

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: 052787	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 02/17/2011
NAME OF PROVIDER OR SUPPLIER ALAMEDA COUNTY DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 10700 MACARTHUR BLVD SUITE 14 OAKLAND, CA 94605		
(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 000	<p>INITIAL COMMENTS</p> <p>The following reflects the findings of the California Department of Public Health during a recertification survey conducted from 02/14/11 to 02/17/11.</p> <p>Representing the Department: Dorothy Rice, HFEN; Nikki Kratt, HFEN; Elida Huerta, HFEN; Hadassah VandenBerg, HFEN (observe only); Helen Ho, HFEN; and Karen Riley, HFEN.</p> <p>The census at the start of the survey was 117 hemodialysis patients.</p> <p>Acronyms and Abbreviations commonly used in this report: CSS clinical service specialist FA facility administrator CHT certified hemodialysis technician RN registered nurse BP blood pressure DM diabetes mellitus ESRD end stage renal disease MR medical record P&P policies and procedures PPE personal protective equipment QAPI quality assurance program improvement</p> <p>Terms used in this report: Dialyzer - Replaces the kidneys' function of filtering the blood of waste products that would ordinarily be excreted as urine. The clear cylinder shape dialyzer contains tube like hollow fibers that filter the blood. Reprocessed dialyzer - A dialyzer that has been used for a dialysis treatment in a patient and then has been cleaned, disinfected, and tested for functioning properly. The dialyzer is stored with</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 set amount of disinfectant inside the dialyzer until the next use by that same patient. Pre-cleaning - Manual rinsing/cleaning of used dialyzers, done to remove as much of the residual blood and blood clots by reverse ultrafiltration by an acceptable water quality through the dialyzer membrane fibers. Pre-cleaning is part of the reprocessing of reused dialyzers.	V 000			
V 110	494.30 CFC-INFECTION CONTROL 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 demonstrated by: Failure to ensure that four staff observed (RN 5, CHTs 4, 6 and 8) used gloves and performed hand hygiene (washed hands or used alcohol based lotion) when caring for patients or touching patients' equipment as instructed by the facility policy and procedure for "Infection Control For Dialysis Facilities" for ten of ten patient observed (Patients 11, 17, 20, 21, 22, and the patients at stations 4, 10, 13, 14, and 20). (V113) Failure to ensure one (CHT 3) of one staff observed followed the policy and procedure regarding the proper use of "clean" and "dirty" sinks. CHT 3 washed hands at a sink designated "dirty" (sink designated for cleaning contaminated items) on two occasions during a twenty minute period. (V114) Failure to ensure two (CHT 8 and RN 4) of two staff observed followed the policy for the storage	V 110			

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V 110	Continued From page 2 of clean and used supplies in the proper designated areas, including two rolls of adhesive tape contaminated by use at two stations 5 and 9. (V116) Failure to ensure six (CHTs 3, 4, 5, 6, 7, and 9) of six staff observed thoroughly cleaned and disinfected the treatment chairs at eight of the 19 stations (Stations 3, 4, 6, 10, 11, 15, 18, and 20). (V122) Failure to follow the Center for Disease Control and Prevention (CDC) Program guidelines in their hepatitis surveillance policy by prematurely testing for hepatitis B surface antibody (HBsAb Quant) and hepatitis B surface antigen (HBsAb) for one (Patient 8) of 12 sampled patients. The early testing could yield "false" positives which could result in the patient not receiving a complete vaccine series to immunize against hepatitis B. (V127) Failure to ensure that three (FA, RN 3, and CHT 1) of 14 staff reviewed received updated annual Infection Control training and education as indicated in the facility's written policy and procedure and established practice. (V132) Failure by staff to follow facility policy for catheter care for two (Patients 3, 11) of 12 sampled patients and three (Patients 16, 17, and 24) random patients. (V147) The cumulative effect of these failures constituted a severe safety breach that limited the facility's ability to furnish adequate care and had the potential to cause patient harm.	V 110			
V 113	494.30(a)(1) IC-WEAR GLOVES/HAND	V 113			

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V 113	<p>Continued From page 3</p> <p>HYGIENE</p> <p>Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.</p> <p>This STANDARD is not met as evidenced by: Based on observation, staff interview, and document review, the facility failed to ensure that four staff observed (RN 5, CHTs 4, 6 and 8) used gloves and performed hand hygiene (washed hands or used alcohol based lotion) when caring for patients or touching patients' equipment as instructed by the facility policy and procedure for "Infection Control For Dialysis Facilities" for ten of ten patient observed (Patients 11, 17, 20, 21, 22, and the patients at stations 4, 10, 13, 14, and 20).</p> <p>The facility's staff failure to consistently perform hand hygiene resulted in potential for cross-contamination between patients and equipment thus increasing the risk of infections in patients receiving hemodialysis treatments, who already have a suppressed immune system.</p> <p>Findings:</p> <p>According to the Center for Disease Control (CDC), hand hygiene is the most important measure to prevent contaminant transmission. CDC recommends the use of gloves as exposure to blood and potentially contaminated items is routinely anticipated during hemodialysis. Staff should wear gloves when touching blood lines, dialyzer or machine during or after a dialysis</p>	V 113			

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V 113	<p>Continued From page 4</p> <p>treatment, when inserting or removing the vascular access needles, when cleaning and disinfecting machines. Gloves should be changed when soiled, when moving from an area/task where there was potential for contamination (i.e. removing lines) to a clean area or task (i.e. after touching one patient or a patient's machine and before providing care to another patient or touching another patient's machine).</p> <p>Review on 2/15/11 of the facility policy titled "Infection Control For Dialysis Facilities", last revised on 9/10, showed the policy instructed staff: "Hand hygiene is to be performed prior to gloving, after removing gloves, after patient and dialysis delivery system contact, and before touching clean areas such as supplies" and "Gloves should be changed when 1.) soiled with blood, dialysate, or other body fluids, 2.) when going from a "dirty" area or task to a "clean" area or task, and 3.) after touching one patient's dialysis delivery system and before arriving to touch another patient's dialysis delivery system."</p> <p>1. During continued observation on 2/15/11 between 12:10 p.m. and 12:20 p.m., CHT 6 went from touching the dialysis machines of three different patients (Patients 20, 21 and 17) to the portable computer keyboard without washing her hands or using alcohol based hand sanitizer:</p> <p>With bare hands, CHT 6 pressed the digital screen of the dialysis machine at station 1, where Patient 21 was receiving treatment, and then went directly to the chair side "snappy" (portable computer station located between two treatment chairs and shared between two patients) and used the keyboard. The snappy was located</p>	V 113			

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V 113	<p>Continued From page 5</p> <p>between stations 1 and 2, being shared by Patient 20 and 17. Without performing hand hygiene, CHT 6 went to station 3 where Patient 21 was receiving treatment and pressed the dialysis machine's screen. Right after, CHT 6 returned to the snappy by station 1 and typed on the keyboard. CHT 6 lifted her left hand several times to touch the dialysis machine screen at station 1 and each time returned her hand back to the keyboard. Further, CHT 6 touched the screen of the dialysis machine at station 2 where Patient 17 was receiving treatment, returned to use the snappy keyboard, then touched the machine at station 1 and back to the keyboard, without performing any hand hygiene.</p> <p>2. During an observation on 2/15/11 at 12:56 p.m., after disinfecting the treatment chair at station 10, CHT 4 took the gloves off, put on a new pair of gloves and proceeded to set up the hemodialysis machine for the next patient's treatment. CHT 4 did not wash her hands or use alcohol gel sanitizer at any time during the observation.</p> <p>3. On 2/17/11 at 9 a.m., CHT 4, wearing gloves on her hands, removed the used dialyzer and tubing from treatment chair at station 11. CHT 4 disposed of the dialysis tubing in the biohazard container, and the used dialyzer in a labeled clear plastic bag that she took to the reuse reprocessing room. CHT 4 removed the gloves, went directly to the chairside snappy and proceeded to type on the keyboard. CHT 4 applied another pair of gloves and removed the dialysis needles from Patient 22's fistula. At no time during the observation did CHT 4 wash or use alcohol gel sanitizer on her hands. It was not</p>	V 113			

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V 113	Continued From page 6 until after she had removed the needles from Patient 22's fistula that she used alcohol hand sanitizer. 4. On 2/15/11 at 1:55 p.m., observation showed RN 5 working at station 16 where Patient 11 was receiving treatment. The dialysis machine was alarming for arterial pressure. With ungloved hands, RN 5 grasped the saline flush line and used the flush line to touch display pads on the dialysis machine. Without performing hand hygiene, RN 5 began typing on the adjacent computer keyboard. The dialysis machine continued to alarm. With ungloved hands, RN 5 resumed grasping the saline flush line to touch display pads on the dialysis machine. Again RN 5 resumed typing on the computer keyboard without performing hand hygiene. During an interview at 3:20 p.m. RN 5 acknowledged she should have worn gloves when touching Patient 11's dialysis machine and saline line and should have performed hand hygiene before touching the computer keyboard. 5. On 2/15/11 at 12:45 p.m., CHT 6 was observed removing a used dialyzer along with the attached contaminated tubing from a dialysis machine at station 20. After discarding the tubing in the biohazard waste container, CHT 6 bagged and labeled the dialyzer and delivered it to the bin outside the reuse room. On her way back to the station, CHT 6 was observed stopping to silence an alarm on a machine at station 4 while still wearing the same contaminated gloves. Upon her return to station 20, CHT 6 was then observed immediately removing approximately a one inch thick stack of wipes from the bleach solution, wringing-out the excess solution back into the same container, and proceeding to wipe-down the machine. When she was finished, CHT 6	V 113			

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V 113	Continued From page 7 discarded half of the wipes in the biohazard waste container, leaving the rest on top of the machine. She then proceeded to remove her gloves. Later the same day at 3:30 p.m., when CHT 6 was interviewed regarding the entire observation, she stated, "I know I shouldn't do that." When asked about the wipes left on the machine, which were potentially contaminated by her used gloves, she stated, "The wipes are left for the technician assigned to that station to clean the chair after the patient leaves (to prepare for the next patient)." During an interview with the facility administrator on 2/17/11 at 9:35 a.m., when informed of the observation, she stated, "That's a no-no!" 6. On 2/15/11 at 2:25 p.m., CHT 8 was observed silencing an alarm on the machine at station 14 with her index finger covered by the gloves wadded-up in her hand. Then, CHT donned the same gloves and proceeded to set-up the machine at station 13 for the next patient. On 2/16/11 at 11:15 a.m., when CHT 8 was interviewed regarding setting-up the machine with contaminated gloves, she appeared to not understand what she did wrong.	V 113			
V 114	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, interview, and record	V 114			

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V 114	Continued From page 8 review, the facility failed to ensure one (CHT 3) of one staff observed followed the policy and procedure regarding the proper use of "clean" and "dirty" sinks. CHT 3 washed hands at a sink designated "dirty" (sink designated for cleaning contaminated items) on two occasions during a twenty minute period. This failure increased the potential for cross-contamination. Findings: During observation initiated at approximately 1:10 p.m. on 2/15/11, CHT 3 washed his hands at a sink designated as "dirty" sink on two occasions within a twenty minute period. During an interview with CHT 3 on 2/17/11, when informed he was observed on two separate occasions washing his hands at a designated "dirty" sink, CHT 3 stated, "I wasn't paying attention. I saw the bottle of hand sanitizer near the sink and assumed it was okay to wash my hands there." During an interview on 2/17/11 at 11:10 a.m., when informed of the observation, the facility administrator stated, "Dirty sinks should not be used for hand washing." Review of facility policy 1-05-01 for "Infection Control For Dialysis Facilities", last revised 9/10, showed the following instructions: "Hand washing sinks should be dedicated only for hand washing purposes and remain clean. Used or contaminated items should be handled in designated utility sinks."	V 114			
V 116	494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT	V 116			

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V 116	Continued From page 9 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, interview, and record review, the facility failed to ensure two (CHT 8 and RN 4) of two staff observed followed the policy for the storage of clean and used supplies in the proper designated areas, including two rolls of adhesive tape contaminated by use at two stations 5 and 9. This failure increased the potential for cross-contamination (transmission of infection from a patient to another). Findings: Review on 2/15/11 of facility policy "1-05-01: Infection Control For Dialysis Facilities" showed the following instructions: "Non-disposable items that cannot be cleaned and disinfected (e.g., adhesive tape) will be dedicated for use only on a single patient. Unused supplies taken to the patient's station	V 116			

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V 116	<p>Continued From page 10</p> <p>should be used only for that patient and should not be returned to a common clean area or used on other patients." "The ChairSideSnappy cart, monitor, and keyboard are considered clean areas."</p> <p>1. During an observation on 2/15/11 at 11:10 a.m., CHT 8 reinforced Patient 8's post-treatment dressings with additional adhesive tape. When finished, CHT 8 set the roll of tape on the chairside computer stand (Snappy cart) shared with the next patient station and continued with her work.</p> <p>2. Following the observation of a catheter dressing change on 2/16/11 at 10:50 a.m., RN 4 returned the roll of adhesive tape that she used to the supply cart. During an interview immediately after the observation, RN 4 opened the top drawer of the cart, pointed to the roll of tape and stated, "I put it in here." and "It's okay...it has lots of tape left on it." When asked what was the facility policy and procedure for nondisposable patient care items that can not be cleaned, RN 4 chuckled and asked, "Throw it away?" RN 4 further stated, "I don't always (throw them away). If it's a small roll, I do...but if it has lots of tape on it, I don't." RN 4 walked to the side of the dialysis machine and, pointing, stated, "Sometimes, some of us will put the roll on the side of the machine to use later." When asked if the roll has been exposed to the patient, RN 4 hesitated and then stated, "Sometimes...but it still has lots of tape on it."</p> <p>During an interview with the facility administrator on 2/17/11 at 11:10 a.m., when informed of the observations, she stated, "If it's taken to a station</p>	V 116			

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V 116	Continued From page 11 and used, it can't be used for another patient or returned to the cart." 3. During an observation on 2/17/11 at 8:36 a.m. CHT 8 removed a roll of tape from the tape drawer at the nurses' station and took the tape to Patient 27's chairside table. CHT 8 torn strips off the roll and returned the roll of tape back to the tape drawer. On 2/17/11 at 11:15 a.m. the Facility Administrator stated rolls of tape that are taken to a patient's chair/chairside should be for that patient only and not used for another patient or returned to the tape drawer. Review of the facility's policy and procedure "Infection Control For Dialysis Facilities', last revised 9/10, identified adhesive tape as a non disposable item that could not be cleaned or disinfected and thus, "...will be dedicated for use only on a single patient".	V 116			
V 122	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. This STANDARD is not met as evidenced by: Based on staff interview, observation and record review, the facility failed to ensure six (CHTs 3, 4, 5, 6, 7, and 9) of six staff observed thoroughly	V 122			

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V 122	<p>Continued From page 12</p> <p>cleaned and disinfected the treatment chairs at eight of the 19 stations (Stations 3, 4, 6, 10, 11, 15, 18, and 20)</p> <p>The failure to thoroughly clean the treatment chairs increased the patients' risk for infections by cross-contamination (transmission of infections from a patient to another).</p> <p>Findings:</p> <p>Review on 2/15/11 of the facility policy and procedure "Infection Control For Dialysis Facilities", last revised 9/10, showed that staff were to "...thoroughly wipe down all non-disposable items and equipment such as the blood pressure cuff...with an appropriate disinfectant after every patient use. The dialysis chairside table, the dialysis chair including opening the chair to reach crevices "... will be wiped with a bleach solution ...before being used on another patient, after spills of blood, throughout the work day, and after each treatment."</p> <p>1. On 2/17/11 at 8:50 a.m., Clinical Coordinator verified with staff that the treatment chairs at stations 6 and 20 were "ready" for the next patient. When the Clinical Coordinator reclined the head of the chairs to an approximately 90 degree angle and opened the chair sides, a moderate amount of dry, dark grayish brown substance was observed in the crevice between the back seat panel and seat cushion, and on the lower right and left chair sides at both station 6 and station 20.</p> <p>2. On 2/17/11 at 10:00 a.m., CHT 3 stated the</p>	V 122			

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V 122	<p>Continued From page 13</p> <p>treatment chair at station 11 was "clean" and ready for the next patient. When CHT 3 fully reclined the back of the chair and opened the chair side panels, a small amount of dark, dry grayish substance was observed in the crevice between back panel and the seat cushion, and on the lower right and left side panels.</p> <p>3. On 2/14/11 at 9:20 a.m., CHT 9 used a wet disinfecting wipe to clean the back, the seat, the arm rests, and the outside of chair arms of treatment chair at station 18. CHT 9 did not recline the treatment chair to expose and wipe down the area between the back and the seat and the area between the seat and the leg/foot rest. CHT 9 picked up the blood pressure cuff for treatment chair 18 from the floor. CHT 9 did not clean/disinfect the blood pressure cuff before she applied it on Patient 2's arm.</p> <p>4. On 2/14/11 at 9:50 a.m., CHT 5 did not recline the chair and did not open up the side wings to expose this areas as he was cleaning/disinfecting the treatment chair at station 15. CHT 5 did not clean/disinfect the blood pressure cuff to be used for the next patient.</p> <p>5. On 2/14/11 at 9:55 a.m., CHT 7 cleaned/disinfected the treatment chair at station 4, but did not recline or open up the chair arms. After CHT 7 was done cleaning the chair, two bright red blood smears were noted on the mid side of the left chair arm rest. The smears extended from the top edge to the lower edge of the side.</p> <p>6. On 2/15/11 at 12:56 p.m., CHT 4 wiped down</p>	V 122			

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

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V 122	<p>Continued From page 14</p> <p>treatment chair 10's seat and back with disinfectant. CHT 4 also swung open the chair side arms and wiped them down. CHT 4 did not recline the treatment chair to expose and wipe down the area between the back and the seat and the area between the seat and the leg/foot rest. At 1:03 p.m. CHT 4 was asked if she had finished cleaning the treatment chair and she stated, "yes". CHT 4 was asked to recline the treatment chair and wipe the exposed areas. Dust particles were visible on the cleaning wipe after CHT 4 wiped the newly exposed chair areas.</p> <p>7. On 2/17/11 at 9:58 a.m., CHT 6 cleaned/disinfected the treatment chair at station 3 without reclining the chair or opening up the arm sides. In the presence of Clinical Coordinator, CHT 6 was asked if she was done cleaning chair 3. CHT 6 stated, "yes". When the chair was reclined and the arm sides were opened, dark black spots, approximately 0.5 cm (centimeters) in size, became visible on the right lower edge between the back of the chair and the seat. The table attached to the left chair arm had light grey areas on the front edge, which the Clinical Coordinator stated were from tape adhesive. The left side of the leg rest was not intact: a portion of the vinyl, approximate 5-6 cm, was gone exposing a light yellow material. The torn chair made it impossible to clean/disinfect the chair between patient uses. Clinical Coordinator stated the chair should be removed from the treatment room.</p> <p>On 2/17/11 at 11:15 a.m. the Facility Administrator and the Clinical Service Specialist were informed of the chair with the torn section. Both stated a chair which was not intact should</p>	V 122			

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V 122	Continued From page 15 not be in the treatment room.	V 122			
V 127	494.30(a)(1)(i) IC-HBV-TEST PTS/STAFF POST LAST DOSE Hepatitis B Screening: Patients and Staff Test all vaccines [patients and staff] for anti-HBs 1-2 months after last primary vaccine dose. -- If anti-HBs is <10 mIU/mL, consider patient or staff member susceptible, revaccinate with an additional three doses, and retest for anti-HBs. -- If anti-HBs are =10 mIU/mL, consider immune, and retest patients annually. -- Give booster dose of vaccine to patients if anti-HBs declines to <10 mIU/mL and continue to retest patients annually. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to follow the Center for Disease Control and Prevention (CDC) Program guidelines in their hepatitis surveillance policy by prematurely testing for hepatitis B surface antibody (HBsAb Quant-molecular structure able to recognize a protein not pertaining to one's body) and hepatitis B surface antigen (HBsAb-foreign protein) for one (Patient 8) of 12 sampled patients. The early testing could yield "false" positives which could result in the patient not receiving a complete vaccine series to immunize against hepatitis B. Findings: Record review on 2/15/11 indicated Patient 8, a hemo-dialysis patient, received the last dose of a three-dose hepatitis B vaccination series on 1/13/11. On 2/8/10, 26 days later, Patient 8's	V 127			

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V 127	Continued From page 16 HBsAb was negative and HBsAb Quant was greater than 150. The policy, "Hepatitis Surveillance, Vaccination and Infection Control Measures", dated December 2008, outlined the procedure to, "Test all vaccinated patient for HBsAb one (1) to (2) months after the last dose of the full vaccine series (adequate response is defined as > or = 10 mIU/ml (milli-international per milliliter). The same policy indicated patients receiving the vaccine series should not have HBsAb drawn within 30 days of a dose because "false" positive hepatitis B surface antigen results may be detected up to 21 days or longer. In an interview on 2/15/11 at 3 p.m., the clinical coordinator (CC), who was in charge of the facility's hepatitis B program stated the facility was implementing the four dose vaccination series. CC also stated that if a patient's hepatitis B antibody result was greater than 10 after the third dose of vaccine, the fourth dose was not necessary. After reviewing Patient 8's result for the test performed on 2/8/10, CC stated the test showed the patient's "immunity went up" and that Patient 8 did not need a "booster" injection. On 2/16/11 at 9:50 a.m., in a follow-up interview, the CC stated Patient 8's 2/8/11 laboratory results may have been falsely positive because the tests were obtained too early.	V 127			
V 132	494.30(a)(1)(i) IC-TRAINING & EDUCATION Infection Control Training and Education Infection control practices for hemodialysis units: intensive efforts must be made to educate new	V 132			

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V 132	<p>Continued From page 17</p> <p>staff members and reeducate existing staff members regarding these practices.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review, the facility failed to ensure that three (FA, RN 3, and CHT 1) of 14 staff reviewed received updated annual Infection Control training and education as indicated in the facility's written policy and procedure and established practice. This failure increased the risk of staff not being knowledgeable of updated informational infection control practices that safeguard against potential infectious bloodbourne diseases.</p> <p>Findings:</p> <p>On 2/16/11 review of the facility policy and procedure, "Injury Prevention and Safety Training", revised 9/08, showed that staff was to attend mandatory infection control training upon hire and then annually. Review of 14 personnel records on 2/16/11 in the presence of facility administrator and Clinical Services Specialist, showed the following:</p> <p>a. The facility administrator (FA) was hired on 12/6/96. There was no Infection Control Training documentation found in FA's personnel file since 6/4/08.</p> <p>b. RN 3 was hired on 7/7/09. There was no Infection Control Training documentation found for RN 3 since 7/13/09.</p> <p>c. CHT 1 was hired on 1/3/04. There was no Infection Control Training documentation found for CHT 1 since 6/10/08.</p>	V 132			

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V 132	Continued From page 18	V 132			
V 147	<p>FA stated on 2/16/11 she was in the midst of obtaining the mandated training for herself, but was unsure why RN 3 and CHT 1 did not have their required updated annual mandatory Infection Control inservice training.</p> <p>494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE</p> <p>Recommendations for Placement of Intravascular Catheters in Adults and Children</p> <p>I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters.</p> <p>II. Surveillance A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site.</p> <p>Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.</p> <p>VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].</p>	V 147			

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V 147	<p>Continued From page 19</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, staff failed to follow facility policy for catheter care for two (Patients 3, 11) of 12 sampled patients and three (Patients 16, 17, and 24) random patients. Failure to consistently perform aseptic technique and correct mask application placed patients at risk for cross-contamination, increasing the risk of infection.</p> <p>Findings:</p> <p>Review on 2/15/11 of the facility policy "Central Venous Catheter (CVC) Cleansing and Dressing Change", revised September 2010, showed the policy instructed staff to , "Ensure patient's face is turned to side opposite CVC exit site." The rationale: "Decreased the risk of aerosolized bacteria contaminating site." After removing the old dressing, staff should "remove gloves and discard. Wash hands and re-glove." The rationale: "Handwashing protects patient and teammate from cross contamination."</p> <p>The facility policy for "Predialysis Central Venous Catheter (CVC) Care (revised September 2010), instructed, "The patient and teammate will wear face masks covering the nose and mouth during a catheter procedure."</p> <p>1. On 2/14/11 at 1:44 p.m., Clinical Coordinator performed catheter limb lead care for Patient 3. The clinical coordinator had on a face shield and face mask; Patient 3 wore a face mask as well. The clinical coordinator placed an impermeable</p>	V 147			

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V 147	<p>Continued From page 20</p> <p>sheet under the catheter limb leads (sections of the catheter which allow for connection to syringes) and removed the dressing covering the limb leads. With the same gloves, he opened packages of povidone iodine (cleansing agent) and preceded to clean the limb leads. At 1:50 p.m., the clinical coordinator prepared to perform catheter exit site (where the catheter exits the body at the skin level) care for Patient 3. After removing the exit site dressing, he removed his gloves and donned a new pair of gloves without first performing hand hygiene. He cleansed the exit site with gauze dressings containing antiseptic cleanser (kills germs), folded a gauze dressing and placed under the catheter, then covered the site with gauze.</p> <p>Following the observation, the clinical coordinator was interviewed at 2:20 p.m. He acknowledge he changed gloves without performing hand hygiene. He noted that the hand sanitizer was not conveniently located, so he removed an alcohol gel dispenser from the central area and placed it on the computer cart for easier access.</p> <p>2. On 2/15/11 at 1:28 p.m., RN 5 prepared to perform catheter care for Patient 11. Wearing a face mask and face shield, she placed a face mask on Patient 11. After tucking an impermeable sheet around the open collar of Patient 11, she opened packets of povidone iodine wipes and gauze. RN 5 then removed the dressing covering the catheter limb leads. Patient 11 looked down toward his catheter to watch. After removing the dressing, RN 5 removed her gloves and donned a new pair of gloves without first performing hand hygiene. RN 5 cleaned the catheter limb leads, using the</p>	V 147			

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V 147	<p>Continued From page 21</p> <p>povidone iodine wipes backed by gauze, leaving them wrapped around the limb leads. Patient 11 continued to watch. RN 5 did not redirect him to look away. RN 5 removed the povidone iodine and gauze from the limb leads. With Patient 11 still watching, RN attached syringes to the ends of the limb leads.</p> <p>At 3:20 p.m. the same day, during an interview, RN 5 acknowledged she did not instruct Patient 11 to turn away while she performed catheter care. She further acknowledged she did not consistently perform hand hygiene after removing her gloves.</p> <p>3. On 2/16/11 at 10:38 a.m., RN 4, wearing a mask, face shield, protective gown and gloves was observed performing catheter care for Patient 16. RN 4's face mask hung over her mouth and under her nostrils. The procedure included removing the old dressing to expose the catheter site, wiping two limb leads with povidone-iodine saturated swabs, attaching syringes to the limb leads, and withdrawing blood.</p> <p>In an interview on 2/16/11 at 2:37 p.m., RN 4 acknowledged the face mask did not cover her nose. She stated the correct placement of the mask was to include covering her nostrils.</p> <p>4. During catheter care on 2/15/11 at 10:30 a.m., RN 6 was wearing a mask and face shield and Patient 17 was wearing a mask. However, neither of them had their nose covered by their mask.</p> <p>During the entire process, RN 6 did not tell Patient 17 to turn her head in the opposite direction. As a result, Patient 17 continuously exhaled directly onto the exposed catheter site.</p>	V 147			

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V 147	<p>Continued From page 22</p> <p>During an interview with RN 6 later the same day, regarding the observation related to the use of a mask during catheter care, RN 6 stated, "I know I don't keep it covered. I'll try harder." When informed of the same observation with Patient 17, RN 6 stated, "She always does that." RN 6 did not explain why she did not instruct Patient 17 to turn the head away from the catheter.</p> <p>5. On 2/16/11 from 12:44 p.m. to 1:07 p.m., RN 4 performed central venous catheter site care and catheter lumen connections for Patient 24. The following were observed:</p> <p>RN 4 had a face mask over her mouth but the mask did not cover her nose. RN 4 exposed the catheter lumens, connected syringes to the catheter lumens, and drew back blood followed by normal saline flushes of the lumens. RN 4's mask was noted to be covering only her chin during the time the catheter lumens were connected to the dialysis tubing.</p> <p>At the start of central venous catheter site care at 12:52 p.m. RN 4's face mask covered her mouth but her nose was exposed. RN 4 removed the outer catheter site dressing, and left the 2 X 2 cm (centimeter) gauze still covering the site. RN took her gloves off and did not wash or use alcohol gel sanitizer on her hands. RN 4 turned to the chairside computer keyboard and typed, then used a wadded glove in her hand to press on Patient 24's dialysis machine screen, returned to type on the keyboard, again with wadded glove pushed on the Patient 24's dialysis machine screen.</p>	V 147			

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V 147	Continued From page 23 At 12:58 p.m., RN 4 removed all the dressing from the catheter site, cleansed area, and redressed site. During the procedure her mouth had been covered but her nose had been exposed. RN 4 at 1:07 p.m. was asked what the facility policy/procedure was for face mask use during catheter lumen exposure and catheter site care. RN 4 stated and showed that the mask was to cover the nose and mouth. RN 4 was informed of the observations where she had her nose exposed and at one time had both nose and mouth exposed, RN 4 stated her mask must have slipped off.	V 147			
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 in effective disinfection. 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.	V 211			

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V 211	<p>Continued From page 24</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 interview, the facility failed to ensure no unused sections of pipe containing uncirculated water were connected to the facility's water distribution system. This failure increased the potential for inoculating bacteria from contaminated water into the water distribution system supplying dialysis machines and dialyzer reuse processing.</p> <p>Findings:</p> <p>On 2/17/11 at 9:10 a.m., observation showed a long piece of PVC pipe, approximately 10 feet long connected into the water distribution system after the reverse osmosis (RO) system. The Area Biomedical Specialist (ABS) confirmed it was a "dead leg", and stated, "We should take it down." A dead leg is a segment of piping shut off from normal water circulation usually by valves located by each end of the pipe. Water present in the dead leg is not circulated and can become a reservoir for contamination. According to the ABS, the inactive segment of pipe would be put into use when the facility needed to bring in de-ionization equipment to remove inorganic contaminants and bacteria normally done by reverse osmosis. The ABS agreed that the dead</p>	V 211			

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V 211	Continued From page 25 leg still connected to the water distribution system contained uncirculated water that could potentially leach bacteria into the main water distribution system. According to the Association for the Advancement of Medical Instrumentation (AAMI), water not continuously circulating as in a dead leg, can stagnate and bacteria can rapidly proliferate and inoculate into the circulating water/distribution system. Additionally biofilms (a complex matrix consisting of a layer of bacteria, its secretions and the surfaces bacteria contacts) form and present another source of contamination for water circulating nearby, placing the patients receiving treatments at the facility (117 hemodialysis patients) at risk for infections.	V 211			
V 213	494.40(a) DIST SYS-CULTURE/LAL/SITES/FREQ(NEW)/LOG 6.3.3 Water distribution systems: culture/LAL sample sites/frequency (new)/log Water distribution piping systems should be monitored for bacteria and endotoxin levels. Bacteria and endotoxins shall not exceed the levels specified in [AAMI] 4.1.2. [(i.e., bacteria <200 CFU/mL and endotoxin <2 EU/mL)] Bacteria and endotoxin testing should be conducted at least monthly. For a newly-installed water distribution piping system, or when a change has been made to an existing system, it is recommended that weekly testing be conducted for 1 month to verify that bacteria or endotoxin levels are consistently within the allowed limits. Monitoring should be accomplished by taking	V 213			

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V 213	<p>Continued From page 26</p> <p>samples from the first and last outlets of the water distribution loop and the outlets supplying reuse equipment and bicarbonate concentrate mixing tanks. If the results of this testing are unsatisfactory, additional testing (e.g., ultrafilter inlet and outlet, RO product water, and storage tank outlet) should be undertaken as a troubleshooting strategy to identify the source of contamination, after which appropriate corrective actions can be taken. Bacteria and endotoxin levels shall be measured as specified in ANSI/AAMI RD62:2001 (see 2.3).</p> <p>All bacteria and endotoxin results should be recorded on a log sheet to identify trends that may indicate the need for corrective action.</p> <p>This STANDARD is not met as evidenced by: Based on interview and document review, the facility failed to follow its policies to disinfect its RO (reverse osmosis) machine quarterly and to identify a pattern of contamination in its purified water distribution system. The failure to disinfect the RO machine timely resulted in test results from multiple sites of the water distribution system exceeding bacterial action levels for two subsequent months. The failure to identify a pattern of contamination delayed prompt investigation and remediation of the cause(s) of contamination in the RO water distribution system, caused extended exposure from contaminated water for all patients undergoing dialysis, increasing their risk for infection.</p> <p>Findings:</p> <p>1. Review on 2/16/11 of the facility's monthly Culture Reports, showed sampling from different</p>	V 213			

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V 213	<p>Continued From page 27</p> <p>testing sites of the RO water distribution system and their corresponding bacterial culture results. Review of the following past results showed:</p> <p>1/11/10 RO product water out was 140 cfu/ml (colony forming units/milliliter- a measure of the amount of bacteria)</p> <p>2/18/10 RO product water out was 70 cfu/ml</p> <p>3/11/10 RO product water out was 70 cfu/ml</p> <p>4/9/10 RO product water out was 190 cfu/ml</p> <p>5/6/10 All sample sites results were less than 50 cfu/ml</p> <p>6/3/10 RO product water out was 50 cfu/ml Water Outlet # 1 was 150 cfu/ml Disinfectant out was 80 cfu/ml Reuse outlet # 3 was 250 cfu/ml Pre-Clean station # 2 was 140 cfu/ml Pre-Clean station # 1 was 110 cfu/ml</p> <p>7/8/10 RO product water out was 60 cfu/ml Water Outlet # 1 was 130 cfu/ml Disinfectant out was 140 cfu/ml Pre-Clean station # 2 was 140 cfu/ml Pre-Clean station # 1 was 200 cfu/ml</p> <p>Review on 2/16/11 of the facility "Water Culture Policy", dated September 2009, showed acceptable culture levels would be below 50 cfu/ml; the action level (level which triggers investigation and retesting) was from 50 to 199 cfu/ml; and unacceptable level was 200 cfu/ml or greater.</p> <p>According to the Association for the Advancement of Medical Instrumentation (AAMI), water that has had chlorine/chloramine (additives that control bacterial growth) removed as is done for hemodialysis, no longer has agents to control bacteria. Any remaining bacteria not removed by</p>	V 213			

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V 213	<p>Continued From page 28</p> <p>the water purification system (reverse osmosis or de-ionization) can proliferate rapidly. Therefore, although the maximum bacterial culture level is 200 cfu/ml (quantity), a lower threshold (action level) is required to give the facility time to correct the source of contamination before the maximum acceptable level is reached.</p> <p>Review of the retested sample sites, as required by the Water Culture Policy, whose original results exceeded the action level or were unacceptable, showed generally acceptable (less than 50 cfu/ml) culture results.</p> <p>The facility's current biomedical technician (BMT) stated during interview on 2/16/11 at approximately 2 p.m. that he underwent BMT training and began at the facility during the spring in 2010. According to BMT, water samples for bacteria culture levels were drawn just before the water distribution system was disinfected. The test results would usually come back three days later and by that time, the water distribution system would have been disinfected. The BMT stated he would then retest those sample sites whose culture results were higher than the action level of 50 cfu/ml. The BMT agreed the retested results reflected a freshly disinfected system. The BMT could offer no explanation why month after month showed unacceptable results in one or more of the testing sites. He stated he did not perform more frequent disinfections, but stated he did notify the facility administrator (FA) whenever he obtained a high result.</p> <p>On 2/16/11, review of the facility policy "Water Treatment System Disinfection", revised in March 2010 and September 2010, showed, "Additionally,</p>	V 213			

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V 213	<p>Continued From page 29</p> <p>the RO and distribution system are disinfected when bacterial cultures and /or endotoxin results indicated the need for disinfection."</p> <p>On 2/16/11, the area biomedical supervisor (ABS) reviewed the monthly Culture Reports. The ABS noted that the current BMT had not authored the monthly reports until April, 2010, and BMTs from other facilities had provided service to the facility the previous months. The ABS confirmed there was a pattern of water contamination noted in every monthly report from 1/11/10 through 7/8/10. He stated, "By the second month (of unacceptable culture results), we (facility) should have done something."</p> <p>Review of the Water Culture Policy showed, "The Facility Administrator or designee is responsible for ensuring that cultures are obtained, results recorded, review and necessary actions taken, as applicable." "Results and trends are reviewed during the facility Quality Improvement/Quality Assurance meetings and documented in the meeting minutes."</p> <p>On 2/17/11 at 8:37 a.m., the facility administrator (FA) stated she first heard of the contaminated water results in 7/10. The FA stated she received monthly Culture Reports from the BMT, but she did not review the original culture results, only looking at the last column showing the results from retested samples that indicated acceptable bacteria culture levels. She also stated she did not review previous monthly Culture Reports to look for trends or patterns of contaminated testing sites. The FA stated she had not undergone formal training about the water distribution system and her only knowledge of the water system</p>	V 213			

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V 213	<p>Continued From page 30</p> <p>came from her prior experience as a patient care technician where she performed tests for the presence of chlorine or drew samples for testing. The FA stated the issue of contaminated water was not addressed at the quality assurance/quality improvement meeting until 8/23/10.</p> <p>2. Review on 2/16/11 of the facility policy for Water Treatment System Disinfection, last revision September 2010, indicated its purpose was, "To disinfect Reverse Osmosis (RO) devices and the distribution system on a regular basis and in response to elevated bacteria and/or endotoxin test results." "Distribution systems are disinfected monthly and the RO machine is disinfected quarterly."</p> <p>During an interview with area biomedical supervisor (ABS) on 2/16/11 at 4:15 p.m., he stated "I got involved in May or June (2010)." He stated as a result of his investigation, "We noticed another procedure, the RO loop (disinfection) was done monthly, but an additional quarterly (disinfection) included the whole RO system and it wasn't being done." The ABS stated only one month was missed, and that it only went an extra month without the quarterly disinfection.</p> <p>Review of the Disinfection Invoices showed the RO machine was disinfected on 2/18/10 and was not disinfected until 7/16/10, five months later and two months past the quarterly disinfecting required by facility policy. The RO machine should have been disinfected sometime during 5/10. Review of the RO results for 6/3/10 and 7/8/10 showed these were the months showing multiple testing areas with culture levels above</p>	V 213			

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V 213	Continued From page 31 the action level of 50 cfu/ml.	V 213			
V 253	<p>During an interview with the facility's current BMT on 2/17/11 10:50 a.m., he stated he knew he was to disinfect the RO loop monthly, but was not aware a quarterly system disinfection that included the RO machine was required as well. He stated when the ABS asked him about the quarterly, he replied "What's that?"</p> <p>494.40(a) MICROB MONITOR-MO DIALYS SAMPLE/COLLECT/FREQ</p> <p>7.2 Microbial monitoring methods: 7.2.1 General: Dialysate: monthly dialysate sample/collection/freq Culture ...dialysate fluid weekly for new systems until a pattern has been established. For established systems, culture monthly unless a greater frequency is dictated by historical data at a given institution.</p> <p>Dialysate samples should be collected from at least two machines monthly and from enough machines so that each machine is tested at least once per year. If testing of any dialysis machine reveals a level of contamination above the action level, an investigation should be conducted that includes retesting the offending machine, reviewing compliance with disinfection and sampling procedures, and evaluating microbiological data for the previous 3 months to look for trends. The medical director also should be notified. An example of a decision tree for this process is given in Figure 1.</p> <p>7.2.2 Sample collection Dialysate samples should be collected from a dialysate port of the dialyzer ... [or] dialysate</p>	V 253			

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V 253	<p>Continued From page 32</p> <p>sampling ports that can be accessed using a syringe. At least 25 mL of fluid, or the volume specified by the laboratory performing the test, should be collected in sterile endotoxin-free specimen containers.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to follow its policy to identify and evaluate patterns or trends of bacterial contamination of dialysate used in dialysis machines and failed to consistently retest machines with prior unacceptable bacterial culture levels.</p> <p>Failure to recognize a consistent pattern of bacteria contamination in the dialysate sampled from 14 of 17 tested dialysis machines delayed a system-wide investigation into the cause of the contamination and delayed implementation of remediations to correct the contamination.</p> <p>Failure to consistently retest machines with bacterial cultures exceeding action levels or unacceptable bacterial culture levels exposed patients to potentially contaminated machines, increasing their risk of infection. These failures resulted in prolonged contamination of dialysate used during dialysis, exposing patients undergoing dialysis to increased risk of infection.</p> <p>Findings:</p> <p>During the facility's dialysis machines preventative maintenance review on 2/16/11, the biomedical technician (BMT) stated he routinely drew samples for bacterial cultures for three dialysis machines each month and tested the</p>	V 253			

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V 253	<p>Continued From page 33</p> <p>dialysis machines sequentially to ensure each machine would be tested at least annually, a facility requirement. The BMT stated, "We sample at the (dialysis) machine. We test at the dialysate port of the dialyzer on the machine (following dialysis)."</p> <p>Review of monthly Culture Report for dialysate cultures from dialysis machines from 1/11 to 8/9/10 showed acceptable levels of bacteria colony forming units/milliliter (cfu/ml- a measure of the amount of bacteria) with only one result exceeding the action limit of 50 cfu/ml. However, prior to 8/9/10, review of earlier machine cultures from past monthly Culture Reports from 1/11/10 through 7/8/10 showed half of the dialysis machines sampled had either unacceptable levels or exceeded the action limit.</p> <p>According to the facility's Dialysis Culture Policy, last revision in September 2010, results were interpreted as "Acceptable level: below 50 cfu/ml; Action level: 50-199 cfu/ml; Unacceptable level: 200 cfu/ml or greater."</p> <p>According to the Association for the Advancement of Medical Instrumentation (AAMI), water that has had chlorine/chloramine (additives that control bacterial growth) removed as is done for hemodialysis, no longer has antimicrobial agents to control bacteria. Any remaining bacteria not removed by the water purification system (reverse osmosis or de-ionization) can proliferate rapidly. Therefore, although the maximum acceptable bacterial culture level is 200 cfu/ml (quantity), a lower threshold (action level) of 50 cfu/ml is required that would give the facility time to correct the source of contamination</p>	V 253			

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V 253	<p>Continued From page 34</p> <p>before the maximum acceptable level is reached. Since dialysate is mixed in the dialysis machine using concentrated dialysate, bicarbonate, and the purified water, the culture results remain the same as for water: acceptable less than 50 cfu/ml, action level from 50 cfu/ml to 199 cfu/ml, and unacceptable level 200 or above cfu/ml.</p> <p>The facility's Dialysis Culture Policy required staff to respond to two different scenarios depending on test results: "Single site (dialysate from one dialysis machine) at or above the action level (all other results in acceptable range) " or " More than one site at or above the action level or any site at or above unacceptable level." For a single site at or above the action level, staff was to "reculture the site within 7 days of collection date. If repeat sampling is below the action level, no further action is required."</p> <p>According to the Dialysis Culture Policy, when more than one site was at or above the action level or any site was at the unacceptable level, staff was to "Notify Facility Administrator/designee, Biomedical Services and Medical Director; Disinfect affected equipment at end of the treatment day in which results are received/reported or as recommended by Medical Director; Reculture of all affected sites within 7 days of collection date; If repeat sampling result(s) is at or above the action level, notify the Facility Administrator/designee, Biomedical Services, Medical Director and enter Troubleshooting Mode. See Troubleshooting-Elevated Bacteria/Endotoxin Policy; If more than one site at or above action level required repeat sampling or any site at or above unacceptable level will be redrawn with the</p>	V 253			

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V 253	<p>Continued From page 35 next regular monthly sample collection."</p> <p>Review of the monthly Culture Reports from 1/11/10 through 6/3/10 for dialysate sampled from dialysis machines showed multiple sites with results exceeding action levels and/or single site with unacceptable levels:</p> <p>For 1/11/10, dialysate from six (7, 9, 11, 12, 13, 14) of seven tested dialysis machines exceeded the action level with machines 11, 12, 13, 14 producing unacceptable results. According to the Dialysis Culture Policy, all six machines should have been retested with the next month's machines, but according to the facility reports, none of them were. The medical director, facility administrator, and biomedical services were to be notified for the multiple results exceeding action levels or unacceptable results, but both the facility administrator (FA) in interview on 2/17/11 at 8:37 a.m. and the area biomedical supervisor (ABS) in interview on 2/16/11 at 4:15 p.m. denied knowing about the problem until several months later.</p> <p>For 2/18/10, dialysate from three dialysis machines were tested. Machine 2 with an unacceptable level was retested the next month on 3/11/10. Machine 3 exceeded the action level, was retested the next month on 3/11/10, and results now showed an unacceptable level at 580 cfu/ml. For 3/11/10, Machine 2 as a retest, had an acceptable result. Machine 3 with its unacceptable result, was not listed as retested the next month, April 2010.</p> <p>According to the Troubleshooting-Elevated Bacteria/Endotoxin Policy, last revision September 2010, the dialysate from Machine 3</p>	V 253			

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V 253	<p>Continued From page 36</p> <p>should have been redrawn (within seven days), medical director, etc notified, equipment disinfected or water system disinfected if necessary. According to the BMT, the facility Environment Trending Report would show dates and results for all samples drawn for all test sites. Review of the Environment Trending Report showed that the dialysate from Machine 3 was indeed redrawn on 3/19/10 but its result exceeded the action limit. According to the Troubleshooting-Elevated Bacteria/Endotoxin Policy, the Medical Director, etc was to be notified and a full troubleshooting protocol initiated that included: "Evaluate/correct sample collection technique, Evaluate/correct bicarbonate preparation /distribution technique, Evaluate/correct water system components, Evaluate/replace equipment ultrafilters, Evaluate/implement biofilm removal protocols. If, following the above protocol, the dialysate culture results exceeded the action level, the medical director, etc was again to be notified and the determination made whether to remove the machine from patient use.</p> <p>According to the ABS, interviewed on 2/16/11 at 4:15 p.m., troubleshooting did not occur until months later when the entire water distribution system was disinfected with hot bleach daily for three days. ABS stated, "We continued to disinfect weekly, then every two weeks then we went back to monthly., then weekly, then every two weeks, and decreased to monthly disinfections upon the return of acceptable culture results." ABS further stated he could not remember the exact month, but thought it was June, July, or August. The ABS was asked why the entire system review took so long to be</p>	V 253			

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V 253	<p>Continued From page 37</p> <p>initiated. The ABS replied, "We thought that if the redraw was okay, the (water distribution) system was okay."</p> <p>Review of the Environment Trending Report showed dialysate from Machine 3 was tested again on 3/26/10 with an unacceptable result of 350 cfu/ml; 3/31/10 with a 50 cfu/ml result that exceeded the action level; 4/5/10 with an unacceptable result of 540 cfu/ml; 4/6/10 again with an unacceptable result of 680 cfu/ml; and finally, on 4/7/10, an acceptable result was obtained.</p> <p>For monthly Culture Report dated 4/9/10, none of the dialysate samples from the three dialysis machines tested had acceptable culture results. Dialysate from machine 5 was unacceptable at 210 cfu/ml. Dialysate from machine 6 exceeded action level with a result of 90 cfu/ml, and dialysate from machine 7 was unacceptable at 310 cfu/ml. According to the next monthly Culture Report, dated 5/6/10, none of these dialysis machines were retested as required by the Dialysate Culture Policy.</p> <p>Review of the Environment Trending Report showed machine 5 was sampled again on 4/14/10 and showed an acceptable result of less than 10 cfu/ml. Contrary to the Dialysate Culture Policy, dialysate from machine 5 was not tested again until 7/15/10 and the result was unacceptable at 470 cfu/ml.</p> <p>Dialysate from machine 6 was retested on 4/14/10 and the result was 50 cfu/ml, the action level. Dialysate from machine 6 was sampled repeatedly: 4/21/10, 20 cfu/ml, result acceptable;</p>	V 253			

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V 253	<p>Continued From page 38</p> <p>4/22/10, 130 cfu/ml, action level; 4/26/10, 830 cfu/ml, unacceptable; 4/28/10, 530 cfu/ml, unacceptable; 5/3/10, 570 cfu/ml, unacceptable; 5/7/10, 500 cfu/ml, unacceptable; 5/10/10, 120 cfu/ml, action level; 5/11/10, 50 cfu/ml, action level; 5/12/10, 50 cfu/ml, action level; 5/17/10, 160 cfu/ml, action level; 5/24/10, 260 cfu/ml, unacceptable; 6/7/10, 320 cfu/ml, unacceptable; 6/14/10, 700 cfu/ml, unacceptable; 6/28/10 360 cfu/ml, unacceptable. The consistent string of unacceptable results should have alerted staff that a pattern of contamination existed. Finally, on 7/6/10, dialysate from machine 6 was acceptable at less than 10 cfu/ml.</p> <p>Dialysate from machine 7 was retested on 4/14/10 and the result was acceptable at less than 10 cfu/ml. Dialysate from machine 7 was not tested again until 7/15/10, contrary to the Dialysate Culture Policy requiring testing the next month.</p> <p>Review of the monthly Culture Report, dated 5/6/10, showed dialysate from two (9, 10) of three dialysis machines exceeded the action limit (machine 9 with 150 cfu/ml) or was unacceptable (machine 10 with 280 cfu/ml). Review of the Environment Trending Report showed dialysate from machine 9 was retested on 5/10/10 and the result of 110 cfu/ml exceeded the action level. Machine 9 was retested a day later on 5/11/10 with an acceptable result of less than 10 cfu/ml and this result appeared on the 5/6/10 report as the "redraw (date)". Machine 10 was retested on 5/10/10 and its result of 130 cfu/ml exceeded the action level. Machine 10 was retested a day later on 5/11/10 within acceptable result of less than 10 and this result appeared on the 5/6/10 report</p>	V 253			

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V 253	<p>Continued From page 39 as the "redraw (date)"</p> <p>Review of the monthly Culture Report, dated 6/3/10 showed dialysate from five (9, 10, 11, 12, 13) of six dialysis machines exceeded the action limit (machine 9, 150 cfu/ml) or were unacceptable (machine 10, 280 cfu/ml; machine 11, 470 cfu/ml; machine 12, 550 cfu/ml; machine 13, 470 cfu/ml). "Reculture results" with no dates indicating when the dialysate samples were redrawn, indicated machines 9, 10, 11, 12, and 13 achieved acceptable levels of 10 or less than 10 cfu/ml. Review of the Environment Trending Report showed dialysate from machines 9, 10, 11, 12, and 13 were documented as retested on 6/21/10, yet no culture results were listed. Dialysate from machines 9, 10, 11, 12, and 13 were retested on 6/29/10. Machine 9's result of 360 cfu/ml was unacceptable; machine 10's result of 510 cfu/ml was unacceptable; machine 11's result of 590 cfu/ml was unacceptable; machine 12's result of 40 cfu/ml was acceptable; and machine 13's result of 410 cfu/ml was unacceptable.</p> <p>Review of the monthly Culture Report dated 7/8/10 showed dialysate samples of machines 14 and 15 had acceptable levels. Machine 16 had a culture level of 190, action level. The five machines from the 6/3/10 report were not listed for retest 7/8/10, contrary to the Dialysate Culture Policy requiring that dialysate from machines not meeting acceptable limits be retested the following month. Machine 16 was retested on 7/12/10 and its culture results were less than 10 cfu/ml which was recorded on Culture Report. Review of the Environment Trending Report showed that staff continued to test the dialysate</p>	V 253			

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V 253	<p>Continued From page 40</p> <p>from machine 16. On 7/13/10, the culture result remained acceptable at 40 cfu/ml. On 7/14/10, the result of 120 cfu/ml now was action level; on 7/19, the result of 420 cfu/ml was now unacceptable at 420 cfu/ml.</p> <p>During interview on 2/16/11 at 3:45 p.m., the BMT stated no dialysis machines were removed from service despite continued high culture results.</p> <p>On 2/16/11 at 4:15 p.m. the area biomedical supervisor (ABS) stated the problem should have been identified after two months. He stated also the policy was to recheck the machine with unacceptable results to ensure it was not a continued problem. Review of testing showed this was not consistently done.</p> <p>Review of the Dialysate Culture Policy indicated, "The Facility Administrator or designee is responsible for ensuring that cultures are obtained, results recorded, reviewed and necessary actions taken, as applicable." "Results and trends are reviewed during the facility Quality Improvement/Quality Assurance (QI/QA) meetings and documented in the meeting minutes."</p> <p>On 2/17/11 at 8:37 a.m., the facility administrator (FA) stated she was not made aware of the contaminated water results until July, 2010, and the issue was addressed facility-wide in the 8/23/10 facility quality assurance meeting. She was asked how she evaluated the monthly water culture reports to determine there were no issues or problems requiring intervention. The FA stated, "They (BMT) bring me the current month (culture results). I just look at the last column." Review of</p>	V 253			

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V 253	Continued From page 41 the monthly Culture Report showed the last column was "Reculture Results". All results seen in the "Reculture Results" were less than 50 cfu/ml, acceptable results. According to the BMT, sometimes additional retesting was done, but not documented or reflected on the monthly Culture Report. Review of the facility's Environment Trending Report showed documentation of multiple resampling of dialysis machines with continued unacceptable high culture levels. Only the last sample with an acceptable culture level was documented on the monthly Culture Report, thus creating the impression that the RO distribution system was fine after its scheduled monthly disinfection. The FA confirmed she did not review past months' culture results to discern a trend or pattern of unacceptable cultures. The FA stated she had not undergone any training about the water distribution system and her only knowledge of the water system came from her prior experience as a patient care technician where she performed tests for the presence of chlorine or pulled samples for testing.	V 253			
V 307	494.50(b)(1) PERSONNEL QUALIFICATIONS 5 Personnel qualifications and training 5.1 Qualifications Personnel shall possess adequate education, training, or experience to understand and perform procedures outlined by the individual dialysis facility relevant to the facility's multiple-use program. Education shall be geared to meet the needs of this wide range of personnel. This STANDARD is not met as evidenced by:	V 307			

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V 307	<p>Continued From page 42</p> <p>Based on interview and document review, the facility failed to ensure that one of two reuse reprocessing technicians working in the reuse dialyzer (artificial kidney for filtering blood outside the body) program was knowledgeable on how to handle chemical spills. Reuse Technician 2 did not have sufficient knowledge on how to deal with a peracetic acid (germicide/disinfectant) concentrate spill, which had the potential to expose patients and staff to the hazards of peracetic acid concentrate, such as permanent injury to eyes, skin and irritation to the nose, throat, and lungs.</p> <p>Findings:</p> <p>During an interview on 2/15/11 at 1:35 p.m. Reuse Technician 2 stated for a cup size floor spill of peracetic acid concentrate he would surround the spill with dry paper cloths and then pour sodium bicarbonate (alkaline substance used the neutralize an acid) on the spill. The Reuse Technician 2 stated he would use the wipes to pick up the spill, put the wipes in a plastic bag, seal the bag, and then dispose of the plastic bag in a biohazard container.</p> <p>Review on 2/15/11 of the facility's policy and procedure, "Peracetic Acid Concentrate Spill Procedure", dated August 2006, showed that a wet mop or sponge was to be used to soak up the spill. The mop or sponge was to be rinsed with water after the clean-up. The policy instructed, "All materials wetted with peracetic acid will be place in unsealed, clean trash bags and discarded as appropriate." The policy also showed that contaminated materials were not to be placed in closed containers "...DUE TO THE</p>	V 307			

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V 307	Continued From page 43 POSSIBILITY OF EXPLOSION FROM THE HIGH PRESSURES OF THE GASES GENERATED."	V 307			
V 332	494.50(b)(1) RINSE/CLEAN-PRECLEAN EQUIP/PRESSURES 11.2 Rinsing/cleaning: precleaning equipment/pressures 11.2.1 When precleaning is done, it is part of the reprocessing procedures. All applicable requirements for design and maintenance of equipment included in this document should be adhered to for precleaning of equipment. The maximum pressures for the dialyzer, or other limits set by the manufacturer, should be adhered to. This STANDARD is not met as evidenced by: Based on observation, interview and document review, the facility failed to ensure that the maximum water pressure allowed by the manufacturer for reprocessing Gambro dialyzers was maintained. The pressure gauge used to monitor the water pressure at the sink during the dilazers' precleaning procedure was broken and showed a higher pressure than the maximum pressure allowed by the manufacturer. The increased watter pressure could cause breaks in the dialyzer fibers and potential blood leakage. Definitions: Dialyzer - Replaces the kidneys' function of filtering the blood of waste products that would ordinarily be excreted as urine. The clear cylinder shape dialyzer contains tube like hollow fibers that filter the blood. Reprocessed dialyzer - A dialyzer that has been used for a dialysis treatment in a patient and then	V 332			

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V 332	<p>Continued From page 44</p> <p>has been cleaned, disinfected, and tested for functioning properly. The dialyzer is stored with set amount of disinfectant inside the dialyzer until the next use by that same patient.</p> <p>Pre-cleaning - Manual rinsing/cleaning of used dialyzers, done to remove as much of the residual blood and blood clots by reverse ultrafiltration by an acceptable water quality through the dialyzer membrane fibers. Pre-cleaning is part of the reprocessing of reused dialyzers.</p> <p>Findings:</p> <p>During an interview with Reuse Technician 2 and observation of the reuse dialyzer process on 2/15/11 from 1:35 p.m. to 3:07 p.m. the following were noted:</p> <ol style="list-style-type: none"> 1. When Reuse Technician 2 was asked what the acceptable maximum water pressure was when the dialyzers were manually rinsed/pre-cleaned, he stated 15 psi. 2. Observation of Reuse Technician 2 performing the rinsing/pre-cleaning task of re-processing the Gambro dialyzers, showed a water pressure gauge located to the left side of the faucets on the pre-cleaning sink. The gauge showed a reading of 30 psi. When the pressure gauge reading was brought to the technician's attention, he stated the gauge was broken. <p>Review of the facility's policy and procedure, "Manual Reverse Ultrafiltration (RUF) Without Header Removal Policy", last revised 3/07, showed, "If Gambro dialyzers are reprocessed, the water pressure must not exceed 20 psi (pounds per square inch) for blood side and 15 psi for RUF."</p>	V 332			

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V 350	<p>494.50(b)(1) GERMICIDE PRESENCE TEST OF EACH DIALYZER</p> <p>12.3.1 Presence test of each hemodialyzer Certain germicide manufacturers require testing for the presence of germicide in each hemodialyzer before the rinsing step. These instructions should be followed.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and document review, the facility failed to ensure three (Clinical Coordinator, CHT 2 and CHT 3) of three staff observed followed the policy and procedure for testing for the presence of peracetic acid (a germicide/disinfectant) in six reprocessed dialyzers prior to their clinical re-use for one (Patients 6) of 12 sampled patients and two (Patients 23 and 26) random patients. This failure increased the chances that a reused dialyzer which did not have an acceptable disinfectant concentration level would go undetected, which could result in micro-organisms/bacterial growth within the reused dialyzer and thus placing patients at risk for infections. Findings: 1. During an observation on 12/14/11 at 10:05 a.m., after Clinical Coordinator and Patient 26 verified the reused dialyzer pertained to Patient 26, Clinical Coordinator proceeded to connect the dialysis tubing and to start the normal saline solution flow through the tubing and the dialyzer. Clinical Coordinator did not check for the presence of the disinfectant in the reused dialyzer before connecting and flushing the dialyzer with normal saline. When the procedure was questioned, Clinical Coordinator confirmed he had not checked for the presence of the</p>	V 350			

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V 350	<p>Continued From page 46</p> <p>disinfectant prior to running the normal saline.</p> <p>2. During an observation on 12/16/11 at 9:15 a.m. CHT 2 did not check Patient 26's reuse dialyzer for the presence of disinfectant. CHT 2 had the normal saline solution infusing through the tubing and dialyzer when she was asked what was the facility's policy for checking the presence of disinfectant in the reprocessed dialyzer. CHT 2 stated testing was usually done from one of the ports of the dialyzer. When reminded that the normal saline solution had already started going through the dialysis tubing and the dialyzer, thus it would not be an accurate test, CHT 2 stated, "Good point".</p> <p>On 2/16/11 at 1:15 p.m. CHT 2 stated she had checked the facility policy and procedure on when to confirm the presence of an acceptable level of disinfectant in stored reused dialyzers. CHT 2 stated reuse dialyzers were to be checked prior to the start of the normal saline solution.</p> <p>3. During observations on 2/17/11 at 9:05 a.m., CHT 3 tore open a clear plastic bag holding a reuse dialyzer that had been reprocessed for Patient 23 (receiving treatment at chair station 12) and at 9:10 a.m. CHT 3 again tore open another clear plastic bag that contained a reuse dialyzer for Patient 6 (chair station 11). CHT 3 placed both dialyzers in there perspective dialysis machines holders and proceeded to connect and start normal saline solution through the dialysis tubing and dialyzers. Neither time did CHT 3 check the reuse dialyzers for the presence of the disinfectant.</p> <p>During an interview on 2/17/11 at 9:25 a.m. CHT 3 was asked why it was important to check that the dialyzer had been reprocessed and stored with an acceptable concentration level of disinfectant, CHT 3 stated to show that the</p>	V 350			

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V 350	Continued From page 47 dialyzer was safe for patient use. During an interview on 2/17/11 at 11:20 a.m., Facility Administrator stated that the CHTs probably assumed that since the reuse dialyzers had been reprocessed they would have had enough disinfectant in them. Review of the facility policy and procedure titled "Priming A Reprocessed Dialyzer Free Of Peracetic Acid Utilizing Gambro Phoenix Dialysis Delivery Systems (Use For Software: 3.3)", last revised 9/09, showed that one of the steps in the procedure was to, "perform peracetic acid presence test per procedure prior to starting the priming procedure (running saline solution through the dialysis tubing and dialyzer)". The policy further indicated, "Test strip must indicate presence of at least 500 ppm (parts per million) of peracetic acid in the reprocessed dialyzer to proceed. Do not proceed if concentration is less than 500 ppm."	V 350			
V 407	494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement). This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure that the vascular access sites were visible throughout the patients' dialysis treatment for three random patients (Patients 18, 25 and 28). The facility's failure to have the patients' vascular access sites exposed and visible had the potential for rapid, fatal exsanguination (massive	V 407			

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V 407	<p>Continued From page 48</p> <p>blood loss) if patients' cannulating needles became dislodged from the access or the tubing accidentally disconnected while hidden from view.</p> <p>Findings:</p> <p>1. On 2/15/11 between 10:45 a.m. and 1:05 p.m., Patient 18 was observed at frequent intervals sleeping during his dialysis treatment. His access was not visible being covered by the sleeve of his thick, navy blue jacket.</p> <p>During this period of time, certified hemodialysis technicians were observed entering data into the chairside computer next to Patient 18 without assessing his access. At 11:05 a.m., RN 6 administered medications directly into the bloodline. After she entered the medications into the computer, RN 6 left without assessing either the patient or his access.</p> <p>During an interview with the facility administrator on 2/17/11 at 11:25 a.m., when informed of the observation, she stated, "Accesses should always be uncovered."</p> <p>2. During the initial tour on 2/14/11 at 8:50 a.m. observation showed a bulletin board mounted on the wall near the patients' entrance to the treatment room. One of the posted documents was a sign advising patients to keep their (vascular) access visible at all times. At 8:52 a.m. observation showed Patient 25 undergoing</p>	V 407			

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V 407	Continued From page 49 dialysis at station 8. Patient 25 was covered by a blanket up to his chin. His vascular access was completely covered with only blood tubing visible outside the blanket by his left shoulder. LPN 1 was standing at the nearby computer keyboard, inputting data. At 8:55 a.m., LPN 1 glanced at Patient 25 but neither exposed Patient 25's access or told him to uncover his access. Patient 25's access was still covered at 9:06 a.m. LPN 1 again walked by Patient 25 on his way to the adjacent keyboard. He neither uncovered Patient 25's access or informed Patient 25 his access needed to be uncovered. Patient 25's access, located on his left upper arm, was not visible until 9:23 a.m. 3. During an observation on 2/15/11 at 12:05 p.m. Patient 28 had his left arm access site covered up with a jacket during the hemodialysis treatment. Continued observations showed that Patient 28's access site remained covered until 12:28 p.m., when RN 5 uncovered the site.	V 407			
V 409	494.60(d)(1) PE-ER PREP STAFF-INITIAL/ANNUAL/INFORM PTS The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following: (i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of- (A) What to do; (B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated; (C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This	V 409			

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V 409	Continued From page 50 contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and (D) How to disconnect themselves from the dialysis machine if an emergency occurs. This STANDARD is not met as evidenced by: Based on staff interview and record review, the facility failed to ensure that one (RN 2) of 14 staff reviewed received annual training in medical emergency procedures as required by the facility's written policy and procedure. This failure increased the risk that RN2 would not be able to actively participate and supervise other staff in case of a medical emergency. Findings: Review on 2/16/11 of the facility's policy and procedure titled "Injury Prevention and Safety Training Inservices", revised 9/08, showed that staff was to attend mandatory "Medical Emergency Procedures" training upon hire, then annually. In the presence of the facility administrator, the review of 14 personnel files showed no documented evidence that RN 3 received Medical Emergency Procedures training annually as required by the facility policy. The last such training was dated 7/1/09.	V 409			
V 416	494.60(d)(4)(iii) PE-CONTACT LOCAL EOC ANNUALLY	V 416			

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V 416	Continued From page 51 The facility must- (iii) Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to annually contact its local disaster management agency. This failure increased the risk that life saving dialysis services will not be available in the event of an emergency and/or the restoration of such services would be delayed. Findings: During an interview on 2/17/11 at 10:50 a.m. with the facility administrator and the clinical service specialist (CSS) for the purpose of discussing the facility's emergency/disaster preparedness, CSS stated the water company and the electric company had both been contacted and had confirmed providing services. When asked if the local disaster management agency of the State or County had been contacted, neither the FA nor the CSS could produce any documentation.	V 416			
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.	V 504			

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V 504	Continued From page 52 This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure staff followed a physician's order for the blood pressure management of one (Patient 5) of 12 sample pateints. For Patient 5, the facility staff failed to administer clonidine (medication that lowers blood pressure) as ordered by the physician. The facility's failure left Patient 5 with continued high blood pressure and at an increased risk for the complications of high blood pressure such as stroke or heart failure. Findings: 1. Review of Patient 5's "Kardex" (includes patient diagnosis, allergies, physicians' orders, home medications, hemodialysis treatment orders,etc.) on 2/15/11 at 11:30 a.m. showed that the physician had ordered blood pressure medication to be given at the end of the dialysis treatment if the blood pressure reading were above certain parameters: when the systolic (first value reported)blood pressure was above 200 and when the diastolic (second value reported) blood pressure was above 90. Review on 2/15/11 of ten "Post Treatment" hemodialysis forms, dated from 1/22/11 to 2/12/1, showed Patient 5's blood pressure had been high at the end of the dialysis treatments: Date: Post Treatment Blood Pressure: 1/22/11 237/145 1/25/11 202/129	V 504			

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V 504	<p>Continued From page 53</p> <p>1/27/11 180/113 1/29/11 180/119 2/1/11 173/114 2/3/11 177/119 2/5/11 185/115 2/8/11 177/100 2/10/11 178/124 2/12/11 197/128</p> <p>The "Medications & Ancillaries Administered" section for all 10 treatment sheets showed that clonidine was not administered to Patient 5, despite the elevated levels of his systolic and diastolic blood pressure at the end of his treatments. The "Post-treatment Data Collection & Assessment" of the treatment sheet showed documentation that only on 1/22/11 had Patient 5 been offered and that he had refused clonidine. There was no evidence that Pateitn 5's physician was notified of the pateitn's refusal to receive ordered treatment.</p> <p>The Facility Administrator on 2/15/11 at 11:30 a.m. stated the nurses needed to document if the clonidine had been given or if Patient 5 had refused the medication.</p> <p>On 2/17/11 at 10:40 a.m. Patient 5 was asked if he had ever gotten blood pressure medication after dialysis treatments while in the dialysis center, he did not remember if he had.</p> <p>Review of the facility's job description for "Registered Nurse - Chronic", dated 10/08, showed the "Essential Duties and Responsibilities" of the registered nurse. The registered nurse was to administer medications per the physician's orders and to "... document in</p>	V 504			

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V 504	Continued From page 54	V 504			
V 507	<p>the patient treatment record".</p> <p>494.80(a)(4) PA-ASSESS ANEMIA</p> <p>The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>(4) Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoiesis-stimulating agent(s).</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to assess one (Patient 11) of 12 sampled patients' hemoglobin status for continued need for Epogen before administering two doses of Epogen. This failure caused Patient 11 to continue to have a higher than clinically-accepted hemoglobin levels, placing the patient at increased risk for clotting and stroke.</p> <p>Finding:</p> <p>Record review on 2/15/11 showed Patient 11 was admitted to the facility on 12/23/10. Review of physician orders, dated 1/5/11 showed Patient 11 was to receive Epogen (brand name) utilizing the Epoetin Alfa (generic name) IV Protocol, a set of standing orders for nursing staff to titrate (alter) the amount of Epogen administered to the level of hemoglobin in the blood. Epogen is a medication that stimulates the bone marrow to produce red blood cells, and is used as a treatment for anemia in chronic renal failure. Review of Patient Progress Notes for anemia management showed</p>	V 507			

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V 507	Continued From page 55 the goal "to keep pt. (patient) within goal of (hemoglobin)10-12 g/ dl." Review of the Rounding Report showed Patient 11's hemoglobin result on 2/10/11 was 13.5 g/dl, well over the goal of 10-12 g/dl. Review of the Epogen order showed the current order of Epogen 11,000 units three times a week (Patient 11's treatment days) was to be discontinued on 2/10/11. Review of Patient 11's treatment records dated 2/10/11 and 2/12/11 showed Epogen 11,000 units was administered by nursing staff on both dates. During an interview with the clinical coordinator on 2/16/11 at 10:20 a.m., he confirmed Patient 11 received two additional unnecessary doses of Epogen. Review of the Epoetin Alfa IV Protocol indicated "Epoetin alfa is held for Hb (hemoglobin level) > (more than) 12 g/dl.	V 507			
V 541	494.90 POC-GOALS=COMMUNITY-BASED STANDARDS 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.	V 541			

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V 541	<p>Continued From page 56</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review, the facility failed to develop an individualized, comprehensive plan of care for one (Patient 9) of 12 sampled patients.</p> <p>There was no plan of care to address Patient 9's high blood sugar levels.</p> <p>Findings:</p> <p>Record review on 2/15/11 showed Patient 9 was admitted on 10/20/04 with a diagnosis of end stage renal disease caused by diabetes mellitus. On 7/11/2007, the physician ordered a blood glucose (sugar) test to be done every treatment. Review of the physician notes, dated 2/24/09, showed Patient 9 presented to the physician's office with uncontrolled diabetes, blurred vision, and reported blood sugar test results of 170 "this am", and of 154 "yesterday". (Normal blood sugar values after a 12-14-hour fast are generally 70 mg. to 100 mg.) The physician also documented on 2/24/09 that Patient 9 had, "never been hospitalized for low glucose, but been in the hospital for high glucose."</p> <p>Patient 9's Blood Glucose History summary on the treatment flowsheet, dated 11/25/10, showed that on 11/23/10 the blood sugar result was 182 mg/dl (milligrams/deciliter) and on 11/25/10 was 200 mg/dl. There was no documented evidence that Patient 9's physician was notified of this values.</p> <p>In an interview on 2/15/11 at approximately 4:40</p>	V 541			

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V 541	Continued From page 57 p.m., Clinical Service Specialist stated that the facility had no policy and procedure for reporting the blood sugar values to the patient's physician. When asked when would she expect the staff to report to the physician elevated blood sugar levels, Facility Administrator stated on 2/15/11 that she would notify the physician of a value of 200 mg/dl, while Clinical Service Specialist stated she would probably not notify the physician. On 2/16/11 at approximately 1:05 p.m., Medical Director stated in an interview that for a patient's with history of having symptoms and requiring hospitalization for blood sugar values of 170 mg/dl, a 200 mg/dl value should be reported to the treating physician.	V 541			
V 627	494.110(a)(1) QAPI-ONGOING;USES INDICATORS=IMPROVEMENT The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors. This STANDARD is not met as evidenced by: Based on interview and document review, the facility's quality assurance/performance improvement process failed to timely identify, analyze, and develop solutions to address persistent contamination of the facility treated product water used to mix with dialysate during dialysis and reprocessing dialyzers for reuse. These failures placed patients at risk for infection by receiving treatment with potentially	V 627			

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V 627	<p>Continued From page 58</p> <p>contaminated water and by using re-used dialyzers reprocessed with potentially contaminated water.</p> <p>Findings:</p> <p>Review of facility logs for culture results for R.O. (reverse osmosis, a process that removes inorganic contaminants such as chlorine, chloramine, and aluminum from water) Water and Dialysate from 1/11/2010 to 7/8/10 showed a pattern of Dialysate and RO Water from various outlets' culture results exceeding the Action level threshold of 50 cfu/ml (colony forming units per ml). According to the Association for the Advancement of Medical Instrumentation (AAMI) the 50 cfu/ml level (set by the recognition of bacteria's ability to replicate rapidly in chemically pure water) would give a facility time to take action before recommended maximum bacteria levels of 200 cfu/ml are exceeded.</p> <p>On 2/17/11 at 8:37 a.m., the facility administrator (FA) stated she was not made aware of the contaminated product water until July, 2010, and the issue was addressed facility-wide in the 8/23/10 facility quality assurance meeting. She stated the quality assurance meeting occurred monthly for the most part, and the biomedical technician (BMT) was not an attendee. She was asked how she, and therefore, the quality assurance committee, evaluated the monthly water culture reports to determine there were no issues or problems requiring intervention. The FA stated, "They (BMT) bring me the current month (culture results). I just look at the last column." Review of the last column showed "Reculture Results" were displayed, results obtained soon</p>	V 627			

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V 627	<p>Continued From page 59</p> <p>after the water distribution system would be disinfected. The "reculture" results showed consistently acceptable levels, results not reflecting the initial unacceptable culture levels exceeding the Action Levels of 50 cfu.</p> <p>The FA confirmed she did not review past months' culture results to discern a trend or pattern of unacceptable cultures. The FA stated she had not undergone any training about the water distribution system and her only knowledge of the water system came from her prior experience as a patient care technician where she performed tests for the presence of chlorine.</p> <p>Review of the facility's Continuous Quality Improvement Program indicated, "Each dialysis facility will have a Continuing Quality Improvement (CQI) Committee comprised of at least the following individuals from the interdisciplinary team: Facility Medical Director Facility Administrator/designee Registered Nurse Biomed Technician Registered Dietitian Social Worker</p> <p>According to the Continuous Quality Improvement Program policy, "The facility will measure, analyze, and track quality indicators or other aspects of performance. The program must include, but not be limited to: ...Other indicators as reflected in the Quality Improvement and Facility Management Meetings minutes form."</p> <p>Review of the "Physical System Review" (PSR) portion of the available Quality Improvement and</p>	V 627			

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V 627	Continued From page 60 Facility Management Meetings minutes, dated 1/12/10, 4/15/10, 5/19/10, 6/29/10, and 7/21/10, showed the note, "PSR no indication of a problem."	V 627			
V 715	Review of the facility's Water Culture Policy, revised September 2009, indicated "Results and trends are reviewed during the facility Quality Improvement/Quality Assurance meetings and documented in the meeting minutes." 494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; This STANDARD is not met as evidenced by: Based on observation, staff interview, and record review, the facility failed to consistently implement its policy and practice to maintain the arterial chambers three- quarter filled with blood during patient treatment at five of 19 stations (Stations 3, 8 13, 18 and 20). This practice increased the risk of air potentially entering the patients blood circulatory system. Findings: On 2/16/11 between 11:55 a.m. and 12:00 noon during patient treatments, the following were noted:	V 715			

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V 715	Continued From page 61 a. At station 18, the blood level in the arterial drip chamber was approximately one eighth (almost emptying). b. At station 13, the blood level in the arterial drip chamber was approximately one half. c. At station 20, the blood level in the arterial drip chamber was approximately one half. Review of the facility's policy, Intradialytic Treatment Monitoring, revised September 2008, showed that, "The arterial and venous drip chamber levels should be observed and adjusted as needed." On 2/16/11 at approximately 12:00 noon, the Clinical Coordinator stated that the facility's established practice was to maintain the arterial and venous drip chambers at least three-quarter blood-filled. On 2/17/11 at approximately 11:05 a.m. during patient treatments, the blood level in arterial drip chambers at station 3 and 8 was only approximately one fourth. When calling the staff's attention to it, RN 1 stated, "Oh, that's not good", and adjusted the blood level in the arterial drip chamber to approximately three-quarters.	V 715			
V 726	494.170 MR-COMPLETE, ACCURATE, ACCESSIBLE The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.	V 726			

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V 726	<p>Continued From page 62</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to have complete and accurate records for two (Patients 5 and 9) of 12 sample patients. There was no discharge summary from the hospital in Patient 9's record and there was an incomplete consent form filed in Patient 5's record. Failure to maintain accurate and complete records place patients at risk of not having their needs met.</p> <p>Findings:</p> <p>1. On 2/15/11, review of facility documents showed Patient 9 expired in the acute care hospital on 12/11/10. Medical record review showed the last treatment Patient 9 received at the facility was on 12/8/10. Patient 9's record did not contain any documentation from the hospital to describe the course of hospitalization.</p> <p>The review of the facility's policy, Medical Record Maintenance, revised September 2010, showed "Discharge summaries will be completed for all patients who ...expire... The discharge summary will be documented in the patient's medical record within 30 days after the patient becomes inactive...".</p> <p>On 2/15/11, Clinical Service Specialist stated Patient 9's medical record should have been complete. At 1:05 p.m., Medical Director stated it was his expectation that the discharge summary be completed within 30 days after the patient's demise.</p> <p>2. Record review on 2/12/11 showed that Patient 5 had signed the "Hepatitis B Vaccine Patient Consent" on 1/17/08. The consent form had a</p>	V 726			

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

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OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 052787	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 02/17/2011
NAME OF PROVIDER OR SUPPLIER ALAMEDA COUNTY DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 10700 MACARTHUR BLVD SUITE 14 OAKLAND, CA 94605		
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V 726	<p>Continued From page 63</p> <p>box in front of each statement that indicated whether he had agreed to receive the vaccine or if he refused the vaccine. Neither box was marked/checked.</p> <p>Review of the facility's "Vaccination Report" for Patient 5 did not show if Patient 5 had received or refused the hepatitis B vaccine.</p> <p>During an interview on 2/14/11 at 4:05 p.m. the Clinical Coordinator had to check the computer files for reports that would indicate as to what Patient 5 had agreed to when he had signed the consent. Review of the "Hepatitis Vaccination" report on the computer print out showed that on 9/27/08 Patient 5 had refused the vaccine.</p>	V 726			