February. Patient responses to the interventions done (normal saline given or turning the fluid removal down or off) were not consistent with the facility policy. Ordered normal saline was not consistently</p>	V 504			

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V 504	<p>Continued From page 39</p> <p>administered for systolic blood pressures less than 100. The nurses' monthly progress notes for January and February 2011 did not reflect the patient's blood pressure decreases during treatment</p> <p>2a. Review of the medical records and treatment sheets for Patient 14 showed the following: * On 1/24/11, the patient had a pre-treatment weight of 61.7 Kg., 5.7 Kg. over her EDW of 56.0 Kg. The fluid removal goal was 3.5 Kg. The patient was discharged at 59.3 Kg., 3.3 Kg. over her EDW. * On 1/26/11 the EDW was increased to 57.0 Kg. Review of the treatment sheets for 1/26, 1/28, 1/31, 2/5, 2/7, 2/9, 3/2 and 3/7/11, showed the fluid removal goal for these treatments was 3.5 Kg. The patient had fluid gains of 4.0 to 4.0 Kg. The fluid removal goal was not based on the amount of fluid the patient had gained over her ordered EDW.</p> <p>On 3/9/11 at 0910 hours, an interview was done with Charge RN 2 regarding the patient's fluid removal goal never being greater than 3.5 Kg. even with the large fluid gains. She stated the patient could only tolerate removal of a maximum of 3.5 Kg. during treatments. Charge RN 2 was unable to provide documentation showing the patient was only able to remove a maximum of 3.5 Kg. during treatment and an assessment of the causitive factors..</p> <p>2b. On 3/7/11, Patient 14's sitting blood pressure was 101/67. At 0755 hours, two hours after the start of the dialysis treatment, the blood pressure decreased to 74/41. The patient was given 200 mL of normal saline but another blood pressure</p>	V 504			

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V 504	<p>Continued From page 40</p> <p>was not taken for one hour after the intervention was done.</p> <p>3. Patient 15's Monthly Progress Notes showed that in November 2010, the patient's treatment time was three hours, the patient had an EDW of 60.0 Kg., fluid restrictions were reinforced and the patient had decreased blood pressures during treatments. Fluid removal was to be as tolerated, and the patient received extra treatments per physician orders. The December 2010 notes showed the patient's EDW had been increased to 61.0 Kg.</p> <p>Review of Patient 15's treatment sheets for January, February and March, showed for 17 treatments, the patient's average pre-treatment blood pressure was 160/80. During treatment, the patient experienced extreme blood pressure decreases that required interventions of normal saline and the fluid removal on the hemodialysis machine being stopped. The documentation showed for some blood pressure decreases the patient did not receive any interventions. Follow up of the interventions was inconsistent and not per policy. It also showed that interventions were done, and no blood pressure was recorded to show why the intervention was needed.</p> <p>For example: * On 1/3/11, the pre-treatment fluid gain was 2.5 Kg. over Patient 15's EDW and the starting blood pressure was 146/79. The fluid removal goal set on the machine was 3.5 Kg. At 0700 hours, the patient's blood pressure was 85/61 and 200 mL of normal saline was given. A follow-up blood pressure for the intervention was not done for 30 minutes. The fluid removal on the machine was</p>	V 504			

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V 504	Continued From page 41 not turned off. The blood pressure at 0730 hours, was 80/64. No interventions were done until 0740 hours, when the patient was given 100 mL of normal saline, but no blood pressure was documented at this time to show why the normal saline was given. * On 1/5/11, Patient 15's fluid gain was 3.5 Kg. over the EDW. The fluid removal goal was set on the machine at 4.2 Kg., and the starting blood pressure was 147/77. At 0600 hours, the blood pressure decreased to 81/55. The patient was given 200 mL of normal saline. At 0620 hours, the blood pressure decreased to 80/(number illegible) and the patient was given another 200 mL of normal saline, and the fluid removal was stopped. At 0650 hours, no blood pressure was documented, but the patient was given another 200 mL of normal saline. At 0700 hours, the blood pressure was 70/illegible, no interventions were done, and another blood pressure was not taken until 0730 hours. At 0730 hours, the blood pressure was 77/65 and another 200 mL of normal saline was given. The patient was given a total of 1400 mL of normal saline and was discharged 0.8 Kg. over the EDW. Post treatment standing blood pressure was 100/66. * On 2/9/11, Patient 15's starting blood pressure was 173/82 at 0450 hours. At 0600 hours, the blood pressure was 109/77. At 0615 hours, the patient was given 200 mL of normal saline, but no blood pressure was documented to show why the saline was given. At 0630 hours, the blood pressure was 100/73, the patient was given 200 mL of normal saline and fluid removal was stopped. At 0655 hours, the patient was given another 200 mL of normal saline, but no blood pressure was documented to show why the saline was given. At 0730 hours, the patient's blood	V 504			

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V 504	<p>Continued From page 42</p> <p>pressure was 109/55, and at 0745 hours, 200 mL of normal saline was given for decreased blood pressure but no blood pressure was documented to show why the normal saline was given.</p> <p>Interventions for low blood pressures and follow up of the interventions were not per policy. There was no documentation to show Patient 15 had been evaluated regarding the low blood pressures experienced during treatment to see if their dialysis needs were met. There was no documentation to show if the patient had any symptoms related to the low blood pressures. Review of Patient 15's Interdisciplinary Team plan of care showed the patient's post systolic blood pressure goals were not met. The interventions were to review fluid restrictions with the patient and to evaluate and achieve the target weight. There were no documented interventions to address the fluid gains between treatments and or the patient's decreased blood pressures during treatment that required interventions.</p> <p>4. On 3/8/11, Patient 5's blood pressure during hemodialysis was observed to be 83/49 at 0820 hours and 89/59 at the end of treatment. The patient appeared to be asleep during these readings. Prior to treatment the patient's blood pressure was 139/63.</p> <p>A review of Patient 5's medical record showed the patient had multiple episodes of low blood pressure. On 2/1/11 at 0720 hours, the patient's blood pressure was 83/44, on 2/5/11 at 0755 hours it was 84/42, on 2/11/11 at 0835 hours it was 77/38, on 2/12/11 it was 80/44, on 2/17/11 it was 83/44 hours and on 3/5/11 at 0655 hours it was 83/45. The patient's pretreatment systolic</p>	V 504			

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V 504	Continued From page 43 blood pressure (upper number) was in the 130's prior to treatment. The hypotensive events were not addressed in the physician's progress notes.  5. On 3/8/11 at 0830 hours, Patient 1 was observed receiving a hemodialysis treatment. A review of the patient's medical record showed the most recent physician's order, dated 11/11/10, for a target weight (weight after a hemodialysis treatment) for the patient was 57 kg. Further review of the patient's medical record showed on 3/1/11 the patient's weight after dialysis was 56.2 kg and on 2/26/11 the patient's weight after dialysis was 55.9 kg. During an interview on 3/8/11 at 0850 hours, Charge RN 1 stated they were challenging the patient's target weight; however, they did not have a physician's order to do this. A review of the policy and procedure showed prescriptions for dialysis are to be written by the attending kidney specialist.  On 3/9/11 at 0910 hours, review of the above treatments sheets for Patients 1, 5, 13, 14 and 15 was done with Charge RN 2. When asked if the patients' physicians were aware of the fluid gains, the decreased blood pressures, and follow-up for the interventions taken were not done as per policy and procedure, Charge RN 2 stated the physicians were aware of the fluid gains and decreased blood pressures for the patients. She also stated this was discussed with the physicians during their weekly rounds. On 3/9/11 at 1045 hours, the decreased blood pressure findings and lack of follow up was discussed with the FA who had no comment.	V 504			
V 541	494.90 POC-GOALS=COMMUNITY-BASED STANDARDS	V 541			

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V 541	<p>Continued From page 44</p> <p>The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure the patient care plan included recent changes in the patients' health and response to treatment for two of 15 patients sampled (Patients 1 and 5). This could potentially result in the failure of the patient's treatment plan to address the patients current health status and care needs.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. On 3/8/11, a review of Patient 1's medical record showed the patient had been hospitalized twice in the past month, on 2/15/11 and 3/3/11. There was no update in the patient's care plan to reflect these hospitalizations. During an interview on 3/8/11 with Charge Nurse 1 at 0845 hours, she stated she was unaware of what the findings were for the patient's hospitalizations.</li> <li>2. On 3/8/11, Patient 5's blood pressure during dialysis was observed to be 83/49 at 0820 hours</li> </ol>	V 541			

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V 541	Continued From page 45 and 89/59 at the end of treatment. The patient appeared to be asleep during these readings. Prior to treatment the patient's blood pressure was 139/63.  A review of Patient 5's medical record showed the patient had multiple episodes of low blood pressure. On 2/1/11 at 0720 hours, the patient's blood pressure was 83/44, on 2/5/11 at 0755 hours it was 84/42, on 2/11/11 at 0835 hours it was 77/38, on 2/12/11 it was 80/44, on 2/17/11 it was 83/44 and on 3/5/11 at 0655 hours it was 83/45. The patient's pretreatment blood pressure was in the 130's systolic (upper number) prior to treatment. The hypotensive events were not addressed in the patient's care plan nor in the physician's progress notes.	V 541			
V 582	494.100(a) H-IDT OVERSEES HOME TRAINING  The interdisciplinary team must oversee training of the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in §494.10) and when the home dialysis caregiver or home dialysis modality changes.  This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure patients on home PD (peritoneal dialysis) had documentation of the patient/caregiver's competence to perform self-dialysis for two of eight patient records reviewed (Patients 3 and 11). This could potentially result in inadequate dialysis, infection and injury for the patients.	V 582			

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V 582	Continued From page 46 Findings:  Review of the facility's patient education for home PD showed a checklist for patient training with a "demonstrated by the staff" section, "performed with supervision" sections and a "cleared" section. The checklist titled "CAPD Training Checklist" had six pages with over 60 items to demonstrate and review with the patient. These included checks on how to check your own blood pressure, adding medications to solutions, signs and symptoms for significant complications of dialysis including abdominal infections, and many more.  On 3/7/11 at 1340 hours, Patient 3 was interviewed and stated he had been on PD for 3 years. A review of Patient 3's medical record failed to show a completed training checklist.  On 3/7/11 at 1530 hours, Patient 11 was interviewed and stated he had received home dialysis training in another state. A subsequent review of Patient 11's medical record failed to show a CAPD training checklist.  On 3/8/11 at 1530 hours, the PD nurse stated she was fairly new to the job and didn't have all the patient records up to date yet.	V 582			
V 587	494.100(b)(2),(3) H-FAC RECEIVE/REVIEW PT RECORDS Q 2 MONTHS  The dialysis facility must - (2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and (3) Maintain this information in the patient ' s	V 587			

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V 587	Continued From page 47 medical record.  This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to review home peritoneal dialysis records for five of eight home dialysis patients reviewed (Patients 3, 7, 8, 9 and 11). This could potentially result in patients' procedural errors or inadequate dialysis not being identified.  Findings:  On 3/9/11, the medical records for Patients 3, 7, 8, 9 and 11 were reviewed. None of the records contained the patient's treatment records/flowsheets for the months of January and February 2011. At 0930 hours on 3/9/11, the PD nurse stated the facility had switched to a new system with data cards that contained the treatment records/flowsheets. She stated the patients had not been bringing the cards in.	V 587			
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.  This STANDARD is not met as evidenced by: Based on observation, interview and record review, the facility failed to ensure the patient's history and physical was updated every 12 months for one of 15 patient records reviewed (Patient 11). The facility failed to ensure the	V 726			

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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	
V 726	Continued From page 48 physician progress notes for one of 15 patients was legible (Patient 1). This could potentially result in documentation of changes in the patient's health status not being accessible to staff for care of the patient.  Findings:  1. On 3/8/11, a review of Patient 11's medical record showed the most recent physician's history and physical was dated 6/22/08, which was verified by the PD nurse.  On 3/9/11 at 1030 hours, the facility's medical director stated the physician should update the patient's history and physical every 12 months.  2. On 3/8/11, a review of Patient 1's physician's progress note for 3/3/11, showed the patient had recently been hospitalized. However, the rest of the progress note was illegible. When the notes were reviewed with Charge RN 1 on 3/8/11 at 0846 hours, she was also unable to read the note.	V 726			
V 756	494.180(a)(4) GOV-ADM RESP FOR RESOURCES FOR QAPI  The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to- (4) Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program as described in §494.110.	V 756			

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V 756	Continued From page 49  This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the governing body failed to prioritize and demonstrate QAPI support and provision of resources to correct identified problems. The lack of support and guidance for proposed areas of improvement could affect patient safety and health outcomes.  Findings:  On 3/7/11 at 0830 hours, during the initial tour of the water treatment system conducted with the Reuse Technician, it was observed the storage of medical supplies and the dialyzer reprocessing area were combined in one room. Issues with maintenance of dialysis chairs, physical environment and infection control risks in the dialyzer reprocessing and storage areas were identified, including security issues of the water treatment system. Cross-reference to V184; V401 #1.  On 3/9/11 at 0800 hours, review of the governing body meeting minutes, dated 12/7/10, revealed the facility had newly installed televisions for the patients. The next project was to replace the cracked dialysis chairs, but a timeframe for replacement was not specified.  On 3/9/11 at 1400 hours, in an interview with the QAPI committee members, they stated the following issues had been identified as areas for improvement by the QAPI committee and expressed to the governing body:	V 756			

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V 756	Continued From page 50 * need for an additional dirty sink for infection control purposes; * general maintenance of the dialysis chairs, linoleum floor, countertops and cabinets; and * the need for more space in the dialyzer reprocessing and sterile supply storage areas. The QAPI committee members stated the governing body had not taken action on these issues. Per the Medical Director, the linoleum floor was discussed with the building maintenance at the last renewal of the lease contract; however, no changes had been made.	V 756			