

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

PRINTED: 02/11/2011
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 052401	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 06/08/2010
NAME OF PROVIDER OR SUPPLIER SIERRA VIEW DISTRICT HOSPITAL DIALYSIS CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 283 NORTH PEARSON DRIVE PORTERVILLE, CA 93257	
(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	INITIAL COMMENTS The following reflects the findings by the California Department of Public Health during a Recertification survey. Representing the Department: Carol Erickson, HFES Janet Parmelee, HFEN The census was 63 hemodialysis patients and the sample size was 7 hemodialysis patients.	V 000		
V 101	494.20 COMPLIANCE WITH FED/STATE/LOCAL LAWS The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure standard nursing practice was followed by permitting a patient to stand during dialysis which resulted in a fall with injury to his head. Findings: An unannounced visit was made to the facility on April 2, 2010 to investigate a complaint of a fall by Patient 12 during hemodialysis treatment on January 2, 2010. During a record review of Patient 12's medical record on April 2, 2010, treatment records	V 101		8/6/10

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 101	<p>Continued From page 1</p> <p>indicated his fluid removal goal for the date of the fall was 3.9 kilograms (8.5 pounds) over a period of 3.5 hours. This fluid removal goal was done at a rate of 2.6 pounds of fluid per hour. Patient 12 was 83 years old with coronary artery disease and alzheimer's disease. The treatment record indicated Patient 12 requested the use of a urinal at 12 PM. His blood pressure was 116/61 (normal is 120/80) and heart rate was 55 (normal is 60-80). Patient Care Technician (PCT) 6 placed a privacy curtain in front of the patient and allowed Patient 12 to stand up while hemodialysis continued. At this time, approximately 200 cc's of blood were outside of Patient 12's body in the dialysis tubing and he had lost 8 pounds of fluid. Patient 12 fell to the ground and hit his head on the privacy screen while still connected to the hemodialysis machine by a catheter inserted into his chest. Patient 12 was assisted to the chair and his blood was returned. He was transported to the emergency room where he received six staples to his forehead.</p> <p>During an interview on April 2, 2010 at 10:15 AM, Charge Nurse (CN)1 acknowledged Patient 12's blood had not been returned prior to allowing him to stand. She stated she was approximately 10 feet away from him when he fell.</p> <p>During an interview on April 2, 2010 at 10:45 AM, PCT 6 stated Patient 12 was standing up in front of the chair and fell. PCT 6 indicated she "couldn't catch him and he hit the privacy curtain and gouged his head."</p> <p>During an interview on April 2, 2010 at 11:35 AM, a policy on allowing patients to stand during hemodialysis treatment was requested from the Director. She stated, "There is no policy." She</p>	V 101			

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V 101	Continued From page 2	V 101			
V 110	also stated falls were reported to Risk Management who tracks and trends the falls. 494.30 CFC-INFECTON CONTROL This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the facility did not meet the Conditions of Participation (COP) for Infection Control by failing to: 1. Provide a sanitary environment in the unit (refer to V111). 2. Follow standard infection control precautions (refer to V112). 3. Demonstrate proper glove and hand hygiene (refer to V113). 4. Wear gowns in patient care area (refer to V115). 5. Dispose, dedicate, or disinfect items at dialysis station (V116). 6. Ensure multiple patient medications were not contaminated during medication pass (refer to V117). 7. Replace bloody transducers during treatment (Refer to V120). 8. Ensure infectious items were separated from clean items (Refer to V121). 9. Clean and disinfect surfaces in dialysis station (Refer to V122).	V 110		8/6/10	

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V 110	Continued From page 3	V 110			
V 111	<p>10. Monitor and implement infection control policies (refer to V142).</p> <p>The cumulative effect of these systemic practices had the potential to transmit infectious disease to all 63 hemodialysis patients and to facility staff.</p> <p>494.30 IC-SANITARY ENVIRONMENT</p> <p>The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to monitor and provide a sanitary environment to minimize the potential of transmission of infectious diseases to a universe of 63 patients.</p> <p>Findings:</p> <p>During the initial tour on June 2, 2010 at 9:30 AM, hydrogen peroxide, alcohol, and iodine swabs were observed on the dirty side of the sink in the rear of the treatment area. These items were used in care of the catheter insertion site on dialysis patients' chest wall and were exposed to contaminated items at the dirty sink. At 10:15 AM, the biohazardous room was entered with Staff 1. A red sign was posted on the door indicating biohazardous waste was contained in the room. Barrels with red bags were observed on the left side of the room. Also present was a cart of clean sharp containers. Staff 1 stated hospital house-keeping was responsible for the biohazardous waste.</p>	V 111		8/10/10	

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V 111	Continued From page 4 During an observation of the treatment area on June 2, 2010 at 1:45 PM, Registered Nurse 4 removed intravenous tubing and the attached one liter bag of normal saline from the dialysis machine for station A2 after the completion of the patient's dialysis. She removed the tubing from the bag and then emptied the bag's contents into the clean sink located by the nursing station. During an observation of the facility's supply room on June 3, 2010 at 9:30 AM with Patient Care Technician (PCT) 1, a large, black wet to dry vacuum cleaner was sitting behind the door and was covered from top to bottom with a gray/brown, clumpy substance. This vacuum was within one foot of a shelf containing intravenous tubing and skin dressings. PCT 1 stated the vacuum was used to clean up spills from the floor at the facility and it was there because there was no other place in the facility to store it. He could not identify the substance on the vacuum. During an interview with PCT 1 on June 3, 2010 at 9:39 AM, he stated sharps containers located in the biohazard room were used, as needed, throughout the facility. He also stated the the normal saline bags from the dialysis machines should not be emptied into the clean sinks, only the dirty sinks. During an observation of the dirty sink at the back of the facility with PCT 1 on June 3, 2010 at 9:50 AM, three bottles of calibration solution used for the calibration of phoenix meters were on the ledge above the dirty sink. A phoenix meter is a syringe style meter that measures conductivity, temperature and pH of dialysate (the solution used for dialysis). There was clear tubing coming	V 111			

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V 111	Continued From page 5 from the solutions to a small white bucket that was in the dirty sink. Three phoenix meters were on the ledge above the dirty sink. PCT 1 stated the phoenix meters are taken to the clean dialysis machines to check the dialysate just before the patients are placed on the dialysis machine.	V 111			
V 112	494.30(a) IC-CDC MMWR 2001 The facility must demonstrate that it follows standard infection control precautions by implementing- (1)(i) The recommendations (with the exception of screening for hepatitis C), found in "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html . The recommendation found under section header "HBV-Infected Patients", found on pages 27 and 28 of RR05 ("Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients"), concerning isolation	V 112		8/11/10	

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V 112	<p>Continued From page 6</p> <p>rooms, must be complied with by February 9, 2009.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, eight facility staff, one visitor, and one patient failed to follow Standard Precautions for infection control which had the potential to put all patients at risk for infection.</p> <p>Findings:</p> <p>During an observation of the treatment area on June 2, 2010 at 9:15 AM, Charge Nurse (CN) 1 was standing in the treatment area by Station A14 talking with staff and the patient. No protective cover garment was observed on CN 1.</p> <p>During an observation on June 2, 2010 at 9:45 AM, a visitor at station A14 was sitting next to the patient and within one foot of the machine during hemodialysis treatment. No protective cover garment was observed on the visitor.</p> <p>During an observation on June 2, 2010 at 2:10 PM, Patient Care Technician (PCT) 5 was observed touching dialysis machines at station A11, A15 and the isolation room with an ink pen. No gloves, handwashing, or sanitizer was used in between machines. The patient in the isolation room had been diagnosed with Methicillin Resistant Staphylococcus Aureus infection (a bacterial infection that is resistant to some antibiotics).</p> <p>During an observation on June 4, 2010 at 8:30 AM, a clipboard was left unattended on the front counter and had seven unlabelled syringes on it.</p>	V 112			

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V 112	<p>Continued From page 7</p> <p>Registered Nurse (RN) 3 returned to the front counter and stated, "I don't usually leave these but I know what they are, they are color coded, some blue and some green." The hubs of the needles attached to the syringes were either blue or green. RN 3 donned a pair of gloves and administered medications into the hemodialysis tubing for stations A4, A5, and A6. RN 3 did not replace gloves or perform hand hygiene between machines.</p> <p>During an observation on June 4, 2010 at 9 AM, PCT 2 was observed with a clipboard and ink pen. PCT 2 went from hemodialysis machines, A11, A12, and A13, pushing buttons on each machine with the tip of the pen. No sanitization of the ink pen was observed between occurrences. During this time, Environmental Services Supervisor (EVS) 1 and EVS 2 were observed in the treatment area with no personal protective equipment (PPE) such as gowns or gloves. They went from dialysis machine to dialysis machine, removing hand sanitizer which was attached to the machine and filled each one. No gloves, hand hygiene, or use of sanitizer was observed.</p> <p>During an interview on June 4, 2010 at 9:20 AM, the facility Director said EVS 1 and EVS 2 were told to don PPE. At 9:30 AM, EVS 1 and EVS 2 were observed with no PPE and continued to refill hand sanitizers on the hemodialysis machines.</p> <p>During an observation on June 4, 2010 at 9:30 AM, PCT 5 was preparing to end the dialysis for Patient 9. He donned new gloves and then touched a syringe, a shoe box, picked up Patient 9's blanket off the floor, moved her personal belongings that were on the floor, handled the intravenous tubing attached to her access site,</p>	V 112			

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V 112	<p>Continued From page 8</p> <p>then removed the tubing from her access site, while wearing the same gloves.</p> <p>During an observation on June 4, 2010 at 9:35 AM, PCT 2 was returning the blood to the patient at station A12. PCT 2 was observed typing on the computer and then clamped the patient's dialysis tubing without donning gloves.</p> <p>During an observation on June 4, 2010 at 10 AM, the patient at station A13 was holding gauze to his left arm access site with no glove on his right hand. The patient departed the facility without hand hygiene performed. PCT 4 touched the hemodialysis machine, and then typed on the computer without hand hygiene or gloves. Also at this time, Registered Nurse 1 (RN 1) took Patient 7 's blood pressure standing and sitting, entered information on the rolling computer, and touched Patient 7's dialysis machine without gloves or sanitizing his hands.</p> <p>During an interview on June 4, 2010 at 1:50 PM, the Director said patients holding their access sites should be given a glove and wash their hands afterward.</p> <p>The facility policy and procedure titled "Handwashing" dated January 2002 and reviewed by the facility on March 2009 read, "Purpose: To provide guidelines for effective handwashing, in order to prevent the transmission of bacteria, germs and infections. Policy: All personnel will use the handwashing techniques, as set forth in the following procedure, after:Each patient encounter.."</p> <p>The facility policy and procedure titled "Standard Precautions" dated January 2002 and reviewed</p>	V 112			

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V 112	Continued From page 9 by the facility on March 2009 read, "Gloves shall be changed between tasks and procedures on the same patient after contact with material that may contain a high concentration of microorganisms."	V 112			
V 113	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure proper hand hygiene was followed by seven staff and one patient which had the potential to expose patients, visitors, and staff to infectious diseases. Findings: During an observation on June 4, 2010 at 8:30 AM, a clipboard was left unattended on the front counter and had seven unlabelled syringes on it. Registered Nurse (RN) 3 returned to the front counter and stated; "I don't usually leave these but I know what they are, they are color coded, some blue and some green." RN 3 donned a pair of gloves and administered medications into the hemodialysis tubing for stations A4, A5, and A6. RN 3 did not replace gloves or perform hand hygiene between machines. During an observation on June 4, 2010 at 9 AM, Patient Care Technician (PCT) 2 was observed with a clipboard and ink pen. PCT 2 went from	V 113		8/10/10	

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V 113	<p>Continued From page 10</p> <p>hemodialysis machines, A11, A12, and A13, pushing buttons on each machine with the tip of the pen. No sanitization of the ink pen was observed between occurrences.</p> <p>During an observation on June 4, 2010 at 9 AM, Environmental Services Supervisor (EVS) 1 and EVS 2 were observed in the treatment area with no personal protective equipment (PPE). They went from machine to machine, removing hand sanitizer which was attached to the machine and filled each one. No gloves, hand hygiene, or use of sanitizer was observed.</p> <p>During an interview on June 4, 2010 at 9:20 AM, the facility Director said EVS 1 and EVS 2 were told to don PPE. At 9:30 AM, EVS 1 and EVS 2 were observed with no PPE and continued to refill hand sanitizers on the hemodialysis machines.</p> <p>During an observation on June 4, 2010 at 9:30 AM, PCT 5 was preparing to end the dialysis for Patient Patient 9. He donned new gloves and then touched a syringe, a shoe box, picked up Patient 9's blanket off the floor, moved her personal belongings that were on the floor, handled the intravenous tubing attached to her access site, then removed the tubing from her acces site, while wearing the same gloves.</p> <p>During an observation on June 4, 2010 at 9:35 AM, PCT 2 was returning the blood to the patient at station A12. PCT 2 was observed typing on the computer and then clamped the patient's tubing without donning gloves.</p> <p>During an observation on June 4, 2010 at 10 AM, the patient at station A13 was holding gauze to his access site with no glove on his hand. The</p>	V 113			

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V 113	Continued From page 11 patient departed the facility without hand hygiene performed. PCT 4 touched the hemodialysis machine, and then typed on the computer without hand hygiene or gloves. Also at this time, RN 1 took Patient 7 's blood pressure standing and sitting, entered information on the rolling computer, and touched Patient 7's dialysis machine without gloves or sanitizing his hands. During an interview on June 4, 2010 at 1:50 PM, the Director said patients holding their access sites should be given a glove and wash their hands afterward. The facility policy and procedure titled "Handwashing" dated January 2002 and reviewed by the facility on March 2009 read, "Purpose: To provide guidelines for effective handwashing, in order to prevent the transmission of bacteria, germs and infections. Policy: All personnel will use the handwashing techniques, as set forth in the following procedure, after:Each patient encounter."	V 113			
V 115	494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and	V 115		8/6/10	

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V 115	<p>Continued From page 12</p> <p>termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to ensure all staff and visitors were wearing protective cover garments in the treatment area during initiation or termination of hemodialysis which had the potential to expose them to blood splatter.</p> <p>Findings:</p> <p>During an observation of the treatment area on June 2, 2010 at 9:15 AM, the Charge Nurse (CN) 1 was standing in the treatment area by Station A14 talking with staff and the patient. No protective cover garment was observed on CN1.</p> <p>During an observation on June 2, 2010 at 9:45 AM, a visitor at station A14 was sitting next to the patient and within one foot of the machine during hemodialysis treatment. No protective cover garment was observed on the visitor.</p> <p>During an observation on June 4, 2010 at 9 AM, Environmental Services Supervisor (EVS) 1 and EVS 2 were observed in the treatment area with no personal protective equipment (PPE). They went from machine to machine, removing hand sanitizer which was attached to the machine and filled each one. No gloves, hand hygiene, or use of sanitizer was observed.</p> <p>During an interview on June 4, 2010 at 9:20 AM, the facility Director said EVS 1 and EVS 2 were told to don PPE. At 9:30 AM, EVS 1 and EVS</p>	V 115			

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V 115	Continued From page 13 were observed with no PPE and continued to refill hand sanitizers on the hemodialysis machines. Several patients were observed terminating dialysis treatments which had the potential to cause blood spatter.	V 115			
V 116	494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient. -- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient. -- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to ensure items taken to each individual hemodialysis stations were either used only for that patient or disinfected or discarded after use which had the potential to expose patients to infectious disease. Findings: During the initial tour on June 2, 2010 at 9 AM, patients at stations A1 and A3 were receiving hemodialysis treatment. On a shelf behind these stations were clean hemodialysis tubing,	V 116		8/6/10	

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V 116	<p>Continued From page 14</p> <p>dialyzers, and shoe boxes containing supplies. These clean supplies were approximately two feet away from the dialysis machine which had the potential to expose them to blood splatter from the machines.</p> <p>During an observation on June 4, 2010 at 8:30 AM, patients at stations A1 and A2 were receiving hemodialysis treatments. Several clean dialyzer and tubing sets were on the shelf behind their hemodialysis machines.</p> <p>During an observation on June 4, 2010 at 8:50 AM, a computer on wheels was observed plugged into the wall at stations A16 and A6. These computers were within two feet of the dialysis machine and patient which exposed the computers to potential blood splatter and infectious disease.</p> <p>During an observation on June 4, 2010 at 9:10 AM, the patient at station A15 was ending treatment. Noted on top of the machine was a plastic bin containing supplies dedicated to this patient. After the treatment was terminated, Patient Care Technician 3 removed the contaminated tubing from the machine, wiped the machine with the bleach rag and placed the contaminated shoe box back on the machine.</p> <p>During an observation on June 4, 2010 at 10:35, Registered Nurse 1 removed a plastic box from the ledge behind the station B3 dialysis machine and placed it on top of the machine without disinfecting it.</p> <p>During an interview on June 4, 2010 at 1:45 PM, the Director acknowledged the clean supplies were placed on the ledge behind contaminated</p>	V 116			

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V 116	Continued From page 15 dialysis machines. The Director was also aware the computers were plugged in next to dialysis machines which caused potential exposure to blood products. She stated the computer batteries were supposed to hold a charge for all day use but they have had to plug them in to charge. She stated the computers should be wiped down between stations.	V 116			
V 117	494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled. When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station. Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to ensure medications delivered to patients were not cross contaminated. Findings:	V 117		8/12/10	

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V 117	Continued From page 16	V 117			
V 120	<p>During an observation and interview on June 4, 2010 at 8:30 AM, a clipboard was left unattended on the front counter and had seven unlabelled syringes on it. Registered Nurse (RN) 3 returned to the front counter and stated; "I don't usually leave these but I know what they are, they are color coded, some blue and some green." RN 3 donned a pair of gloves and administered medications into the hemodialysis tubing for stations A4, A5, and A6. RN 3 did not replace gloves or perform hand hygiene between machines.</p> <p>494.30(a)(1)(i) IC-TRANSDUCER PROTECTORS-NOT WETTED/CHANGED</p> <p>Use external venous and arterial pressure transducer filters/protectors for each patient treatment to prevent blood contamination of the dialysis machines' pressure monitors.</p> <p>If the external transducer protector becomes wet, replace immediately and inspect the protector. If fluid is visible on the side of the transducer protector that faces the machine, have qualified personnel open the machine after the treatment is completed and check for contamination. This includes inspection for possible blood contamination of the internal pressure tubing set and pressure sensing port. If contamination has occurred, the machine must be taken out of service and disinfected using either 1:100 dilution of bleach (300-600 mg/L free chlorine) or a commercially available, EPA-registered tuberculocidal germicide before reuse.</p> <p>Change filters/protectors between each patient treatment, and do not reuse them. Internal transducer filters do not need to be changed</p>	V 120		7/30/10	

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V 120	Continued From page 17 routinely between patients. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to replace bloody transducers (filters attached to the hemodialysis tubing which should remain free of blood and fluids) during hemodialysis which had the potential to contaminate the hemodialysis machine with blood. Findings: During the initial tour on June 2, 2010 at 9:45 AM, the hemodialysis machines at station A9 and A10 were observed to have blood in the transducer line which stained the transducer red. This indicated blood had potentially reached the inside of the machine causing potential exposure to blood between patients using this machine. During an interview on June 8, 2010 at 3 PM, the Director stated staff was expected to change transducers when bloody.	V 120			
V 121	494.30(a)(4)(i) IC-HANDLING INFECTIOUS WASTE [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- (i) Handling, storage and disposal of potentially infectious waste;	V 121		8/11/10	

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V 121	<p>Continued From page 18</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to ensure infectious items were separated from clean items, which had the potential to expose all 63 dialysis patients to infectious disease.</p> <p>Findings:</p> <p>During the initial tour on June 2, 2010 at 9:30 AM, hydrogen peroxide, alcohol, and iodine swabs were observed on the dirty side of the sink in the rear of the treatment area. At 10:15 AM, the biohazardous room was entered with Staff 1. A red sign was posted on the door indicating biohazardous waste was contained in the room. Barrels with red bags were observed on the left side of the room. Also present was a cart of clean sharp containers. Staff 1 stated hospital house-keeping was responsible for the biohazardous waste.</p> <p>During the initial tour on June 2, 2010 at 9 AM, patients at stations A1 and A3 were receiving hemodialysis treatment. On a shelf behind these stations were clean hemodialysis tubing, dialyzers, and shoe boxes containing supplies. These clean supplies were approximately two feet away from the dialysis machine which had the potential to expose them to blood splatter from the machines.</p> <p>During an observation of the on June 2, 2010 at 1:45 PM, Registered Nurse (RN) 4 removed intravenous tubing and the attached 1 liter bag of normal saline from the dialysis machine for station A2 after the completion of the patient's dialysis. She removed the tubing from the bag and then emptied the bag's contents in the the</p>	V 121			

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V 121	<p>Continued From page 19</p> <p>clean sink located by the nursing station.</p> <p>During an observation of the facility's supply room on June 3, 2010 at 9:30 AM with Patient Care Technician (PCT) 1, a large, black wet to dry vacuum cleaner was sitting behind the door and was covered from top to bottom with a gray/brown, clumpy substance. This vacuum was within one foot of a shelf containing intravenous tubing and skin dressings. PCT 1 stated the vacuum was used to clean up spills from the floor at the facility and the it was there because there was no other place in the facility to store it. He could not identify the substance on the vacuum.</p> <p>During an interview with PCT 1 on June 3, 2010 at 9:39 AM, he stated sharps containers located in the biohazard room were used, as needed, throughout the facility. He also stated the the normal saline bags from the dialysis machines should not be emptied into the clean sinks, only the dirty sinks.</p> <p>During an observation on June 4, 2010 at 8:30 AM, patients at stations A1 and A2 were receiving hemodialysis treatments. Several clean dialyzer and tubing sets were on the shelf behind their hemodialysis machines.</p> <p>During an observation on June 4, 2010 at 8:50 AM, a computer on wheels was observed plugged into the wall at stations A16 and A6. These computers were within two feet of the dialysis machine and patient which exposed the computers to potential infectious disease.</p> <p>During an observation on June 4, 2010 at 9:10 AM, the patient at station A15 was ending treatment. Noted on top of the machine was a</p>	V 121			

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V 121	Continued From page 20 plastic bin containing supplies dedicated to this patient. After the treatment was terminated, PCT 3 removed the contaminated tubing from the machine, wiped the machine with the bleach rag and placed the contaminated shoe box back on the machine.	V 121			
V 122	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to ensure contaminated surfaces were disinfected which exposed patients to infectious disease. Findings: During an observation of station A12 on June 2, 2010 at 2:05 PM, the current dialysis patient's backpack was on the back ledge, directly behind the dialysis machine, leaning on the clean supplies for the next patient's dialysis. During an observation of station A13 on June 2, 2010 at 2:15 PM, the current dialysis patient's lunch box and sweater was on the back ledge, directly behind the dialysis machine, leaning on the clean supplies for the next patient's dialysis.	V 122	8/10/10		

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V 122	Continued From page 21 During an observation of the facility's supply room on June 3, 2010 at 9:30 AM with Patient Care Technician (PCT) 1, a large, black wet to dry vacuum cleaner was sitting behind the door and was covered from top to bottom with a gray/brown, clumpy substance. This vacuum was within one foot of a shelf containing intravenous tubing and skin dressings. PCT 1 stated the vacuum was used to clean up spills from the floor at the facility and the vacuum was there because there was no other place in the facility to store it. He could not identify the substance on the vacuum. During an interview with PCT 1 on June 3, 2010 at 9:39 AM, he stated patients should not put their personal items on the ledge behind the dialysis machines because clean supplies and shoe boxes belonging to other patients were kept there, which could lead to contamination of those items. During an observation on June 4, 2010 at 9:10 AM, the patient at station A15 was ending treatment. Noted on top of the machine was a plastic bin containing supplies dedicated to this patient. After the treatment was terminated, PCT 3 removed the contaminated tubing from the machine, wiped the machine with the bleach rag and placed the contaminated shoe box back on the machine. During an observation on June 4, 2010 at 10:35, Registered Nurse 1 removed a plastic box from the ledge behind station B3 dialysis machine and placed it on top of the machine without disinfecting it.	V 122			
V 142	494.30(b)(1) IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P	V 142		8/10/10	

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V 142	<p>Continued From page 22</p> <p>The facility must-</p> <p>(1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit;</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to monitor infection control practices which had the potential to expose 63 patients to infectious diseases.</p> <p>Findings:</p> <p>During an observation on June 2, 2010 at 2:10 PM, Patient Care Technician 5 was observed touching dialysis machines at station A11, A15 and the isolation room with an ink pen. No gloves, handwashing, or sanitizer was used in between machines. The patient in the isolation room had been diagnosed with Methicillin Resistant Staphylococcus Aureus infection (a bacterial infection that is resistant to some antibiotics).</p> <p>During an interview on June 4, 2010 at 3:40 PM, Patient 8 said he had acquired a Methicillin Resistant Staphylococcus Aureus (MRSA) infection in his access and had been hospitalized recently. He stated the physician said he acquired it in the dialysis facility. He further stated the patient care technicians did not pay attention to the disinfection of his site while preparing for needle insertion.</p> <p>During a record review on June 7, 2010 at 8 AM, the Infection Control Tracking log indicated two dialysis patients had MRSA infections in May</p>	V 142			

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V 142	Continued From page 23 2010 and one patient had MRSA infection in April 2010. The hospitalization log indicated Patient 8 had been admitted for sepsis on May 11, 2010 and was discharged on May 13, 2010 with MRSA. During an interview on June 7, 2010 at 1:05 PM, the Infection Control Nurse stated her role was oversight and she visited the facility about once a month. She stated she was not involved in dialysis infection control training and the hospital provided annual infection control training which was not specific to dialysis. At 1:10 PM, the facility Director stated they had performed hand hygiene surveillance in May; however, no documentation or evaluation was available.	V 142			
V 178	494.40(a) BACT OF H2O-MAXIMUM & ACTION LEVELS 4.1.2 Bacteriology of water: max & action levels Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse, shall contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration lower than 2 EU/mL The action level for the total viable microbial count in the product water shall be 50 CFU/mL, and the action level for the endotoxin concentration shall be 1 EU/mL. If those action levels are observed in the product water, corrective measures shall promptly be taken to reduce the levels. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to implement an action plan when test results of the product water used to prepare	V 178		6/21/10	

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V 178	Continued From page 24 dialysate (solution use for dialysis treatment) indicated high microbial levels which had the potential to result in life threatening infection to 63 patients. Findings: During an interview on June 3, 2010 at 10:30 AM, Patient Care Technician 1 stated he performed the water culture testing each month. He stated, "AAMI (American Association for Medical Instrumentation) guidelines say action is to be taken above 200 cfu/ml (colony forming units per milliliter) and no action is necessary below 200." During a record review of dialysis water culture reports on June 4, 2010 at 1:30 PM, results dated July 15, 2009 indicated the colony count was 50 cfu/ml and October 12, 2009 was 70 cfu/ml. No action plan was documented for these elevated cultures. During a record review on June 7, 2010 at 8:55 AM, the facility policy titled, "Water Cultures" dated March 2009 read, "Action plan starts when RO (reverse osmosis) (the equipment that removes contaminates from water) culture is greater than 50 cfu/ml " An action plan will be written and presented to the Medical Director for his/her approval within 24 hours of receiving the elevated culture." During an interview on June 8, 2010 at 8:30 AM, the Medical Director stated she was responsible for the water treatment and was not aware the staff were not taking action when cultures exceeded 50 cfu/ml.	V 178			
V 403	494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU	V 403		6/21/10	

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V 403	Continued From page 25 The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to maintain the equipment in the water treatment room to prevent leaks which exposed dialysate to bacteria. Findings: During an observation and interview on June 7, 2010 at 11 AM, the water treatment room was entered with Patient Care Technician (PCT) 2. Wet towels were observed on the floor underneath the acid mixer. A white crumbly substance was observed on the hose connection of the mixer. PCT 2 acknowledged the wet towels and the leak.	V 403			
V 408	494.60(d) PE-EMERGENCY PREPAREDNESS-PROCEDURES The dialysis facility must implement processes and procedures to manage medical and non medical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.	V 408		8/11/10	

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V 408	<p>Continued From page 26</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to implement their emergency preparedness and disaster manual which had the potential to expose a universe of 63 patients to life-threatening conditions during a disaster.</p> <p>Findings:</p> <p>During a review on June 2, 2010, the facility policy titled "Emergency Preparedness and Disaster Manual" (undated) indicated the facility had an emergency box which should contain advance directives, flashlight, batteries, camera, list of critical services providers, and mutual aid agreements. The emergency box was inspected on June 4, 2010 at 2:30 PM and these items were not found.</p> <p>During an interview on June 4, 2010 at 10:45 AM, Patient 7 stated he had received no training on what to do in an emergency situation.</p> <p>During an interview on June 4, 2010 at 10:50 AM, Patient 10 stated he did not know what to do in an emergency situation.</p> <p>During an interview on June 4, 2010 at 2:15 PM, the Director of Facility Engineering stated he was responsible for fire extinguisher, fire alarms, and fire drills but the patient evacuation drills were to be done by the facility director. The Director stated the facility had not conducted patient evacuation drills.</p> <p>During an interview with the Medical Director on June 8, 2010 at 8:30 AM, when asked if the patients were trained on what to do during an emergency, she stated, "I don't know if we train</p>	V 408			

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V 408	Continued From page 27	V 408			
V 412	<p>the patients or not."</p> <p>494.60(d)(2) PE-ER PREP-PTS ORIENTED/TRAINED</p> <p>The facility must provide appropriate orientation and training to patients, including the areas specified in paragraphs (d)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to train/retrain patients on emergency disaster procedures.</p> <p>Findings:</p> <p>During an interview on June 4, 2010 at 10:45 AM, Patient 7 stated he had not received training on what to do in an emergency situation.</p> <p>During an interview on June 4, 2010 at 10:50 AM, Patient 10 stated he did not know what to do in an emergency situation.</p> <p>During an interview on June 4, 2010 at 2:15 PM, the Director of Facility Engineering stated he was responsible for fire extinguisher, fire alarms, and fire drills but the patient evacuation drills were to be done by the facility director. The Director stated the facility had not conducted patient evacuation drills.</p> <p>During a record review on June 7, 2010 at 2 PM, the Director provided signed copies of hemodialysis patients "Clamp and Cut or Clamp and Cap Procedures" which provided written instructions on emergency removal from the hemodialysis machines. Of 63 total patients, only 31 had signed the procedure (49 percent). No additional information was provided by the</p>	V 412		8/9/10	

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V 412	Continued From page 28	V 412			
V 415	<p>Director.</p> <p>494.60(d)(4)(ii) PE-ANNUAL EVAL-EMERGENCY/DISASTER PLANS</p> <p>The facility must- Evaluate at least annually the effectiveness of the emergency and disaster plans and update them as necessary;</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to annually evaluate the effectiveness of their disaster preparedness which had the potential to cause harm to patients if a disaster occurred.</p> <p>Findings:</p> <p>During an interview on June 4, 2010 at 2:15 PM, the Director of Facility Engineering stated he was responsible for fire extinguisher, fire alarms, and fire drills but the patient evacuation drills were to be done by the facility director. The Director stated the facility had not conducted patient evacuation drills.</p> <p>During an interview with the Medical Director on June 8, 2010 at 8:30 AM, when asked if the patients were trained on what to do during an emergency, she stated, "I don't know if we train the patients or not."</p> <p>During an interview with the Director on June 8, 2010 at 1 PM, when asked if the facility did an annual evaluation of the effectiveness of their disaster preparedness, she stated, "We didn't do a write-up on that." When asked how the facility knows if their disaster preparedness was</p>	V 415		8/10/10	

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V 415	Continued From page 29 adequate, she stated, "I think repeating the drills should be enough to re-enforce." No documentation was provided for annual evaluations of the effectiveness of the facility's disaster preparedness. During a record review on June 7, 2010 at 2 PM, the Director provided signed copies of hemodialysis patients "Clamp and Cut or Clamp and Cap Procedures" which provided written instructions on emergency removal from the hemodialysis machines. Of 63 total patients, only 31 had signed the procedure (49 percent). No additional information was provided by the Director.	V 415			
V 458	494.70(a)(7) PR-INFORMED-ALL MODALITIES/SETTINGS The patient has the right to- (7) Be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis), and in-facility hemodialysis. The patient has the right to receive resource information for dialysis modalities not offered by the facility, including information about alternative scheduling options for working patients; This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to provide information on alternative modalities such as home dialysis and transplantation.	V 458		8/10/10	

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V 458	Continued From page 30 Findings: During an interview on June 8, 2010 at 8:20 AM, the Medical Director (MD) 1 stated her goal for transplantation was for "everyone younger, like 35 to 40 years old, to have a transplant. I really urge them, even if they don't want to." During an interview on June 8, 2010 at 10 AM, Social Worker (SW) 2 stated she was not doing transplantation or home dialysis training and "that should come from the doctor." SW 2 did not know if any patients were interested in home dialysis or transplant and was unable to find a transplantation referral log. On June 8, 2010 at 2 PM, the Director provided a brochure titled "Living Kidney Donation" and stated "This is what we give our new patients." The brochure described the process for donating a kidney.	V 458			
V 513	494.80(a)(10) PA-TRANSPLANTATION REFERRAL The patient's comprehensive assessment must include, but is not limited to, the following: (10) Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis for nonreferral must be documented in the patient's medical record. This STANDARD is not met as evidenced by: Based on interview and record review, the facility	V 513		8/10/10	

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V 513	<p>Continued From page 31</p> <p>failed to evaluate patients for transplantation referral.</p> <p>Findings:</p> <p>During an interview with Patient 7 on June 4, 2010 at 10:45 AM, he stated he has required dialysis for about seven months and at first the doctor told him dialysis might be temporary but around January 2010, the doctor told him it was a permanent situation. Since that time, no one from the facility has discussed with him the option of kidney transplant. He stated he would consider a kidney transplant now that he knows dialysis will be a permanent treatment. When asked his current age, he stated, "I'm 68."</p> <p>The clinical record for Patient 7 was reviewed on June 4, 2010 at 11 AM. The Hemodialysis Multidisciplinary Assessment dated November 20, 2009 indicated Patient 7 had refused a kidney transplant because he had been told that the need for dialysis may be temporary. No other assessment for transplant suitability was found in his chart and no follow-up documentation was available.</p> <p>During an interview on June 8, 2010 at 8:20 AM, the Medical Director (MD) 1 stated her goal for transplantation was for "everyone younger, like 35 to 40 years old, to have a transplant. I really urge them, even if they don't want to."</p> <p>During an interview on June 8, 2010 at 10 AM, Social Worker (SW) 2 stated she was not doing transplantation or home dialysis training and "that should come from the doctor." SW 2 did not know if any patients were interested in home dialysis or transplant and was unable to find a</p>	V 513			

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V 513	Continued From page 32 transplantation referral log.	V 513			
V 625	494.110 CFC-QAPI This CONDITION is not met as evidenced by: Based on interview and record review, the facility failed to meet the Condition of Participation (COP) for Quality Assessment and Performance Improvement (QAPI) by failing to: 1. Ensure that a data driven program was implemented, maintained and evaluated which resulted in ineffective prevention, identification and monitoring of health and safety outcomes (refer to V626). 2. Ensure program was ongoing and achieved measurable improvement of health outcomes and reduction of medical errors (refer to V627). 3. Measure, analyze, and track quality indicators that reflect processes of care (refer to V628). 4. Measure, analyze, and develop an action plan for adequacy of dialysis (refer to V629). 5. Identify goal, action plan, and timetable for increasing albumin as an indicator for nutritional status (refer to V630). 6. Identify a goal, action plan, and timetable for	V 625		8/11/10	

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V 625	Continued From page 33 management of renal bone disease (refer to V631). 7. Identify a goal, action plan, and timetable for management of anemia (refer to V632). 8. Identify a goal, action plan, and timetable for reducing catheter use (refer to V633). 9. Identify, track, and trend medical injuries and medical errors (refer to V634). 10. Identify, track and trend infection control (refer to V637). The cumulative effect of these systemic practices had the potential to result in multiple risks to patients' healthy and safety.	V 625			
V 626	494.110 QAPI-COVERS SCOPE SERV/EFFECTIVE/IDT INVOL The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS. This STANDARD is not met as evidenced by:	V 626		8/11/10	

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V 626	<p>Continued From page 34</p> <p>Based on interview and record review, the facility failed to ensure a measurable, data driven program was implemented, maintained, and evaluated which resulted in ineffective prevention, identification and monitoring of health outcomes in a universe of 63 patients.</p> <p>Findings:</p> <p>During a record review of the annual Quality Assessment and Performance Improvement (QAPI) meeting minutes on June 3, 2010, the attendees included Medical Director (MD) 1, Social Worker (SW) 1, Registered Dietitian (RD) 1 and the Director. The administrator attended two meetings (April and May) in the past year.</p> <p>The May 29, 2009 minute meetings indicated water/machine cultures were reviewed but no other quality performance indicators were identified.</p> <p>The June 19, 2009 meeting minutes indicated the Director of Performance improvement attended and the quarterly performance improvement report was reviewed. The attached report listed: patient satisfaction with no goals, trending, or action plans; medical injuries/errors with no goals, trending, or action plans; dialysis adequacy with a goal of 65 percent (%) but no goals, trending, or action plans were indicated; nutritional status with desirable albumin levels but no goals, trending, or action plans; renal bone disease with desirable laboratory values but no goals, trending, or action plans; anemia management with desirable laboratory values but no goals, trending, or action plans. Attached to the minutes was a list of patient hemoglobin and hematocrits that had been averaged, i.e., all patients values were</p>	V 626			

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V 626	<p>Continued From page 35</p> <p>added together and divided by the number of patients. This provided no individualized tracking and trending for the patients. The report also identified access goal of 65% AVF identified but no tracking; access infection goal of 0 but no tracking; vaccination goal of 90% identified but no tracking; goal of 100% quarterly preventative maintenance checks but no tracking; water and dialysate goal of 0; however, no data provided; health outcomes and patient survival indicators have no goals and no data.</p> <p>The July 31, 2009 meeting minutes indicated the quarterly performance improvement report had been reviewed; however, no data was provided. Attached to the minutes was a list of patient hemoglobins ranging from 8.3 to 13.5 (desirable 11-12) that had been averaged i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The August 28, 2009 meeting minutes indicated the water/machine cultures were reviewed. Also the albumin levels were reviewed, the minutes indicated "low in general, how to raise." No specific goal was identified or trended. Other quality measurement indicators were not addressed. Attached to the minutes was a list of patient hemoglobin ranging from 8.8 to 14.2 that had been averaged. This provided no individualized tracking and trending for the patients.</p> <p>The September 18, 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed. Attached to the</p>	V 626			

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V 626	<p>Continued From page 36</p> <p>minutes was a list of patient hemoglobins ranging from 8.2 to 14.5 that had been averaged. This provided no individualized tracking and trending for the facility.</p> <p>The October 16, 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed. Attached to the minutes was a list of patient hemoglobins ranging from 8.5 to 14.5 that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The November 20, 2009 meeting minutes indicated the water/machine cultures, the hemoglobins and albumin levels were reviewed. However, no albumin data was documented in the minutes and attached to the minutes was a list of patient hemoglobins ranging from 9.1 to 15 that had been averaged. This provided no individualized tracking and trending for the patients.</p> <p>The December 11, 2009 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were reviewed. Attached to the minutes was a list of patient hemoglobins ranging from 9 to 14 that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The January 15, 2010 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were</p>	V 626			

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V 626	<p>Continued From page 37 reviewed.</p> <p>The February 12, 2010 meeting minutes indicated water and machine cultures were reviewed. The albumins and hemoglobins were reviewed; however, no goals, trending or action plans were developed. Attached to the minutes was a list of patient hemoglobins ranging from 8.8-15.3 that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The March 19, 2010 meeting minutes indicated water/machine cultures were reviewed. Three infections were identified but no trending was reported nor action plans developed. Patient access were reported; however, no goal, trending, or action plans were developed. Hemoglobin levels were measured and 48% were above 12 (standard is 10-12); however, no goal or trending or action plan was developed. No other quality performance indicators were reviewed.</p> <p>The April 16, 2010 meeting minutes indicated 61 patients had URR (urea reduction rate) drawn and 13 were under 65% and, the performance improvement report indicated January had 37 patients meeting the goal, February had 39 patients meeting the goal, and March had 46 patients meeting the goal. No action plan was identified to increase number of patients achieving adequacy. The performance improvement report read "Unknown" for the number of patients referred for transplant. No benchmark was identified for positive outcomes following dialysis and was measured as "yes".</p> <p>The April 2010 performance improvement</p>	V 626			

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V 626	<p>Continued From page 38</p> <p>reported indicated a benchmark of 4.0 for albumin; however, this is a laboratory value, not an acceptable goal. The report also identified the benchmark for parathyroid hormone (PTH) which is an indicator for renal bone disease as 150-300 which is a laboratory value. No measurable goal is identified. The report identified the benchmark for phosphorous as 3.5-5.5 which is a laboratory value; not an acceptable goal.</p> <p>The April 2010 performance improvement report identified the benchmark for hemoglobins as greater than or equal to 11. The professionally accepted standard for hemoglobin is 10-12 g/dl. January 2010 indicated 86% of the patients had acceptable hemoglobins; however, March 2010 had dropped to 78% acceptable and no action plan was identified.</p> <p>In the April 2010 performance improvement report no medical injuries or errors were reported or identified as a quality performance indicator in January, February, or March; however, the meeting minutes indicate an incident took place January 2, 2010. No benchmark, trending, or action plan was identified for medical injuries or errors.</p> <p>The May 2010 meeting minutes indicated no medical injuries/errors were found; however, an occurrence report indicated on May 10, 2010 due to an incident, 911 was activated. Another occurrence on April 19, 2010 which required Emergency Medical Services contact was not indicated on the performance improvement minutes. In addition, the minutes also indicated only 20% of patients had achieved goal of 3.7 for albumin; however, no action plan was developed.</p>	V 626			

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NAME OF PROVIDER OR SUPPLIER SIERRA VIEW DISTRICT HOSPITAL DIALYSIS CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 283 NORTH PEARSON DRIVE PORTERVILLE, CA 93257		
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V 626	Continued From page 39 During an interview on June 8, 2010 at 8:30 AM, the MD 1 stated she did not attend Quality Improvement meetings. She stated if she has an issue, she tells the Director or Administrator. During an interview on June 8, 2010 at 10 AM, SW 2 stated she was "not familiar with QAPI" and had never seen a performance improvement report for dialysis. During an interview on June 8, 2010 at 10:40 AM, RD stated the QAPI meetings were held with the multidisciplinary meetings. During an interview with the administrator on June 8, 2010 at 1 PM, he stated he had not been active in QAPI until April and "Basically, right now the governing body, interdisciplinary and QAPI meetings are all together."	V 626			
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 record review, the facility failed to measure quality improvement indicators and to demonstrate progression towards improvement of health and safety outcomes. Findings: During a record review of the annual Quality	V 627		8/10/10	

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V 627	<p>Continued From page 40</p> <p>Assessment and Performance Improvement (QAPI) meeting minutes on June 3, 2010, the attendees included Medical Director (MD) 1, Social Worker (SW) 1, Registered Dietician (RD) 1 and the Director. The administrator attended two meetings (April and May) in the past year.</p> <p>The May 29, 2009 minute meetings indicated water/machine cultures were reviewed but no other quality performance indicators were identified.</p> <p>The June 19, 2009 meeting minutes indicated the Director of Performance improvement attended and the quarterly performance improvement report was reviewed. The attached report listed: patient satisfaction with no goals, trending, or action plans; medical injuries/errors with no goals, trending, or action plans; dialysis adequacy with a goal of 65 percent (%) but no goals, trending, or action plans were indicated; nutritional status with desirable albumin levels but no goals, trending, or action plans; renal bone disease with desirable laboratory values but no goals, trending, or action plans; anemia management with desirable laboratory values but no goals, trending, or action plans. Attached to the minutes was a list of patient hemoglobin and hematocrits that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients. The report also identified access goal of 65% AVF identified but no tracking; access infection goal of 0 but no tracking; vaccination goal of 90% identified but no tracking; goal of 100 % quarterly preventative maintenance checks but no tracking; water and dialysate goal of 0; however, no data provided; health outcomes and patient survival indicators</p>	V 627			

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V 627	<p>Continued From page 41 have no goals and no data.</p> <p>The July 31, 2009 meeting minutes indicated the quarterly performance improvement report had been reviewed; however, no data was provided. Attached to the minutes was a list of patient hemoglobins ranging from 8.3 to 13.5 (desirable 11-12) that had been averaged i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The August 28, 2009 meeting minutes indicated the water/machine cultures were reviewed. Also the albumin levels were reviewed, the minutes indicated "low in general, how to raise." No specific goal was identified or trended. Other quality measurement indicators were not addressed. Attached to the minutes was a list of patient hemoglobin ranging from 8.8 to 14.2 that had been averaged. This provided no individualized tracking and trending for the patients.</p> <p>The September 18, 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed. Attached to the minutes was a list of patient hemoglobins ranging from 8.2 to 14.5 that had been averaged. This provided no individualized tracking and trending for the facility.</p> <p>The October 16, 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed. Attached to the minutes was a list of patient hemoglobins ranging from 8.5 to 14.5 that</p>	V 627			

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V 627	<p>Continued From page 42</p> <p>had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The November 20, 2009 meeting minutes indicated the water/machine cultures, the hemoglobins and albumin levels were reviewed. However, no albumin data was documented in the minutes and attached to the minutes was a list of patient hemoglobins ranging from 9.1 to 15 that had been averaged. This provided no individualized tracking and trending for the patients.</p> <p>The December 11, 2009 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were reviewed. Attached to the minutes was a list of patient hemoglobins ranging from 9 to 14 that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The January 15, 2010 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were reviewed.</p> <p>The February 12, 2010 meeting minutes indicated water and machine cultures were reviewed. The albumins and hemoglobins were reviewed; however, no goals, trending or action plans were developed. Attached to the minutes was a list of patient hemoglobins ranging from 8.8-15.3 that had been averaged, i.e., all patients values were added together and divided by the number of</p>	V 627			

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V 627	<p>Continued From page 43</p> <p>patients. This provided no individualized tracking and trending for the patients</p> <p>The March 19, 2010 meeting minutes indicated water/machine cultures were reviewed. Three infections were identified but no trending was reported nor action plans developed. Patient access were reported; however, no goal, trending, or action plans were developed. Hemoglobin levels were measured and 48% were above 12 (standard is 10-12); however, no goal or trending or action plan was developed. No other quality performance indicators were reviewed.</p> <p>The April 16, 2010 meeting minutes indicated 61 patients had URR (urea reduction rate) drawn and 13 were under 65% and, the performance improvement report indicated January had 37 patients meeting the goal, February had 39 patients meeting the goal, and March had 46 patients meeting the goal. No action plan was identified to increase number of patients achieving adequacy. The performance improvement report read "Unknown" for the number of patients referred for transplant. No benchmark was identified for positive outcomes following dialysis and was measured as "yes".</p> <p>The April 2010 performance improvement reported indicated a benchmark of 4.0 for albumin; however, this is a laboratory value, not an acceptable goal. The report also identified the benchmark for parathyroid hormone (PTH) which is an indicator for renal bone disease as 150-300 which is a lab value. No measurable goal is identified. The report identified the benchmark for phosphorous as 3.5-5.5 which is a laboratory value; not an acceptable goal.</p>	V 627			

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V 627	<p>Continued From page 44</p> <p>The April 2010 performance improvement report identified the benchmark for hemoglobins as greater than or equal to 11. The professionally accepted standard for hemoglobin is 10-12 g/dl. January 2010 indicated 86% of the patients had acceptable hemoglobins; however, March 2010 had dropped to 78% acceptable and no action plan was identified.</p> <p>In the April 2010 performance improvement report no medical injuries or errors were reported or identified as a quality performance indicator in January, February, or March; however, the meeting minutes indicate an incident took place January 2, 2010. No benchmark, trending, or action plan was identified for medical injuries or errors.</p> <p>The May 2010 meeting minutes indicated no medical injuries/errors were found; however, an occurrence report indicated on May 10, 2010 due to an incident, 911 was activated. Another occurrence on April 19, 2010 which required Emergency Medical Services contact was not indicated on the performance improvement minutes. In addition, the minutes also indicated only 20% of patients had achieved goal of 3.7 for albumin; however, no action plan was developed.</p> <p>During an interview on June 8, 2010 at 8:30 AM, the MD 1 stated she did not attend Quality Improvement meetings. She stated if she has an issue, she tells the Director or Administrator.</p> <p>During an interview on June 8, 2010 at 10 AM, the SW 2 stated she was "not familiar with QAPI" and had never seen a performance improvement report for dialysis.</p>	V 627			

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V 627	Continued From page 45 During an interview on June 8, 2010 at 10:40 AM, RD stated the QAPI meetings were held with the multidisciplinary meetings. During an interview with the administrator on June 8, 2010 at 1 PM, he stated he had not been active in QAPI until April and "Basically, right now the governing body, interdisciplinary and QAPI meetings are all together." He was unable to identify benchmarks for quality indicators. During a record review and interview on June 8, 2010 at 1:30 PM, the facility director was asked to identify the benchmark for medical errors and injuries. The facility performance improvement document had no benchmark and reported no incidents for the first quarter of 2010. The facility director was not aware of any medical injuries or errors occurring in the facility (9 medical injuries and 6 medication errors were identified from occurrence logs). The director was unable to identify a benchmark or an action plan for performance improvement. During an interview with the Director on June 8, 2010 at 1:30 PM, she stated she did not have a benchmark for adequacy but "we should trend up with a final goal of 100%." She was not able to identify benchmarks for albumins but stated, "100%". She was not able to identify benchmarks for medical injuries/errors and stated she was not aware they should be measured.	V 627			
V 628	494.110(a)(2) QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops	V 628		8/10/10	

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V 628	<p>Continued From page 46</p> <p>that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to measure quality improvement indicators and to demonstrate progression towards improvement of health and safety outcomes.</p> <p>Findings:</p> <p>During a record review of the annual Quality Assessment and Performance Improvement (QAPI) meeting minutes on June 3, 2010, the attendees included Medical Director (MD) 1, Social Worker (SW) 1, Registered Dietician (RD) 1 and the Director. The administrator attended two meetings (April and May) in the past year.</p> <p>The May 29, 2009 minute meetings indicated water/machine cultures were reviewed but no other quality performance indicators were identified.</p> <p>The June 19, 2009 meeting minutes indicated the Director of Performance improvement attended and the quarterly performance improvement report was reviewed. The attached report listed: patient satisfaction with no goals, trending, or action plans; medical injuries/errors with no goals, trending, or action plans; dialysis adequacy with a goal of 65 percent (%) but no goals, trending, or action plans were indicated; nutritional status with desirable albumin levels but no goals, trending, or action plans; renal bone disease with desirable laboratory values but no goals, trending, or action plans; anemia management with desirable</p>	V 628			

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V 628	<p>Continued From page 47</p> <p>laboratory values but no goals, trending, or action plans. Attached to the minutes was a list of patient hemoglobin and hematocrits that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients. The report also identified access goal of 65% AVF identified but no tracking; access infection goal of 0 but no tracking; vaccination goal of 90% identified but no tracking; goal of 100% quarterly preventative maintenance checks but no tracking; water and dialysate goal of 0; however, no data provided; health outcomes and patient survival indicators have no goals and no data.</p> <p>The July 31, 2009 meeting minutes indicated the quarterly performance improvement report had been reviewed; however, no data was provided. Attached to the minutes was a list of patient hemoglobins ranging from 8.3 to 13.5 (desirable 11-12) that had been averaged i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The August 28, 2009 meeting minutes indicated the water/machine cultures were reviewed. Also the albumin levels were reviewed, the minutes indicated "low in general, how to raise." No specific goal was identified or trended. Other quality measurement indicators were not addressed. Attached to the minutes was a list of patient hemoglobin ranging from 8.8 to 14.2 that had been averaged. This provided no individualized tracking and trending for the patients.</p>	V 628			

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V 628	<p>Continued From page 48</p> <p>The September 18, 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed. Attached to the minutes was a list of patient hemoglobins ranging from 8.2 to 14.5 that had been averaged. This provided no individualized tracking and trending for the facility.</p> <p>The October 16, 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed. Attached to the minutes was a list of patient hemoglobins ranging from 8.5 to 14.5 that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The November 20, 2009 meeting minutes indicated the water/machine cultures, the hemoglobins and albumin levels were reviewed. However, no albumin data was documented in the minutes and attached to the minutes was a list of patient hemoglobins ranging from 9.1 to 15 that had been averaged. This provided no individualized tracking and trending for the patients.</p> <p>The December 11, 2009 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were reviewed. Attached to the minutes was a list of patient hemoglobins ranging from 9 to 14 that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p>	V 628			

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

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V 628	Continued From page 49 The January 15, 2010 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were reviewed. The February 12, 2010 meeting minutes indicated water and machine cultures were reviewed. The albumins and hemoglobins were reviewed; however, no goals, trending or action plans were developed. Attached to the minutes was a list of patient hemoglobins ranging from 8.8-15.3 that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients. The March 19, 2010 meeting minutes indicated water/machine cultures were reviewed. Three infections were identified but no trending was reported nor action plans developed. Patient access were reported; however, no goal, trending, or action plans were developed. Hemoglobin levels were measured and 48% were above 12 (standard is 10-12); however, no goal or trending or action plan was developed. No other quality performance indicators were reviewed. The April 16, 2010 meeting minutes indicated 61 patients had URR (urea reduction rate) drawn and 13 were under 65% and, the performance improvement report indicated January had 37 patients meeting the goal, February had 39 patients meeting the goal, and March had 46 patients meeting the goal. No action plan was identified to increase number of patients achieving adequacy. The performance improvement report read; "Unknown" for the number of patients referred for transplant. No	V 628			

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V 628	<p>Continued From page 50</p> <p>benchmark was identified for positive outcomes following dialysis and was measured as "yes".</p> <p>The April 2010 performance improvement reported indicated a benchmark of 4.0 for albumin; however, this is a laboratory value, not an acceptable goal. The report also identified the benchmark for parathyroid hormone (PTH) which is an indicator for renal bone disease as 150-300 which is a lab value. No measurable goal is identified. The report identified the benchmark for phosphorous as 3.5-5.5 which is a laboratory value; not an acceptable goal.</p> <p>The April 2010 performance improvement report identified the benchmark for hemoglobins as greater than or equal to 11. The professionally accepted standard for hemoglobin is 10-12 g/dl. January 2010 indicated 86% of the patients had acceptable hemoglobins; however, March 2010 had dropped to 78% acceptable and no action plan was identified.</p> <p>In the April 2010 performance improvement report no medical injuries or errors were reported or identified as a quality performance indicator in January, February, or March; however, the meeting minutes indicate an incident took place January 2, 2010. No benchmark, trending, or action plan was identified for medical injuries or errors.</p> <p>The May 2010 meeting minutes indicated no medical injuries/errors were found; however, an occurrence report indicated on May 10, 2010 due to an incident, 911 was activated. Another occurrence on April 19, 2010 which required Emergency Medical Services contact was not indicated on the performance improvement</p>	V 628			

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V 628	Continued From page 51 minutes. In addition, the minutes also indicated only 20% of patients had achieved a goal of 3.7 for albumin; however, no action plan was developed. During an interview on June 8, 2010 at 8:30 AM, the MD 1 stated she did not attend Quality Improvement meetings. She stated if she has an issue, she tells the Director or Administrator. During an interview on June 8, 2010 at 10 AM, the SW 2 stated she was "not familiar with QAPI" and had never seen a performance improvement report for dialysis. During an interview on June 8, 2010 at 10:40 AM, the RD stated the QAPI meetings were held with the multidisciplinary meetings. During an interview with the administrator on June 8, 2010 at 1 PM, he stated he had not been active in QAPI until April and "Basically, right now the governing body, interdisciplinary and QAPI meetings are all together." He was unable to identify benchmarks for quality indicators. During an interview with the Director on June 8, 2010 at 1:30 PM, she stated she did not have a benchmark for adequacy but "we should trend up with a final goal of 100%" She was not able to identify benchmarks for albumins but stated "100%". She was not able to identify benchmarks for medical injuries/errors and stated she was not aware they should be measured.	V 628			
V 629	494.110(a)(2)(i) QAPI-INDICATOR-ADEQUACY OF DIALYSIS The program must include, but not be limited to, the following:	V 629		8/10/10	

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V 629	<p>Continued From page 52</p> <p>(i) Adequacy of dialysis.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to identify a benchmark for dialysis adequacy which prevented tracking, trending and performance improvement and had the potential for inadequate dialysis for 63 patients.</p> <p>Findings:</p> <p>During a record review of the annual Quality Assessment and Performance Improvement (QAPI) meeting minutes on June 3, 2010, the attendees included Medical Director (MD) 1, Social Worker (SW) 1, Registered Dietician (RD) 1 and the Director. The administrator attended two meetings (April and May) in the past year.</p> <p>The May 2009 minute meetings indicated water/machine cultures were reviewed but no quality performance indicators for dialysis adequacy were identified.</p> <p>The June 2009 meeting minutes indicated the Director of Performance improvement attended and the quarterly performance improvement report was reviewed. The attached report listed: patient satisfaction with no goals or tracking; medical injuries with no goals or tracking; errors with no goals or tracking; dialysis adequacy with a goal of 65 percent (%) but no tracking numbers indicated; nutritional status with desirable albumin levels but no goals and no tracking; renal bone disease with desirable laboratory values but no goals and no tracking; anemia management with desirable laboratory values but no goals and no tracking.</p>	V 629			

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V 629	Continued From page 53 The July 2009 meeting minutes indicated the quarterly performance improvement report had been reviewed; however, no performance indicators were provided. The August 2009 meeting minutes indicated the water/machine cultures were reviewed. Also the albumin levels were reviewed, the minutes indicated "low in general, how to raise." No goal was identified or trending. Other quality measurement indicators were not addressed. The September 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed. The October 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed. The November 2009 meeting minutes indicated the water/machine cultures, the hemoglobins and albumin levels were reviewed. No other quality performance indicators were reviewed. The December 2009 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were reviewed. The January 2010 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were reviewed. The February 2010 meeting minutes indicated water and machine cultures were reviewed. The	V 629			

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V 629	Continued From page 54 albumins and hemoglobins were reviewed; however, no goals, trending or action plans were developed. No other quality performance indicators were reviewed. The March 2010 meeting minutes indicated water/machine cultures were reviewed. Three infections were identified but no trending was reported nor action plans developed. Patient access were reported; however, no goal, trending, or action plans were developed. Hemoglobin levels were measured; however, no goal or trending or action plan was developed. No other quality performance indicators were reviewed. The April 2010 meeting minutes indicated 61 patients had URR (urea reduction rate) drawn and 13 were under 65%; however, the performance improvement report indicated January had 37 patients meeting the goal, February had 39 patients meeting the goal, and March had 46 patients meeting the goal. No action plan was identified to increase the adequacy. During a record review and interview on June 8, 2010 at 1 PM, the facility director was asked to identify the benchmark for dialysis adequacy. The facility performance improvement document indicated a benchmark of 65%. The facility reported the measures in patient numbers and not percentages; therefore, the data was not accurate. The Director stated the final goal was 100% and they should be trending up. Neither the administrator nor the Director was not able to identify the action plan and timetable to achieve this goal.	V 629			
V 630	494.110(a)(2)(ii)	V 630		8/10/10	

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V 630	<p>Continued From page 55</p> <p>QAPI-INDICATOR-NUTRITIONAL STATUS</p> <p>The program must include, but not be limited to, the following: (ii) Nutritional status.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to identify a benchmark for nutritional status which prevented tracking, trending, and performance improvement for 63 patients.</p> <p>Findings:</p> <p>During a record review of the annual Quality Assessment and Performance Improvement (QAPI) meeting minutes on June 3, 2010, the attendees included Medical Director (MD) 1, Social Worker (SW) 1, Registered Dietician (RD) 1 and the Director. The administrator attended two meetings (April and May) in the past year.</p> <p>The May 2009 minute meetings indicated water/machine cultures were reviewed but no other quality performance indicators were identified.</p> <p>The June 2009 meeting minutes indicated the Director of Performance improvement attended and the quarterly performance improvement report was reviewed. The attached report listed: patient satisfaction with no goals or tracking; medical injuries with no goals or tracking; errors with no goals or tracking; dialysis adequacy with a goal of 65% but no tracking numbers indicated; nutritional status with desirable albumin levels but no goals and no tracking; renal bone disease with desirable laboratory values but no goals and no</p>	V 630			

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V 630	<p>Continued From page 56</p> <p>tracking; anemia management with desirable laboratory values but no goals and no tracking. The July 2009 meeting minutes indicated the quarterly performance improvement report had been reviewed; however, no data was provided. Attached to the minutes was a list of patient hemoglobin and hematocrits that had been averaged i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The August 2009 meeting minutes indicated the water/machine cultures were reviewed. Also the albumin levels were reviewed, the minutes indicated "low in general, how to raise." No goal was identified, no trending done, or action plan.</p> <p>The September 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed.</p> <p>The October 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed.</p> <p>The November 2009 meeting minutes indicated the water/machine cultures, the hemoglobins and albumin levels were reviewed. However, no albumin data was documented in the minutes and attached to the minutes was a list of patient hemoglobin and hematocrits that had been averaged. This provided no individualized tracking and trending for the patients.</p> <p>The December 2009 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were</p>	V 630			

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V 630	Continued From page 57 reviewed. The January 2010 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were reviewed. The February 2010 meeting minutes indicated water and machine cultures were reviewed. The albumins and hemoglobins were reviewed; however, no goals, trending or action plans were developed. The March 2010 meeting minutes indicated water/machine cultures were reviewed. Three infections were identified but no trending was reported nor action plans developed. Patient access were reported; however, no goal, trending, or action plans were developed. Hemoglobin levels were measured; however, no goal or trending or action plan was developed. No other quality performance indicators were reviewed. During a record review and interview on June 8, 2010 at 10:30 AM, RD 1 was asked to identify the benchmark for nutritional status. The facility performance improvement document indicated a benchmark of 4.0, which is the optimal albumin level. The facility had identified a laboratory value and instead of percentages; therefore, the data was not accurate. RD 1 was unable to identify the facility's goal and stated, "I think the goal is to see an increase and I'm not sure if we set a number."	V 630			
V 631	494.110(a)(2)(iii) QAPI-INDICATOR-CKD-MBD The program must include, but not be limited to, the following:	V 631		8/9/10	

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V 631	<p>Continued From page 58</p> <p>(iii) Mineral metabolism and renal bone disease.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to identify a benchmark for mineral metabolism and renal bone disease which prevented tracking, trending, and performance improvement for 63 patients.</p> <p>Findings:</p> <p>During a record review and interview on June 8, 2010 at 1:15 PM, the facility director was asked to identify the benchmark for mineral metabolism and renal bone disease. The facility performance improvement document indicated a benchmark of 3.5-5.0 which is the laboratory value for phosphorous and 150-300 which is a laboratory value for parathyroid hormone. The data was reported in percentages but the benchmark was not. The facility director stated the goal as 100% but had no action plan or timetable in order to measure progress.</p> <p>During a record review of the annual Quality Assessment and Performance Improvement (QAPI) meeting minutes on June 3, 2010, the attendees included Medical Directory (MD) 1, Social Worker (SW) 1, Registered Dietician (RD) 1 and the Director. The administrator attended two meetings (April and May) in the past year.</p> <p>The May 2009 minute meetings indicated water/machine cultures were reviewed but no quality performance indicators were identified.</p> <p>The June 2009 meeting minutes indicated the Director of Performance improvement attended</p>	V 631			

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V 631	<p>Continued From page 59</p> <p>and the quarterly performance improvement report was reviewed. The attached report listed: patient satisfaction with no goals or tracking; medical injuries with no goals or tracking; errors with no goals or tracking; dialysis adequacy with a goal of 65 percent (%) but no tracking numbers indicated; nutritional status with desirable albumin levels but no goals and no tracking; renal bone disease with desirable laboratory values but no goals and no tracking; anemia management with desirable laboratory values but no goals and no tracking. The July 2009 meeting minutes indicated the quarterly performance improvement report had been reviewed; however, no data was provided. Attached to the minutes was a list of patient hemoglobin and hematocrits that had been averaged i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The August 2009 meeting minutes indicated the water/machine cultures were reviewed. Also the albumin levels were reviewed, the minutes indicated "low in general, how to raise." No goal was identified or trending. Other quality measurement indicators were not addressed.</p> <p>The September 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed.</p> <p>The October 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed.</p> <p>The November 2009 meeting minutes indicated the water/machine cultures, the hemoglobins and</p>	V 631			

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V 631	<p>Continued From page 60</p> <p>albumin levels were reviewed. However, no albumin data was documented in the minutes and attached to the minutes was a list of patient hemoglobin and hematocrits that had been averaged.</p> <p>The December 2009 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were reviewed.</p> <p>The January 2010 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were reviewed.</p> <p>The February 2010 meeting minutes indicated water and machine cultures were reviewed. The albumins and hemoglobins were reviewed; however, no goals, trending or action plans were developed.</p> <p>The March 2010 meeting minutes indicated water/machine cultures were reviewed. Three infections were identified but no trending was reported nor action plans developed. Patient access were reported; however, no goal, trending, or action plans were developed. Hemoglobin levels were measured; however, no goal or trending or action plan was developed. No other quality performance indicators were reviewed.</p> <p>The April 2010 performance improvement reported indicated a benchmark of 4.0 for albumin; however, this is a laboratory value, not an acceptable goal. The report also identified the benchmark for PTH as 150-300 which is a laboratory value. No measurable goal is</p>	V 631			

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V 631	Continued From page 61 identified. The report identified the benchmark for phosphorous as 3.5-5.5 which is a laboratory value; not an acceptable goal.	V 631			
V 632	494.110(a)(2)(iv) QAPI-INDICATOR-ANEMIA MANAGEMENT The program must include, but not be limited to, the following: (iv) Anemia management. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to identify an accurate benchmark for anemia management which prevented tracking, trending, and performance improvement. Findings: During a record review and interview on June 8, 2010 at 1:20 PM, the facility director was asked to identify the benchmark for anemia management. The facility performance improvement document indicated a benchmark of greater than or equal to 11 which is a laboratory value for hemoglobin and not a percentage. The percentage of patients in the first quarter of 2010 was declining. The facility director was not able to identify an accurate benchmark and indicated she was the anemia manager for the facility. The May 29, 2009 minute meetings indicated water/machine cultures were reviewed but no other quality performance indicators were identified. The June 19, 2009 meeting minutes indicated the Director of Performance improvement attended and the quarterly performance improvement	V 632		8/9/10	

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V 632	<p>Continued From page 62</p> <p>report was reviewed. The attached report listed: patient satisfaction with no goals, trending, or action plans; medical injuries/errors with no goals, trending, or action plans; dialysis adequacy with a goal of 65 percent (%) but no goals, trending, or action plans were indicated; nutritional status with desirable albumin levels but no goals, trending, or action plans; renal bone disease with desirable laboratory values but no goals, trending, or action plans; anemia management with desirable laboratory values but no goals, trending, or action plans. Attached to the minutes was a list of patient hemoglobin and hematocrits that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients. The report also identified access goal of 65% AVF identified but no tracking; access infection goal of 0 but no tracking; vaccination goal of 90% identified but no tracking; goal of 100% quarterly preventative maintenance checks but no tracking; water and dialysate goal of 0; however, no data provided; health outcomes and patient survival indicators have no goals and no data.</p> <p>The July 31, 2009 meeting minutes indicated the quarterly performance improvement report had been reviewed; however, no data was provided. Attached to the minutes was a list of patient hemoglobins ranging from 8.3 to 13.5 (desirable 11-12) that had been averaged i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The August 28, 2009 meeting minutes indicated the water/machine cultures were reviewed. Also</p>	V 632			

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V 632	<p>Continued From page 63</p> <p>the albumin levels were reviewed, the minutes indicated "low in general, how to raise." No specific goal was identified or trended. Other quality measurement indicators were not addressed. Attached to the minutes was a list of patient hemoglobin ranging from 8.8 to 14.2 that had been averaged. This provided no individualized tracking and trending for the patients.</p> <p>The September 18, 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed. Attached to the minutes was a list of patient hemoglobins ranging from 8.2 to 14.5 that had been averaged. This provided no individualized tracking and trending for the facility.</p> <p>The October 16, 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed. Attached to the minutes was a list of patient hemoglobins ranging from 8.5 to 14.5 that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The November 20, 2009 meeting minutes indicated the water/machine cultures, the hemoglobins and albumin levels were reviewed. However, no albumin data was documented in the minutes and attached to the minutes was a list of patient hemoglobins ranging from 9.1 to 15 that had been averaged. This provided no individualized tracking and trending for the patients.</p>	V 632			

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

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V 632	<p>Continued From page 64</p> <p>The December 11, 2009 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were reviewed. Attached to the minutes was a list of patient hemoglobins ranging from 9 to 14 that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The January 15, 2010 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were reviewed.</p> <p>The February 12, 2010 meeting minutes indicated water and machine cultures were reviewed. The albumins and hemoglobins were reviewed; however, no goals, trending or action plans were developed. Attached to the minutes was a list of patient hemoglobins ranging from 8.8-15.3 that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The March 19, 2010 meeting minutes indicated water/machine cultures were reviewed. Three infections were identified but no trending was reported nor action plans developed. Patient access were reported; however, no goal, trending, or action plans were developed. Hemoglobin levels were measured and 48% were above 12 (standard is 10-12); however, no goal or trending or action plan was developed. No other quality performance indicators were reviewed.</p> <p>The April 16, 2010 meeting minutes indicated 61</p>	V 632			

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V 632	<p>Continued From page 65</p> <p>patients had URR (urea reduction rate) drawn and 13 were under 65% and, the performance improvement report indicated January had 37 patients meeting the goal, February had 39 patients meeting the goal, and March had 46 patients meeting the goal. No action plan was identified to increase number of patients achieving adequacy. The performance improvement report read "Unknown" for the number of patients referred for transplant. No benchmark was identified for positive outcomes following dialysis and was measured as "yes".</p> <p>The April 2010 performance improvement reported indicated a benchmark of 4.0 for albumin; however, this is a laboratory value, not an acceptable goal. The report also identified the benchmark for parathyroid hormone (PTH) which is an indicator for renal bone disease as 150-300 which is a laboratory value. No measurable goal is identified. The report identified the benchmark for phosphorous as 3.5-5.5 which is a laboratory value; not an acceptable goal.</p> <p>The April 2010 performance improvement report identified the benchmark for hemoglobins as greater than or equal to 11. The professionally accepted standard for hemoglobin is 10-12 g/dl. January 2010 indicated 86% of the patients had acceptable hemoglobins; however, March 2010 had dropped to 78% acceptable and no action plan was identified.</p> <p>In the April 2010 performance improvement report no medical injuries or errors were reported or identified as a quality performance indicator in January, February, or March; however, the meeting minutes indicate an incident took place January 2, 2010. No benchmark, trending, or</p>	V 632			

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V 632	Continued From page 66 action plan was identified for medical injuries or errors.	V 632			
V 634	<p>The May 2010 meeting minutes indicated no medical injuries/errors were found; however, an occurrence report indicated on May 10, 2010 due to an incident, 911 was activated. Another occurrence on April 19, 2010 which required Emergency Medical Services contact was not indicated on the performance improvement minutes. In addition, the minutes also indicated only 20% of patients had achieved goal of 3.7 for albumin; however, no action plan was developed.</p> <p>494.110(a)(2)(vi) QAPI-INDICATOR-MEDICAL INJURIES/ERRORS</p> <p>The program must include, but not be limited to, the following: (vi) Medical injuries and medical errors identification.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to:</p> <ol style="list-style-type: none"> 1. Identify a benchmark for medical errors and injuries. 2. Failed to report medical errors and injuries. 3. Failed to trend medical errors and injuries. 4. Failed to identify an action plan to prevent medical errors and injuries. <p>Findings:</p> <p>During an interview on April 2, 2010 at 11:35 AM, a policy on allowing patients to stand during hemodialysis treatment was requested from the Director. She stated, "There is no policy." She</p>	V 634		8/9/10	

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V 634	<p>Continued From page 67</p> <p>also stated falls were reported to Risk Management who tracks and trends the falls.</p> <p>During an interview on April 5, 2010 at 3 PM, the administrator stated the Quality Assurance Performance Improvement (QAPI) program was performed by the Performance Improvement department of the hospital and stated he did not attend the Performance Improvement meetings. At this time, the policy titled, "Performance Improvement Plan" dated January 2002, reviewed February 2009 was reviewed. This policy indicated, "The Renal Services Clinical Coordinator is responsible for establishing and implementing a dialysis services performance improvement program." The administrator stated the title of Renal Services Clinical Coordinator was not used and stated the Director was responsible for performance improvement.</p> <p>During an interview on April 5, 2010 at 4 PM, the Director of Performance Improvement stated she did not have minutes for dialysis QAPI. The Performance Improvement indicators for 2009 included access and infection. No adequacy, nutrition, mineral metabolism, anemia, grievances, or injuries were tracked.</p> <p>The policy titled, "Performance Improvement Plan" indicated, "The frequency of reporting will be as defined in the hospital wide PI (Performance Improvement) plan, but not less than quarterly. Documentation and reports shall include: findings from monitoring activities; conclusions regarding identified opportunities for improvement; recommendations concerning potential actions; actions taken to effectuate change; outcome of actions effectiveness (results of follow-up monitoring performed to determine</p>	V 634			

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V 634	Continued From page 68 extent of effectiveness and that improvements made are sustained." During a review of the facility's 2009 Performance Improvement Report on April 5, 2010, no tracking was present for adequacy of dialysis, medical errors/injuries, nutrition, bone disease, or anemia management. The May 2010 meeting minutes indicated no medical injuries/errors were found; however, an occurrence report indicated on May 10, 2010 due to an incident, 911 was activated. Another occurrence on April 19, 2010 which required Emergency Medical Services contact was not indicated on the performance improvement minutes. During a record review and interview on June 8, 2010 at 1:30 PM, the facility director was asked to identify the benchmark for medical errors and injuries. The facility performance improvement document had no benchmark and reported no incidents for the first quarter of 2010. The facility director was not aware of any medical injuries or errors occurring in the facility (nine medical injuries and six medication errors were identified from occurrence logs). The director was unable to identify a benchmark or an action plan for performance improvement.	V 634			
V 637	494.110(a)(2)(ix) QAPI-INDICATOR-INF CONT-TREND/PLAN/ACT The program must include, but not be limited to, the following: (ix) Infection control; with respect to this component the facility must- (A) Analyze and document the incidence of infection to identify trends and establish baseline	V 637		8/9/10	

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V 637	<p>Continued From page 69</p> <p>information on infection incidence; (B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and (C) Take actions to reduce future incidents.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to identify a benchmark, action plan, or analysis of infections which prevented performance improvement.</p> <p>Findings:</p> <p>During an interview on June 7, 2010 at 1:05 PM, the Infection Control Nurse stated her role was oversight and she visited the facility about once a month. She stated she was not involved in dialysis infection control training and the hospital provided annual infection control training which was not specific to dialysis. At 1:10 PM, the facility director stated they had performed hand hygiene surveillance in May; however, no documentation or evaluation was available.</p> <p>During a record review on June 8, 2010 at 1:40 PM, the facility director was asked to identify the benchmark for infections. The facility performance improvement document had no benchmark and the facility director identified the benchmark as "zero". The facility had seven infections in the first quarter of 2010. The director was unable to identify an action plan or timetable for performance improvement.</p> <p>The May 2009 minute meetings indicated water/machine cultures were reviewed but no other quality performance indicators were</p>	V 637			

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V 637	<p>Continued From page 70 identified.</p> <p>The June 2009 meeting minutes indicated the Director of Performance improvement attended and the quarterly performance improvement report was reviewed. The attached report listed: patient satisfaction with no goals or tracking; medical injuries with no goals or tracking; errors with no goals or tracking; dialysis adequacy with a goal of 65 percent (%) but no tracking numbers indicated; nutritional status with desirable albumin levels but no goals and no tracking; renal bone disease with desirable laboratory values but no goals and no tracking; anemia management with desirable laboratory values but no goals and no tracking. Attached to the minutes was a list of patient hemoglobin and hematocrits that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients. The report also identified access goal of 65% AVF identified but no tracking; access infection goal of 0 but no tracking; vaccination goal of 90% identified but no tracking; goal of 100% quarterly preventative maintenance checks but no tracking; water and dialysate goal of 0; however, no data provided; health outcomes and patient survival indicators have no goals and no data.</p> <p>The July 2009 meeting minutes indicated the quarterly performance improvement report had been reviewed; however, no data was provided.</p> <p>The August 2009 meeting minutes indicated the water/machine cultures were reviewed. Also the albumin levels were reviewed, the minutes indicated "low in general, how to raise." No goal was identified or trending. Other quality</p>	V 637			

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V 637	<p>Continued From page 71</p> <p>measurement indicators were not addressed.</p> <p>The September 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed.</p> <p>The October 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed.</p> <p>The November 2009 meeting minutes indicated the water/machine cultures, the hemoglobins and albumin levels were reviewed. However, no albumin data was documented in the minutes and attached to the minutes was a list of patient hemoglobin and hematocrits that had been averaged.</p> <p>The December 2009 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were reviewed.</p> <p>The January 2010 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were reviewed.</p> <p>The February 2010 meeting minutes indicated water and machine cultures were reviewed. The albumins and hemoglobins were reviewed; however, no goals, trending or action plans were developed.</p> <p>The March 2010 meeting minutes indicated water/machine cultures were reviewed. Three infections were identified but no trending was reported nor action plans developed.</p>	V 637			

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V 710	<p>494.150 CFC-RESPONSIBILITIES OF THE MEDICAL DIRECTOR</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the facility failed to ensure that the Condition of Participation regarding medical director responsibilities was met as follows:</p> <ol style="list-style-type: none"> 1. The Medical Director failed to ensure an action plan was implemented for water cultures above 50 CFU/ml (refer to V178). 2. The Medical Director failed to provide operational responsibility for the emergency preparedness of the facility (refer to V408). 3. The Medical Director failed to provide operational responsibility for the Quality Assessment and Performance Improvement (QAPI) program and an effective data driven program (refer to V712). 4. The Medical Director failed to ensure the staff adhered to policies and procedures regarding infection control and the QAPI program (Refer to V715). <p>The cumulative effect of these systemic problems resulted in the facility's inability to ensure quality health care and patient safety.</p>	V 710		10/1/10	
V 712	<p>494.150(a) MD RESP-QAPI PROGRAM</p> <p>Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program.</p> <p>This STANDARD is not met as evidenced by:</p>	V 712		8/11/10	

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V 712	<p>Continued From page 73</p> <p>Based on observation, interview, and record review, the medical director failed to ensure the Quality Assessment and Performance Improvement (QAPI) program was operational and an effective data driven program was implemented and maintained which resulted in ineffective monitoring of prevention and reduction of medical injuries and medical errors.</p> <p>Findings:</p> <p>During a record review of the annual QAPI meeting minutes on June 3, 2010, the attendees included the Medical Director (MD) 1, Social Worker (SW) 1, Registered Dietician (RD) 1 and the Director. The administrator attended two meetings (April and May) in the past year.</p> <p>The May 29, 2009 minute meetings indicated water/machine cultures were reviewed but no other quality performance indicators were identified.</p> <p>The June 19, 2009 meeting minutes indicated the Director of Performance improvement attended and the quarterly performance improvement report was reviewed. The attached report listed: patient satisfaction with no goals, trending, or action plans; medical injuries/errors with no goals, trending, or action plans; dialysis adequacy with a goal of 65 percent (%) but no goals, trending, or action plans were indicated; nutritional status with desirable albumin levels but no goals, trending, or action plans; renal bone disease with desirable lab values but no goals, trending, or action plans; anemia management with desirable laboratory values but no goals, trending, or action plans. Attached to the minutes was a list of patient hemoglobin and hematocrits that had been</p>	V 712			

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

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V 712	<p>Continued From page 74</p> <p>averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients. The report also identified access goal of 65% AVF identified but no tracking; access infection goal of 0 but no tracking; vaccination goal of 90% identified but no tracking; goal of 100% quarterly preventative maintenance checks but no tracking; water and dialysate goal of 0; however, no data provided; health outcomes and patient survival indicators have no goals and no data.</p> <p>The July 31, 2009 meeting minutes indicated the quarterly performance improvement report had been reviewed; however, no data was provided. Attached to the minutes was a list of patient hemoglobins ranging from 8.3 to 13.5 (desirable 11-12) that had been averaged i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The August 28, 2009 meeting minutes indicated the water/machine cultures were reviewed. Also the albumin levels were reviewed, the minutes indicated "low in general, how to raise." No specific goal was identified or trended. Other quality measurement indicators were not addressed. Attached to the minutes was a list of patient hemoglobin ranging from 8.8 to 14.2 that had been averaged. This provided no individualized tracking and trending for the patients.</p> <p>The September 18, 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance</p>	V 712			

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V 712	<p>Continued From page 75</p> <p>indicators were reviewed. Attached to the minutes was a list of patient hemoglobins ranging from 8.2 to 14.5 that had been averaged. This provided no individualized tracking and trending for the facility.</p> <p>The October 16, 2009 meeting minutes indicated the water/machine cultures were reviewed. No other quality performance indicators were reviewed. Attached to the minutes was a list of patient hemoglobins ranging from 8.5 to 14.5 that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The November 20, 2009 meeting minutes indicated the water/machine cultures, the hemoglobins and albumin levels were reviewed. However, no albumin data was documented in the minutes and attached to the minutes was a list of patient hemoglobins ranging from 9.1 to 15 that had been averaged. This provided no individualized tracking and trending for the patients.</p> <p>The December 11, 2009 meeting minutes indicated the water/machine cultures had been reviewed. No other quality performance indicators were reviewed. Attached to the minutes was a list of patient hemoglobins ranging from 9 to 14 that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The January 15, 2010 meeting minutes indicated the water/machine cultures had been reviewed.</p>	V 712			

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V 712	<p>Continued From page 76</p> <p>No other quality performance indicators were reviewed.</p> <p>The February 12, 2010 meeting minutes indicated water and machine cultures were reviewed. The albumins and hemoglobins were reviewed; however, no goals, trending or action plans were developed. Attached to the minutes was a list of patient hemoglobins ranging from 8.8-15.3 that had been averaged, i.e., all patients values were added together and divided by the number of patients. This provided no individualized tracking and trending for the patients.</p> <p>The March 19, 2010 meeting minutes indicated water/machine cultures were reviewed. Three infections were identified but no trending was reported nor action plans developed. Patient access were reported; however, no goal, trending, or action plans were developed. Hemoglobin levels were measured and 48% were above 12 (standard is 10-12); however, no goal or trending or action plan was developed. No other quality performance indicators were reviewed.</p> <p>The April 16, 2010 meeting minutes indicated 61 patients had URR (urea reduction rate) drawn and 13 were under 65% and, the performance improvement report indicated January had 37 patients meeting the goal, February had 39 patients meeting the goal, and March had 46 patients meeting the goal. No action plan was identified to increase number of patients achieving adequacy. The performance improvement report read "Unknown" for the number of patients referred for transplant. No benchmark was identified for positive outcomes following dialysis and was measured as "yes".</p>	V 712			

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V 712	<p>Continued From page 77</p> <p>The April 2010 performance improvement reported indicated a benchmark of 4.0 for albumin; however, this is a laboratory value, not an acceptable goal. The report also identified the benchmark for parathyroid hormone (PTH) which is an indicator for renal bone disease as 150-300 which is a laboratory value. No measurable goal is identified. The report identified the benchmark for phosphorous as 3.5-5.5 which is a laboratory value; not an acceptable goal.</p> <p>The April 2010 performance improvement report identified the benchmark for hemoglobins as greater than or equal to 11. The professionally accepted standard for hemoglobin is 10-12 g/dl. January 2010 indicated 86% of the patients had acceptable hemoglobins; however, March 2010 had dropped to 78% acceptable and no action plan was identified.</p> <p>In the April 2010 performance improvement report no medical injuries or errors were reported or identified as a quality performance indicator in January, February, or March; however, the meeting minutes indicate an incident took place January 2, 2010. No benchmark, trending, or action plan was identified for medical injuries or errors.</p> <p>The May 2010 meeting minutes indicated no medical injuries/errors were found; however, an occurrence report indicated on May 10, 2010 due to an incident, 911 was activated. Another occurrence on April 19, 2010 which required Emergency Medical Services contact was not indicated on the performance improvement minutes. In addition, the minutes also indicated only 20% of patients had achieved goal of 3.7 for albumin; however, no action plan was developed.</p>	V 712			

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V 712	Continued From page 78	V 712			
V 715	<p>During an interview on June 8, 2010 at 8:30 AM, the MD 1 stated she did not attend Quality Improvement meetings. She stated if she has an issue, she tells the Director or Administrator.</p> <p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P</p> <p>The medical director must-</p> <p>(2) Ensure that-</p> <p>(i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers;</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility's Medical Director failed to ensure staff adhered to policies and procedures regarding: 1) Infection control; 2) Water cultures; and, 3) Emergency Preparedness which resulted in risks to patients health and safety.</p> <p>Findings:</p> <p>1. During an observation of the treatment area on June 2, 2010 at 9:15 AM, the Charge Nurse (CN) 1 was standing in the treatment area by Station A14 talking with staff and the patient. No protective cover garment was observed on CN 1.</p> <p>During the initial tour on June 2, 2010 at 9:30 AM, hydrogen peroxide, alcohol, and iodine swabs were observed on the dirty side of the sink in the rear of the treatment area. At 10:15 AM, the biohazardous room was observed with Staff 1. Barrels with red bags were observed on the left</p>	V 715		10/1/10	

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V 715	<p>Continued From page 79</p> <p>side of the room. Also present was a cart of clean sharp containers. Staff 1 stated hospital house-keeping was responsible for the biohazardous waste.</p> <p>During an observation on June 2, 2010 at 9:45 AM, a visitor at station A14 was sitting next to the patient and within one foot of the machine during hemodialysis treatment. No protective cover garment was observed on the visitor.</p> <p>During an observation of the on June 2, 2010 at 1:45 PM, Registered Nurse (RN) 4 removed intravenous tubing and the attached one liter bag of normal saline from the dialysis machine for station A2 after the completion of the patient's dialysis. She removed the tubing from the bag and then emptied the bag's contents in the the clean sink located by the nursing station.</p> <p>During an observation of the facility's supply room on June 3, 2010 at 9:30 AM with Patient Care Technician (PCT) 1, a large, black wet to dry vacuum cleaner was sitting behind the door and was covered from top to bottom with a gray/brown, clumpy substance. This vacuum was within 1 foot of a shelf containing intravenous tubing and skin dressings. PCT 1 stated the vacuum was used to clean up spills from the floor at the facility and the it was there because there was no other place in the facility to store it. He could not identify the substance on the vacuum.</p> <p>During an interview with PCT 1 on June 3, 2010 at 9:39 AM, he stated sharps containers located in the biohazard room were used, as needed, throughout the facility. He also stated the the normal saline bags from the dialysis machines should not be emptied into the clean sinks, only</p>	V 715			

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V 715	<p>Continued From page 80</p> <p>the dirty sinks.</p> <p>During an observation of the dirty sink at the back of the facility with PCT 1 on June 3, 2010 at 9:50 AM, three bottles of chemicals used for the calibration meters (a syringe style meter that measures conductivity, temperature and pH of dialysate) were sitting on the ledge above the dirty sink. There was clear tubing coming from the chemicals to a small white bucket that was sitting in the dirty sink. Three calibration meters were sitting on the ledge above the dirty sink. He stated the calibration meters are taken to the clean dialysis machines to check calibration just before the patients are hooked up to the tubing.</p> <p>During an observation on June 4, 2010 at 8:30 AM, a clipboard was left unattended on the front counter and had seven unlabelled syringes on it. RN 3 returned to the front counter and stated, "I don't usually leave these but I know what they are, they are color coded, some blue and some green." RN 3 donned a pair of gloves and administered medications into the hemodialysis tubing for stations A4, A5, and A6. RN 3 did not replace gloves or perform hand hygiene between machines.</p> <p>During an observation on June 4, 2010 at 9 AM, PCT 2 was observed with a clipboard and ink pen. PCT 2 went from hemodialysis machines, A11, A12, and A13, pushing buttons on each machine with the tip of the pen. No sanitization of the ink pen was observed between occurrences.</p> <p>During an observation on June 4, 2010 at 9 AM, Environmental Services Supervisor (EVS) 1 and EVS 2 were observed in the treatment area with no personal protective equipment (PPE). They</p>	V 715			

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V 715	<p>Continued From page 81</p> <p>went from machine to machine, removing hand sanitizer which was attached to the machine and filled each one. No gloves, hand hygiene, or use of sanitizer was observed.</p> <p>During an interview on June 4, 2010 at 9:20 AM, the facility Director said EVS 1 and EVS 2 were told to don PPE. At 9:30 AM, EVS 1 and EVS were observed with no PPE and continued to refill hand sanitizers on the hemodialysis machines.</p> <p>During an observation on June 4, 2010 at 9:30 AM, PCT 5 was preparing to end the dialysis for Patient 9. He donned new gloves and then touched a syringe, a shoe box, picked up Patient 9's blanket off the floor, moved her personal belongings that were on the floor, handled the intravenous tubing attached to her access site, then removed the tubing from her access site, while wearing the same gloves.</p> <p>During an observation on June 4, 2010 at 9:35 AM, PCT 2 was returning the blood to the patient at station A12. PCT 2 was observed typing on the computer and then clamped the patient's tubing without donning gloves.</p> <p>During an observation on June 4, 2010 at 10 AM, the patient at station A13 was holding gauze to his access site with no glove on his hand. The patient departed the facility without hand hygiene performed. PCT 4 touched the hemodialysis machine, and then typed on the computer without hand hygiene or gloves. Also at this time, RN 1 took Patient 7 's blood pressure standing and sitting, entered information on the rolling computer, and touched Patient 7's dialysis machine without gloves or sanitizing his hands.</p>	V 715			

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V 715	<p>Continued From page 82</p> <p>During an interview on June 4, 2010 at 1:50 PM, the Director said patients holding their access sites should be given a glove and wash their hands afterward.</p> <p>The facility policy and procedure titled "Handwashing" dated January 2002 and reviewed by the facility on March 2009 read, "Purpose: To provide guidelines for effective handwashing, in order to prevent the transmission of bacteria, germs and infections. Policy: All personnel will use the handwashing techniques, as set forth in the following procedure, after:Each patient encounter."</p> <p>The facility policy and procedure titled "Standard Precautions" dated January 2002 and reviewed by the facility on March 2009 read, "Gloves shall be changed between tasks and procedures on the same patient after contact with material that may contain a high concentration of microorganisms."</p> <p>During an interview on June 8, 2010 at 8:30 AM, the Medical Director (MD) 1 stated she did not attend Quality Improvement meetings. She stated if she has an issue, she tells the Director or Administrator.</p> <p>2. During an interview on June 3, 2010 at 10:30 AM, PCT 1 stated he performed the water culture testing each month. He stated, "AAMI (American Association for Medical Instrumentation) guidelines say action is to be taken above 200 cfu/ml (colony forming units per milliliter) and no action is necessary below 200."</p> <p>During a review of dialysis water culture reports on June 4, 2010 at 1:30 PM, results dated July</p>	V 715			

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V 715	<p>Continued From page 83</p> <p>15, 2009 indicated the colony count was 50 cfu/ml and October 12, 2009 was 70 cfu/ml. No action plan was documented for these elevated cultures.</p> <p>During a record review on June 7, 2010 at 8:55 AM, the facility policy titled, "Water Cultures" dated March 2009 read, "Action plan starts when RO (reverse osmosis) (the equipment that removes contaminates from water) culture is greater than 50 cfu/ml" An action plan will be written and presented to the Medical Director for his/her approval within 24 hours of receiving the elevated culture."</p> <p>During an interview on June 8, 2010 at 8:30 AM, the MD 1 stated she was responsible for the water treatment and was not aware the staff were not taking action when cultures exceeded 50 cfu/ml.</p> <p>3. During a review on June 2, 2010, the facility policy titled, "Emergency Preparedness and Disaster Manual" (undated) indicated the facility had an emergency box which should contain advance directives, flashlight, batteries, camera, list of critical services providers, and mutual aid agreements. The emergency box was inspected on June 4, 2010 at 2:30 PM and these items were not found.</p> <p>During an interview on June 4, 2010 at 10:45 AM, Patient 7 stated he had received no training on what to do in an emergency situation.</p> <p>During an interview on June 4, 2010 at 10:50 AM, Patient 10 stated he did not know what to do in an emergency situation.</p> <p>During an interview on June 4, 2010 at 2:15 PM,</p>	V 715			

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V 715	Continued From page 84 the Director of Facility Engineering stated he was responsible for fire extinguisher, fire alarms, and fire drills but the patient evacuation drills were to be done by the facility director. The Director stated the facility had not conducted patient evacuation drills.	V 715			
V 750	494.180 CFC-GOVERNANCE During an interview with the MD 1 on June 8, 2010 at 8:30 AM, when asked if the patients were trained on what to do during an emergency, she stated, "I don't know if we train the patients or not."	V 750		8/11/10	
V 751	494.180 GOV-ID GOV BODY W/FULL AUTHORITY/RESPONS This CONDITION is not met as evidenced by: Based on interview and record review, it was determined the facility did not meet the Condition of Participation (COP) for Governing Body by failing to: 1. Identify members of the governing body and provide meeting minutes (refer to V751). 2. Provide necessary staff and resources for the Quality Assessment and Performance Improvement (QAPI) program (refer to V756). The cumulative effect of these systemic problems resulted in the facility's inability to ensure quality health care and patient safety.	V 751		8/24/10	
	The ESRD facility is under the control of an identifiable governing body, or designated person(s) with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and				

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V 751	Continued From page 85 enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients ' personal and property rights, and to the general operation of the facility. This STANDARD is not met as evidenced by: Based on interview, the facility failed to identify members of the governing body and provide meeting minutes. Findings: During an interview with the Medical Director on June 8, 2010 at 8:30 AM, she stated she does not attend the governing body meetings. She stated the administrator takes any issues she has to the governing body but she was not certain if he attended those meetings or not. During an interview with the administrator on June 8, 2010 at 1 PM, he stated he had not been active in Quality Assessment and Performance Improvement (QAPI) until April and "Basically, right now the governing body, interdisciplinary and QAPI meetings are all together."	V 751			
V 756	494.180(a)(4) GOV-ADM RESP FOR RESOURCES FOR QAPI The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to- (4) Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program as described	V 756		8/24/10	

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V 756	Continued From page 86 in §494.110. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to provide necessary staff and resources for the Quality Assessment and Performance Improvement (QAPI) program. Findings: During a record review of the provided QAPI/Multidisciplinary meeting minutes on June 3, 2010, the attendees included the medical director (MD) 1, the facility director, social worker (SW) 2, and registered dietician (RD). The administrator attended two meetings (April and May) in the past year. During an interview on June 8, 2010 at 8:30 AM, the MD 1 stated she did not attend Quality Improvement meetings. She stated if she has an issue, she tells the Director or Administrator. During an interview on June 8, 2010 at 10 AM, the SW 2 stated she was "not familiar with QAPI" and had never seen a performance improvement report for dialysis. During an interview on June 8, 2010 at 10:40 AM, the RD stated the QAPI meetings were held with the multidisciplinary meetings. During an interview with the administrator on June 8, 2010 at 1 PM, he stated he had not been active in QAPI until April and "Basically, right now the governing body, interdisciplinary and QAPI meetings are all together."	V 756			

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

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