

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

PRINTED: 02/10/2011  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>052651</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>11/01/2010</b>
NAME OF PROVIDER OR SUPPLIER  <b>FMC DS BERKELEY</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2895 SEVENTH STREET BERKELEY, CA 94710</b>	
(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 of the California Department of Public Health during a recertification survey from 10/26/10 to 11/1/10.  Representing the Department: Nikki Kratt, HFEN; Elida Huerta, HFEN; and Dorothy Rice, HFEN.	V 000		
V 110	The census of the facility on 10/26/10 was 129. 494.30 CFC-INFECTIOIN CONTROL  This CONDITION is not met as evidenced by: Based on observation of care delivery, interview with staff, and record review, the facility failed to comply with the Condition for Coverage for Infection Control as demonstrated by:  Failure to ensure staff followed policies for glove changes and hand hygiene for Patient 7 and for seven patients at stations 5, 7, 9, 13, 14, 15 and 17. This failure increased the risk for cross-contamination. (V113)  Facility staff's failure to follow the policy to maintain the transducer protectors clean and dry during dialysis treatments for four of 19 dialysis machines observed. This failure increased the potential for cross-contamination and for inaccurate venous and /or arterial pressures. (V120)  Failure to ensure that patients' blood pressure cuffs were cleaned and disinfected on a consistent basis after each patient dialysis treatment for seven (Patients 14, 17, 18, 22, 24, 25 and a patient at station 1) of seven patients observed. This failure increased the risk for	V 110		

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 110	Continued From page 1 cross-contamination and bloodborne infections. (V122)  Failure to follow the policy and procedure, "Patient Tuberculin Skin Testing Mantoux" (test for tuberculosis-TB) for one (Patient 2) of 13 sampled patients. For Patient 2, the facility failed to have documentation that a tuberculin skin test had been done on the first admission to the facility and on a subsequent admission. When Patient 2's tuberculin test had been positive, there was no documentation as to what the follow up had been. The facility's practice had the potential to put other patients in the facility at risk for tuberculosis. (V142)  Failure to follow its policy to remove expired medications from use. In the medication refrigerator there was one vial of expired Tubersol (tuberculin product). This failure increased the risk of product degradation that could result in inaccurate results for tuberculosis (TB-highly infectious respiratory illness) testing. (V143)  Failure to ensure staff followed its policy and procedure to maintain aseptic technique while performing catheter care for two (Patients 4 and 9) sampled and one random (Patient 19) of three patients with catheters observed. This failure resulted in cross-contamination and increased the potential for infection. (V147)  The cumulative effect of these failures constituted a severe safety breach that limited the facility's ability to furnish adequate care and had the potential to cause patient harm.	V 110			
V 113	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE	V 113			

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V 113	<p>Continued From page 2</p> <p>Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure staff followed policies for glove changes and hand hygiene for Patient 7 and for patients at stations 5, 7, 9, 13, 14, 15 and 17. This failure increased the risk for cross-contamination.</p> <p>Findings:</p> <p>According to the Center for Disease Control (CDC), hand hygiene is the most important measure to prevent contaminant transmission. CDC recommends the use of gloves as exposure to blood and potentially contaminated items is routinely anticipated during hemodialysis. Staff should wear gloves when touching blood lines, dialyzer or machine during or after a dialysis treatment, when inserting or removing the vascular access needles, when cleaning and disinfecting machines. Gloves should be changed when soiled, when moving from an area/task where there was potential for contamination (i.e. removing lines) to a clean area or task (i.e. after touching one patient or a patient's machine and before providing care to another patient or touching another patient's machine.</p> <p>1. During the initial tour on 10/26/10 at 10:45 a.m., CHT (Certified Hemodialysis Technician) N was observed wearing gloves and carrying blood tubing filled with diluted blood and saline bag and</p>	V 113			

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V 113	<p>Continued From page 3</p> <p>tubing to the dirty sink and hazardous waste container. After draining the saline bag into the sink, she dropped all the tubing and bag into the hazardous waste container. Wearing the same gloves, she walked to station 5 and began cleaning off the dialysis machine with a cloth wetted with cleaning solution. CHT N was interviewed afterward and asked if she should have performed an action after handling dirty equipment and before cleaning the dialysis machine for the next patient. CHT N replied "I should change my gloves." After prompting, she added "Wash my hands."</p> <p>2. On 10/27/10 at approximately 11:50 a.m., HCT K was observed walking to station 15 in response to a dialysis machine alarm. HCT K was not wearing gloves at the time. He slipped his right hand inside his cover gown sleeve and touched the screen on the dialysis machine. He then walked to a table 20 feet away and donned gloves without washing his hands. He walked to station 13 and touched the dialysis machine screen. He picked up the patient ' s clip board stored on top of the dialysis machine and wrote down some information. Touching the patient ' s chair, he told the patient his blood pressure was going down. HCT K handled the patient ' s blood lines, readjusted the patient ' s blood pressure cuff, again picked up the clipboard and wrote more information, touched the machine screen, and raised the foot rest on the treatment chair to elevate the patients ' legs.</p> <p>With the same gloves on, CHT K walked to Station 17 which did not yet have a patient, but had been set up with new lines so was presumably clean. Without removing his gloves and performing hand hygiene, CHT K picked up</p>	V 113			

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V 113	<p>Continued From page 4</p> <p>the clipboard briefly from the top of the dialysis machine, replaced it, then picked up a small object off the floor. CHT K then removed his gloves and touched the machine screen without performing hand hygiene first and putting on new gloves. He then performed hand hygiene with alcohol gel, rubbing his hands very briefly. He walked over to station 14 where a patient was dialyzing and picked up the clipboard to write without first putting on gloves. He then touched the machine screen. He did not perform hand hygiene after touching the patient ' s equipment on station 14, but grabbed a new pair of gloves which he donned before walking over to station 7 where a patient was dialyzing. He touched the machine screen, then removed the patient ' s food from the affixed tray table, and touched the lid of the waste container in order to throw the food away. He then removed his right glove only without performing hand hygiene and without donning new gloves before touching the machine screen at station 7 to input data.</p> <p>CHT K then walked to station 9 to address an alarm from the dialysis machine. He slipped his ungloved right hand into his cover gown sleeve to touch the machine screen. He used his still gloved left hand to write down information. He manipulated the blood pressure cuff on the patient at station 9 with his bare right hand. He then put his old right glove back on, touched the patient, touched the machine screen, and held the clipboard with his right hand while writing info with left hand. He manipulated blood tubing, the arterial chamber, touched the machine screen, back to the blood lines, and elevated the patient ' s legs. He removed his gloves and rubbed his hands with alcohol gel. With his bare hands he went back to station 9, picked up the clipboard,</p>	V 113			

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V 113	<p>Continued From page 5</p> <p>wrote, touched the machine screen, and returned the clipboard. Without performing hand hygiene and donning gloves, he walked to station 7, touched the machine screen, moved to the computer screen and typed, then tucked his right hand into his right sleeve and touched the display screen.</p> <p>CHT K was interviewed at 12:10 p.m. immediately after the observations and informed he was observed working from patient to patient and station to station without changing his gloves and performing hand hygiene. He stated that the gloves were located too far away and with patients with low (blood) pressure, " You have to check right away. I can't go all the way over to the gloves. " He stated he did not talk to anyone at the facility to make gloves more accessible in his work area.</p> <p>On 11/1/10, the facility clinical manager (CM 1) stated boxes of gloves will be made available on each nursing cart.</p> <p>3. Record review on 10/27/10 showed that Patient 7 was positive for the hepatitis B virus. Patient 7's hemodialysis treatments (blood is removed from the body and put through a filter where waste products are removed, then the blood is return back to the body) were done in the designated isolation room. On 10/27/10 observation of Patient 7's dialysis treatment from outside the isolation room showed:</p> <p>CHT M (Certified Hemodialysis Technician) at 9:36 a.m. removed his regular protective gown (white gown) and placed it on top of the free</p>	V 113			

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V 113	Continued From page 6 standing cabinet outside the isolation room. CHT M then put on PPE (personal protective equipment) prior to entering the isolation room. At 9:50 a.m. CHT M removed his PPE and exited the hepatitis isolation room without washing his hands or using alcohol sanitizer. CHT M put on the regular gown (white gown) that he had left outside the isolation room. The CHT M then walked over to a supply cart and without performing any hand hygiene after he had cared for the patient in the isolation room, CHT M opened drawers on the cart. It was only after touching the cart that he went to the sink adjacent to the nurses' station and washed his hands. CHT M at 10:54 a.m. again was observed exiting the isolation room without washing his hands or using alcohol hand sanitizer and applying the white gown. By not performing hand hygiene after caring for a positive hepatitis B patient and prior to applying the white gown, CHT M contaminated the white gown.  Facility policy for "Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+)", dated 2/24/10, on page 4 of 8 instructed, "Hand hygiene must be practiced when entering and leaving the isolation room."	V 113			
V 120	494.30(a)(1)(i) IC-TRANSDUCER PROTECTORS-NOT WETTED/CHANGED  Use external venous and arterial pressure transducer filters/protectors for each patient treatment to prevent blood contamination of the dialysis machines' pressure monitors.  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	V 120			

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V 120	<p>Continued From page 7</p> <p>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 routinely between patients.</p> <p>This STANDARD is not met as evidenced by: Based on observation, staff interview, and record review, facility staff failed to follow their policy to maintain the transducer protectors clean and dry during dialysis treatments for four of 19 dialysis machines observed. This failure increased the potential for cross-contamination or inaccurate venous and /or arterial pressures.</p> <p>Findings:</p> <p>1. During the initial tour on 10/26/10 at 9 a.m., observation showed blood in the venous transducer protector and blood in the pressure monitoring line on the dialysis machine on station 22. Registered nurse (RN) E, who was present during the observation, was asked if anything should be done. She stated, "We change the transducer (protector)." RN E acknowledged that no one had changed the transducer protector, but agreed it should be changed.</p>	V 120			

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V 120	<p>Continued From page 8</p> <p>2. During the initial tour on 10/26/10 at 10:44 a.m., observation of the dialysis machine at station 1 showed blood in both arterial and venous transducer protectors and blood actively pulsing in the arterial pressure monitoring line. At 10:50 a.m., certified hemodialysis technician (CHT) N was observed putting in data at station 1. She did not look at the dialysis machine to ensure the transducer protectors were free of blood. At 10:55 a.m., RN E saw the blood in the pressure line and transducer protectors and stated, "They should be changed. When they (CHTs) start the treatment, the saline might be too high. They should have changed this earlier." RN E added, "When the transducer (protector) is wet, you need to change it to decrease the risk of infection."</p> <p>Review of the facility policy "Monitoring During Patient's Treatment" indicated "The venous chamber should be filled to the full level marker line on the chamber. The venous chamber side arm is clamped. Adjust the level as needed." The rationale given in the policy was to, "Prevent blood from entering the venous monitor line and transducer filter." Also, "The transducer protector must be free of blood in order to transmit accurate readings. If the transducer protector is contaminated, it should be changed and the line must be cleared of fluid or blood."</p> <p>Review of the dialysis machine manufacturer's manual indicated, "If the transducer protectors get wet, it will cause inaccurate pressures."</p> <p>3. On 10/27/10 at approximately 8:00 a.m. during treatment, a transducer line extending from an over-filled blood chamber</p>	V 120			

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V 120	Continued From page 9 to the machine's transducer filter cover was completely filled with blood at Station 12. This observation was acknowledged by RN D who removed the transducer and corrected the levels.	V 120			
V 122	4. On 10/28/10 at 7:35 am, a transducer line from an over-filled blood chamber was observed approximately 4/5 filled with blood at Station 8. 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, staff interview, and document review, the facility failed to ensure that patients' blood pressure cuffs were cleaned and disinfected on a consistent basis after each patient dialysis treatment for six (Patients 17, 18, 22, 24, 25 and a patient at station 1) of six patients observed. This failure by the facility had the potential to increase the risk of cross-contamination with bloodborne viruses and bacteria.  Findings:  Observations on 10/26/10 at 10:25 a.m. and 10/29/10 at 10:38 a.m. showed there were two open faced cabinets, one for patients scheduled for dialysis on Monday, Wednesday, and Friday	V 122			

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V 122	<p>Continued From page 10</p> <p>(MWF) and the second cabinet for patients scheduled for dialysis on Tuesday, Thursday, and Saturday (TTHS). Each cabinet had 50 small cubicles with patients' names. The MWF cabinet had 14 cubicles and the TTHS cabinet had eight cubicles that were each shared by two patients.</p> <p>Certified hemodialysis technician (CHT) Q on 10/29/10 at 8:25 a.m. was asked how the patients' blood pressure cuffs were cleaned after their dialysis treatment. CHT Q stated the patients' blood pressure cuffs were wiped down with a bleach solution after the patients' dialysis treatment.</p> <p>Observations of blood pressure cuff care and handling showed:</p> <p>a. On 10/26/10 at 10:25 a.m. after Patient 18 was done with his dialysis treatment CHT O placed Patient 18's blood pressure cuff in that patient's designated cubicle. CHT O did not clean/disinfect the blood pressure cuff prior to placing it in the cubicle.</p> <p>b. CHT O on 10/28/10 at 1:35 p.m. placed Patient 17's blood pressure cuff after termination of the dialysis treatment in the patient's cubicle without cleaning/disinfecting it first.</p> <p>c. On 10/28/10 at 2:30 p.m. CHT P placed Patient 22's blood pressure cuff in its designated cubicle after his dialysis treatment without cleaning/disinfecting it first.</p> <p>d. On 10/29/10 at 10:45 a.m. the cubicle labeled as "extra cuffs" contained three blood pressure cuffs, two of the three cuffs were labeled for Patient 24 and Patient 27. The third blood</p>	V 122			

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V 122	Continued From page 11 pressure cuff was not labeled. CHT N was observed taking off the blood pressure cuff from Patient 24; it was labeled with Patient 25's name. Patient 25, who at the same time as Patient 24 was receiving dialysis treatment, was observed to have a blood pressure cuff with no name on it.  RN D at 10:50 a.m. stated Patient 27 was no longer treated at the facility. RN D was asked what was done with a patient's blood pressure cuff when he/she was no longer a patient at the facility. RN D stated the blood pressure cuff should be thrown away.  Review of the facility's policy and procedure "Cleaning the Dialysis Station Between Patient Treatments", dated 10/10/08, showed that one of the steps in disinfection was to clean and disinfect blood pressure cuffs after each patient treatment with 1:100 concentration solution of bleach.	V 122			
V 142	494.30(b)(1) IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P  The facility must- (1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit;  This STANDARD is not met as evidenced by:	V 142			

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V 142	<p>Continued From page 12</p> <p>Based on staff interview and record review, the facility failed to follow the policy and procedure, "Patient Tuberculin Skin Testing Mantoux" (test for tuberculosis-TB) for one (Patient 2) of 13 sampled patients. For Patient 2, the facility failed to have documentation that a tuberculin skin test had been done on the first admission to the facility and on a subsequent admission. When Patient 2's tuberculin test had been positive, there was no documentation as to what the follow up had been. The facility's practice had the potential to put other patients in the facility at risk for tuberculosis.</p> <p>Findings:</p> <p>Review of the facility's policy and procedure, "Patient Tuberculin Skin Testing Mantoux", dated 2/17/10 and reviewed on 10/29/10, showed that on admission to the facility each patient was to have a tuberculin skin test (tuberculin is an extract of TB protein). Staff were to document in the patient's medical record the results of the tuberculin skin test and any other required follow-up care.</p> <p>Review of Patient 2's medical record on 10/29/10 showed that Patient 2, admitted to the facility on 1/19/10, had tested positive to the tuberculin skin test administered on 4/3/10, nearly three months after his initial admission. Patient 2's tuberculin test record showed that if a patient had a positive reading a follow-up chest x-ray was required; there was no documentation that any action had been taken. There was no documentation that Patient 2 had been assessed for the risk of active tuberculosis.</p> <p>On 10/29/10 at 2:10 p.m. the CM stated a patient</p>	V 142			

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V 142	Continued From page 13 who had a positive tuberculin skin test and who did not have a follow-up chest x-ray could still receive hemodialysis (blood is removed from the body and put through a filter where waste products are removed, then the blood is return back to the body) treatments in the facility as long as they had been assessed as not having any symptoms. The clinical manager (CM) checked both the present record and previous admission record of 2/20/07; there was no record of a tuberculin skin test being done on the previous admission or of a tuberculin risk assessment questionnaire (to assess for presence of symptoms of TB) on either the previous or the present record.	V 142			
V 143	494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS  [The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and  This STANDARD is not met as evidenced by: Based on observation, interview, and document review, the facility failed to follow its policy to remove expired medications from use. In the medication refrigerator there was one vial of expired Tubersol (tuberculin product). This failure increased the risk of product degradation that could result in inaccurate results for tuberculosis (TB-highly infectious respiratory illness) testing.  Finding:  During the initial tour on 10/26/10 at 10 a.m.,	V 143			

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V 143	Continued From page 14 inspection of the medication refrigerator showed a vial of Tubersol, a drug that tests for exposure to TB, with the date 9/17/10 written on it in pen.  On 11/1/10 at 10:35 a.m., the clinical manager opened the medication refrigerator. The vial of Tubersol was still there. The clinical manager confirmed the date the vial was opened as 9/17/10. She confirmed the bottle should be discarded if the opened date was more than 30 days.  Review of the manufacturer's product information indicated, "A vial of Tubersol which has been entered (opened) and in use for 30 days should be discarded because oxidation and degradation may have reduced the potency."  Review of the facility "Medication Policy", dated 1/25/05, indicated "Multi-dose vials of medications with preservative may be kept and used for 30 days once the vial has been entered. The vial should be dated on the first date of use and discarded 30 days from this initial date."	V 143			
V 147	494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE  Recommendations for Placement of Intravascular Catheters in Adults and Children  I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters.  II. Surveillance	V 147			

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V 147	<p>Continued From page 15</p> <p>A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site.</p> <p>Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.</p> <p>VI. Catheter and catheter-site care</p> <p>B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure staff followed its policy and procedure to maintain aseptic technique while performing catheter care for two (Patients 4 and 9) sampled and one random (Patient 19) of three patients with catheters observed. This failure resulted in cross-contamination and increased the potential for infection.</p> <p>Findings:</p> <p>According to the CDC, handwashing is the most important measure to prevent contaminant transmission. Because exposure to blood and potentially contaminated items is routinely anticipated during hemodialysis treatments, the use of gloves is required whenever staff takes</p>	V 147			

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V 147	<p>Continued From page 16</p> <p>care of a patient. Furthermore, the CDC's "Guideline for Hand Hygiene in Healthcare Settings" (2002) reads, "Hand hygiene is required regardless of whether gloves are used or changed. Failure to remove gloves after patient contact or between "dirty" and "clean" body-site care on the same patient must be regarded as nonadherence to hand-hygiene recommendations." "Hand hygiene" includes either washing hands with soap and water (when hands are visibly soiled), or using a waterless alcohol-based antiseptic rub, and should be done by rubbing hands together "vigorously" for 15 seconds. The CDC recommends that hand hygiene be performed immediately after gloves are removed, because even with glove use, hand hygiene is necessary as hands could be contaminated through small defects in gloves and from the outer part of the gloves during removal.</p> <p>1. On 10/27/10 at 2:37 p.m., RN B, wearing a face mask and face shield, prepared to do catheter care for Patient 9. Rubbing her hands for fewer than five seconds with alcohol gel, she donned a pair of gloves. RN B placed a Chux under Patient 9's catheter, and gave a face mask to Patient 9 to put on. Without removing her gloves, performing hand hygiene, and donning new gloves, she repositioned several gauze dressings that were to be used for catheter care. Placing a povidone-iodine swab on each gauze dressing, she cleaned the ends of the limb leads. She then removed the dressing that covered the limb leads. After removing the old dressing, and without removing her gloves, performing hand hygiene, and donning new gloves, she proceeded to clean the limb leads. She then withdrew blood using syringes inserted into each catheter limb lead. After placing the syringes into the sharps</p>	V 147			

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V 147	<p>Continued From page 17</p> <p>container, she touched the dialysis machine screen to prepare Patient 9 for dialysis. Using the same gloves, at 2:48 p.m., RN B prepared to do catheter site care for Patient 9. RN B removed the old dressing over the catheter exit site. She then removed her gloves and donned a new pair of gloves without first performing hand hygiene. She placed povidone-iodine swabs onto gauze dressings and proceeded to clean the exit site.</p> <p>2. On 10/28/10 at 1:55 p.m., RN A prepared to access Patient 4's catheter. Patient 4 was wearing a shirt that was unbuttoned and tee shirt pushed aside to allow access to his catheter located by his left collar bone. RN A placed a Chux under his catheter and taped Patient 4's tee shirt to keep it away from the catheter. At 2:07 p.m. RN A prepared to do catheter site care. With clean gloves, RN A removed the dressing over the catheter exit site. RN A then removed her gloves, performed hand hygiene, and donned new gloves. Before RN A could clean the exit site, she pushed the edge of Patient 4's tee shirt away because it was approximately one inch from the exit site area. Without removing her gloves, performing hand hygiene, and donning clean gloves, she proceeded to wipe the exit site first with alcohol swabs, then with povidone-iodine swabs. The tee shirt had moved again and was again approximately one inch from the exit site area. RN A pushed the tee shirt away again. With the same gloves, RN A opened a small dry sterile dressing packet, removed the sterile dressing, folded the dressing and placed it under the catheter leads close to the exit site. She then covered the exit site with a sterile dressing.</p> <p>RN A was interviewed afterward and informed that cross-contamination was observed when she</p>	V 147			

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V 147	<p>Continued From page 18</p> <p>touched the patient's clothing without removing gloves and performing hand hygiene, then touched and folded a dry sterile dressing to place under the catheter limb leads. She stated she understood.</p> <p>3. On 10/29/10 at 9:55 a.m., observation showed RN D preparing to do catheter care for Patient 19. Wearing gloves, RN D removed the catheter exit site dressing and without removing his gloves, performing hand hygiene, and donning new gloves, began to clean the catheter exit site with an alcohol swab. He opened up a sterile gauze dressing packet and povidone-iodine packets and placed a povidone swab on each dressing. He swabbed the exit site with each povidone-iodine dressing. He then handled Patient 19's blood lines attached to the catheter limb leads before completing the dressing change. RN D opened a sterile gauze dressing packet, picked up the gauze, folded it and placed it under the catheter close to the exit site, then covered the site with an adhesive dressing.</p> <p>RN D was interviewed immediately following Patient 19's catheter care. He stated he "forgot to use clean gloves" after removing the old dressing and handling Patient 19's blood lines.</p> <p>According to the facility policy "Changing Central Venous Catheter Dressing" (dated 1/16/09), reviewed on 10/29/10, prior to changing a catheter dressing, staff should, "Wash hands and don PPE (personal protective equipment). Remove old dressing to assess for signs of infection. Discard old dressing and gloves in appropriate waste container. Wash hands and don clean gloves or sterile gloves per contracted "hospital" policy." After cleaning the site, staff was to, "Place a sterile 2 X 2 under the exposed</p>	V 147			

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V 147	Continued From page 19 catheter. Place another sterile dressing over the catheter exit site."	V 147			
V 401	494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT  The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.  This STANDARD is not met as evidenced by: Based on observation and staff interview, the facility failed to maintain a safe environment of dry floor areas for patients and staff. This failure created a high risk of falls for patients and staff.  Findings:  On 10/26/10 during the initial tour, a moderate pool of clear fluid was observed on the floor near the treatment chair and dilaysis machine at station 3. Registered nurse (RN) C was notified of the hazard. At that moment, two staff members hurriedly walked right through the pool of fluid. RN C immediately alerted the facility staff to the falls hazard caused by the standing fluid and had the fluid cleaned from the floor.	V 401			
V 402	494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY  The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public.	V 402			

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V 402	<p>Continued From page 20</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview the facility failed to ensure that all portions of the emergency call light system were functioning for two of two emergency bathroom call lights. For both the lobby and treatment room bathrooms the alarm system had been manually turned off at the nurses station, which resulted in no audible alarm warning staff that the emergency call light had been activated by a patient in immediate need of help.</p> <p>Findings:</p> <p>1. During the environmental tour of the facility on 10/26/10 the patients' waiting room bathroom emergency call light was activated for testing at 8:28 a.m. A light fixture mounted on the wall adjacent to the bathroom lit up. At 8:31 a.m., the facility's unit secretary appeared in the patient's waiting room. She was asked how staff was alerted if the emergency call light was activated, as by a patient experiencing an emergency condition. She stated staff would hear the alarm in the treatment room and would respond by coming to the waiting room. She was informed no staff member had yet to appear several minutes after the emergency call light was activated. Observations at 8:35 a.m., 8:40 a.m., and at 9:35 a.m., showed the emergency call light remained unanswered.</p> <p>2. On 10/26/10 at 9:58 a.m., observation in the treatment room showed a small panel on the right</p>	V 402			

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V 402	Continued From page 21 side of the nursing station with two lighted red lights. One light was labled "Treatment RR (rest room) " and the other light was labeled "Lobby RR". The panel also contained a toggle switch to the left of the lights. The toggle switch was in the down position. RN C was standing at the nurses' station. She stated she did not know what the lighted red lights indicated, but stated the alarm for emergency call light activation was "so loud". At 10:10 a.m. observation showed the treatment room patient bathroom's emergency light also was on. Inside the treatment room bathroom, the emergency call cord indicated it had been activated. RN E confirmed the treatment room bathroom emergency call light was on and went to the nurses' station to investigate. RN E flicked the toggle switch on the small panel to the "up" position. A very audible alarm sounded. She stated she did not know why the alarm had been switched off. She was informed that the emergency light had been on in the lobby for over an hour and no one from the treatment room had come to investigate.	V 402			
V 405	494.60(c)(2) PE-COMFORTABLE TEMPERATURE  The dialysis facility must: (i) Maintain a comfortable temperature within the facility; and (ii) Make reasonable accommodations for the patients who are not comfortable at this temperature.  This STANDARD is not met as evidenced by: Based on observation, patient and staff interview, the facility failed to maintain a comfortable temperature for five (14, 15, 16, 17, and 18) of the 24 hemodialysis stations within the facility. The thermostat located on the wall adjacent to	V 405			

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V 405	<p>Continued From page 22</p> <p>station 16 was affected by the close proximity of a heat source that falsely gave warm readings, resulting in inadequate heating provided for the dialysis stations in the vicinity.</p> <p>Findings:</p> <p>1. During the initial tour of the facility on 10/26/10 at 10:25 a.m. the section that included dialysis station 13 on the left side and dialysis stations 18 and 19 on the right side seemed quite cool in temperature. The adjacent area that included the medication prep area and dialysis stations 14-17 was uncomfortably cold. Despite the chill, the thermostat next to chair 16 registered 74° fahrenheit (F).</p> <p>Observation on 10/27/10 at 12:15 p.m. showed Patient 15 in station 19 was covered with a blanket while receiving dialysis treatment. Patient 15 stated at times the temperature in this area will be warm when he first gets in, then it will get cold. Patient 15 stated his present station was a lot better than his prior station 14. Patient 15 stated when he was seated in station 14 he could feel the cold air coming down; his face would get real cold, "like ice". Patient 15 was asked if he ever informed facility staff about being cold while he was in station 14, he stated he had and that they had told him that the thermostat reading showed that the temperature was ok.</p> <p>Patient 14 on 10/27/10 at 12:17 p.m. was observed seated in station 14 receiving dialysis. He was covered with a blanket up to chin level with his left arm access site exposed. This section of the treatment room was noticeably colder than the rest of the room. Patient 14 stated he had been at this station assignment the last 5</p>	V 405			

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V 405	<p>Continued From page 23</p> <p>months and it had always been cold. He had informed facility staff, could not remember that person's name, but he felt he had been ignored.</p> <p>On 10/27/10 at 12:20 p.m., accompanied by registered nurse (RN) F, the thermostat located on the wall next to station 16 registered 73° F. RN G at 12:21 p.m. referred to the section of dialysis stations 14-17 as a "cold spot". Accompanied again by RN F, the second thermostat located closest to the isolation room and the third thermostat located more centrally within the treatment room, both read 74°. These locations were noticeably warmer as well.</p> <p>On 10/27/10 at 12:23 p.m. CM 2 (Clinical Manager from sister facility) was asked to have their maintenance staff take a temperature reading of this area. The BMS (Building Maintenance Staff) stated he could not take an air temperature reading. BMS stated the gun temperature reader could only take temperature readings of objects so he pointed the temperature reader a few inches from Patient 14's chair to get a reading of 68°, not a temperature that reflected the chilled air draft coming from the overhead ventilation. The thermostat for the affected section was located low on the wall and to the right of station 16. BMS directed the gun temperature reader at the thermostat on the wall; the temperature read 76°. BMS stated the suspended television (which was on at the time) on chair station 16 was too close to the thermostat and the heat the television was putting out was affecting the thermostat temperature regulation. CM 2 measured the very short distance between the back of the television and the thermostat and found it was only five inches.</p>	V 405			

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V 405	Continued From page 24 Patient 23 on 10/28/10 at 1:45 p.m. stated that a "few years ago" she had sat at station 14 for months and had demanded to be moved because it had been too cold for her.	V 405			
V 407	2. On 10/27/10 at 11:50 a.m., observation showed Patient 20 undergoing dialysis in chair 18. He was completely covered up to his neck by a thick blanket. His access was not visible. He was checked again at 12:35 p.m. He was again covered up to his chin and his access was covered. He was informed his access was covered. He stated "I know, but I'm so cold."  494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS  Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement).  This STANDARD is not met as evidenced by: 4. On 10/26/10 during the initial tour of the facility while patients were receiving treatment, the following observations were noted: a. At approximately 9:10 am, the patient at station 3 was observed with his/her catheter access covered with a blanket. b. At approximately 9:25 am, the patient at station 10 was observed with his/her fistula access covered with a blanket.  Based on observation, interview, and record review, staff failed to follow facility policy to ensure every patient's vascular access was visible at all times while undergoing hemodialysis.	V 407			

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V 407	<p>Continued From page 25</p> <p>This failure increased the potential for unwitnessed disconnection and fatal rapid blood loss (exsanguination).</p> <p>Findings:</p> <p>1. During the initial tour on 10/26/10 at 10:18 a.m., observation showed Patient 17 asleep in treatment chair 16. She had headphones on and was covered by a fleece blanket. Her vascular access was not visible. On Patient 17's left side, only the part of the blood tubing connected to the dialysis machine was visible. At 10:20 a.m., patient 17's access was still covered. CHT O walked to Patient 17's dialysis machine, but did not look toward Patient 17 to assure her vascular access was exposed. At 10:25 a.m., CHT O went to Patient 17's dialysis machine again, but did not look at Patient 17, whose vascular access was still covered. At 10:36 a.m., CHT O was asked where Patient 17's vascular access was located. He looked at Patient 17 and uncovered her access, which was located on her right arm. He stated "She keeps covering it up", and agreed he needed to keep checking to assure the vascular access remained visible.</p> <p>2. On 10/27/10 at 9:49 a.m., observation showed Patient 14 asleep in treatment chair 14. He was completely covered up to his neck by a blanket. CHT L walked right by Patient 14 and did not tell Patient 14 he needed to uncover his access. At 10 a.m. Patient 14's access was still covered. CHT L walked right by him on her way to the patient in the adjacent treatment chair (15) and again failed to alert Patient 14 to uncover his access. At 10:07 a.m., CHT L was again observed working on the dialysis machine at station 15. At 10:10 a.m., she again walked right</p>	V 407			

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V 407	Continued From page 26 by Patient 14 without alerting him to uncover his access. A dialysis technician in training (CHT in training S) helping another CHT approximately 20 feet away was asked if he could identify a problem with Patient 14's access. He looked at Patient 14 and stated "He should keep it uncovered." Patient 14 was then asked to uncover his access, over 25 minutes after he was first observed.  The facility policy "Monitoring During Patient's Treatment" indicated "All patients are continually under visual observation by patient care staff. To facilitate monitoring, patients should be instructed to leave access site uncovered so that they are readily visible." 3. Observation on 10/28/10 at 1:45 p.m. showed Patient 23 was undergoing a hemodialysis (blood is removed from the body and put through a filter where waste products are removed, then the blood is return back to the body) treatment. Patient 23 had a blanket that reached up and covered her chest and arms. Patient 23's dialysis access site was not visible. At 1:56 p.m. Patient 23's access site still remained covered. At 2:12 p.m. and again at 2:13 p.m. CM 2 (Clinical Manager from sister facility) had each time approached and spoken to Patient 23, neither time did CM 2 uncover Patient 23's access site or tell Patient 23 she needed to uncover her access. Continued observation showed it was not until 2:30 p.m. that the DOO (Director of Operations) approached and spoke to Patient 23 that she uncovered her access site.	V 407			
V 411	494.60(d)(1) PE-NURS STAFF TRAINED IN ER EQUIP & MEDS  Staff training must be provided and evaluated at least annually and include the following:	V 411			

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V 411	<p>Continued From page 27</p> <p>(iii) Ensuring that nursing staff are properly trained in the use of emergency equipment and emergency drugs.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the facility failed to implement its policy and procedure regarding emergency medication storage in the facility. This failure increased the risk of staff not knowing which emergency medications were available for use, their location, and their potential expiration dates.</p> <p>Findings:</p> <p>On 10/26/10 at 10: 5 a.m. during the initial tour of the facility, and accompanied by registered nurse (RN) A, RN B, the facility's emergency cart was inspected. When the evaluator found only five (1,000cc/liter) bags of normal saline solution (with no monitoring mechanism in place for potential expiration dates) and no other emergency medications stored in the emergency cart and asked about possible alternate storage location, the nurses looked at each other and discontinued the inspection task. RN A stated that she had only worked in the facility for three months and was not aware of the emergency medications location. RN C stated that she only worked in the facility for one month and did not know where the emergency medications were stored.</p> <p>After an extended search, RN A and RN B stated that they found the emergency medications stored in a container on the shelf in the locked medication cabinet storage area. The container labeled, " Anaphylactic Emergency Procedures Protocol " showed the procedural use of epinephrine (emergency medication)</p>	V 411			

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V 411	Continued From page 28 administration during an anaphylactic situation. (An anaphylactic condition is a life-threatening hypersensitivity reaction to a substance.) Inspection showed only Epinephrine and Benadryl medications with no monitoring mechanism in place for potential expired medications. (Epinephrine is indicated for hypersensitivity reaction, anaphylaxis. Benadryl is indicated for lesser allergic reactions.) When asked if there were any other medications stored for emergency situations, RN A stated that glucose (for diabetic conditions) might possibly needed to be stored, but that the physician would need to order it.  The review of the facility's Emergency Equipment/Supplies Policy showed the following: " Emergency supplies are maintained at this dialysis facility for use in life threatening circumstances ...It is the responsibility of the Medical Director in conjunction with the Governing Body and medical staff to determine the medications ...that are to be kept in the emergency cart/box ... " The policy also indicated that staff was to check emergency supplies on a weekly/monthly basis to ensure expiration dates " relative to medications and sterility. " The clinical manager (CM) 1 acknowledged the deficient practice and stated that the medical director would take care of the issue.	V 411			
V 412	494.60(d)(2) PE-ER PREP-PTS ORIENTED/TRAINED  The facility must provide appropriate orientation and training to patients, including the areas specified in paragraphs (d)(1)(i) of this section.  This STANDARD is not met as evidenced by:	V 412			

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V 412	<p>Continued From page 29</p> <p>Based on patient and staff interview and record review, the facility failed to provide:</p> <ol style="list-style-type: none"> <li>1. Identification of patients who required assistance for disconnection of dialysis and evacuation during an emergency, potentially delaying their ability to be disconnected and evacuated.</li> <li>2. Emergency training to one randomly selected patient (Patient 27) who was not able to describe what she would do if during an emergency situation, potentially affecting her ability to disconnect and evacuate the facility safely.</li> </ol> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. On 10/28/10 at approximately 9:50 am during the Emergency Disaster review, there was no Emergency Disaster plan found and available for review. CM (Clinical Manager)1 and CM 2 acknowledged that there was no informational system in place to identify patients requiring assistance during an emergency. At 11:05 after intensive research, CM 1 and CM 2 stated that the facility had not yet developed a comprehensive Disaster and Emergency plan and none was available for review.</li> <li>2. On 10/29/10 at approximately 8:00 am during an interview regarding external facility emergency procedures, Patient 27 stared at the evaluator and stated, " I don ' t know what I would do if there was an earthquake. " The review of the Disaster Plan signed by Patient 27 on 7/16/10 showed that staff presented Earthquake Disaster Plan information to the patient " in a manner that he/she understands " . CM 1 stated that staff presented the emergency preparation instructions contained in the Patient Disaster Guide to each patient.</li> </ol>	V 412			

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V 412	Continued From page 30 However, there was no indication that staff provided sufficient patient training in order that Patient 27 was able to describe what he/she would do, where to go, who to contact during an emergency situation outside of the facility, nor any measure of patient understanding, such as return teaching or demonstration.	V 412			
V 415	3. On 11/1/10 at 2:45 p.m. Clinical Manager (CM) 1 stated patients requiring assistance were identified during the admission process, but confirmed no such identification of patients requiring assistance was located on the schedule or any other location so staff would be able to quickly identify those patients requiring assistance.  494.60(d)(4)(ii) PE-ANNUAL EVAL-EMERGENCY/DISASTER PLANS  The facility must- Evaluate at least annually the effectiveness of the emergency and disaster plans and update them as necessary;  This STANDARD is not met as evidenced by: Based on staff interview and record review, the facility failed to provide documentation of an annual evaluation of an emergency and disaster plan in order to ensure its effectiveness during an actual emergency/disaster.  Findings:  On 10/28/10 during the Emergency Disaster review, there was no Disaster/Emergency plan available for review. After extensive research at 11:05 a.m., Clinical Manager (CM) 1 and CM 2 stated that the facility had not yet developed a	V 415			

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V 415	Continued From page 31	V 415			
V 416	comprehensive disaster plan, that it was still in the planning stage, and none was available for review. Subsequently, CM 1 located and presented a formerly utilized Disaster Plan, but there was no documentation of its annual evaluation to ensure it was still effective.  494.60(d)(4)(iii) PE-CONTACT LOCAL EOC ANNUALLY  The facility must-  (iii) Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency.  This STANDARD is not met as evidenced by: Based on staff interview and record review, the facility failed to annually contact the local disaster management agency of its emergency/disaster plan. This increased the risk that the local agency would not be knowledgeable of the facility's specific needs for the restoration of services during emergency conditions.  Findings:  On 10/28/10 during the Emergency Disaster review, there was no documentation found of any communication between the facility and the local disaster management agency that would assure the local disaster agency was aware of the facility's needs during emergencies or disasters. Clinical Manager (CM) 1 stated that she was unable to locate any documentation that showed the facility had ever communicated with the local disaster management agency.	V 416			
V 470	494.70(c) PR-RIGHTS POSTED,STATE/NW	V 470			

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V 470	Continued From page 32 ONTACT INFO  The dialysis facility must prominently display a copy of the patient's rights in the facility, including the current State agency and ESRD network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients.  This STANDARD is not met as evidenced by: Based on observation and staff interview, the facility failed to display a copy of patient's rights or outside agency contact information where it could be viewed by patients entering the facility. This failure removed reminders to patients regarding their rights or their ability to contact the State agency or Network for complaints.  Findings:  On 10/26/10 at approximately 8:30 a.m. upon entering the facility, there was no patient's rights information observed posted in the entrance lobby. On 10/27/10 at approximately 3:20 p.m., the clinical manager (CM) 1 and the unit secretary verified no patient's rights information posting in the lobby. Subsequently, the unit secretary stated (in the presence of CM 1) that the information was not re-posted after the lobby walls were repainted months ago.	V 470			
V 503	494.80(a)(2) PA-APPROPRIATENESS OF DIALYSIS RX  The patient's comprehensive assessment must include, but is not limited to, the following:  (2) Evaluation of the appropriateness of the dialysis prescription,	V 503			

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V 503	Continued From page 33  This STANDARD is not met as evidenced by: Based on observation, staff interview and record review, the facility failed to deliver the prescribed hemodialysis prescription to one (Patient 5) of 13 patients. The facility's failure to deliver the correct prescribed dialysate during treatment increased the risk of possible heart problems for Patient 5.  Findings:  1. On 10/26/10, review of the facility's policy entitled "Priming a Dry Hollow Fiber Dialyzer Using Pre-pump Arterial Monitoring and the Fresenius 2008H or K Machine" and dated, 1/11/06 showed the following: " Prior to initiating the priming procedure, verify correct patient dialysate concentration ... " when priming the dialyzer prior to the start of treatment.  Review of the facility's "Setting Up The Individual Dialysis Machine" policy and procedure, dated 2/28/03 directed staff to "Check physician's order for correct dialysate prescription " when setting up the machine prior to the start of treatment. However, these policies and procedures were not followed as indicated below.  On 10/26/10 at approximately 8:45 am, observations during the initial tour of the treatment room showed patients receiving treatment with the Fresenius 2008 K machines. At approximately 9:10 am during the tour, the dialysate line extending from the machine was observed connected to the 2.0 (mEq/L) potassium (K) dialysate port in the receptacle	V 503			

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V 503	<p>Continued From page 34</p> <p>behind the machine at station 3 for Patient 5. (Dialysate is a solution that carries away the waste materials and fluid removed from the blood during the hemodialysis treatment procedure. This solution contains a specific order of concentrated chemical element compound composition such as potassium. Potassium is an element that helps to regulate the heart muscle, and normal adult levels are 3.5 to 5.3 mEq/L [milliequivalent per liter] . High or low potassium levels can adversely affect heart function, even causing cardiac arrest. Patient's dialysate orders are adjusted by the physician for the amount of potassium that needs to be removed during dialysis.</p> <p>During the reconciliation of the order at the chair side computer with staff, the prescription showed orders for a 3.0 K dialysate solution composition, indicating Patient 5's usual potassium level was not very high, so less potassium needed to be removed during dialysis. At this time the certified hemodialysis technician (CHT) R verified 2.00 K dialysate solution was connected and being delivered instead of the ordered 3.0 K dialysate to Patient 5 ' s machine. CHT R stated that Patient 5 had been running (receiving treatment) on the machine for about three and one half hours, and was about " ready to get off " (discontinue treatment). CHT R further stated that since the patient had a catheter (access placement), an RN had to "put the patient on " (manipulate the catheter for treatment initiation). At approximately 9:15 am, the treatment discontinued and Patient 5 was disconnected from the machine. Subsequently, RN C who initiated the treatment stated that it was an oversight and notified the physician who ordered a "Stat [immediate] K " blood (serum) level test to determine if Patient 5's</p>	V 503			

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V 503	Continued From page 35 potassium level was dangerously low.	V 503			
V 715	<p>On 10/26/10, the review of the record showed that Patient 5 was admitted to the facility on 10/30/09 with a prescription for a 2.0 K dialysate. Further review of the record showed that the dialysate order, dated 11/20/09 was changed to a 3.0 K dialysate bath solution. According to RN C ' s research that included the computerized record system review, there was no additional updated, changed dialysate order for Patient 5.</p> <p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&amp;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, staff interview and record review, the facility failed to implement its policies, procedures and current practices pertaining to blood chamber levels, medication storage, and updating plan of care for one (Patient 3) of 13 sampled patients. These failures increased the risk of adverse effects on patient care and safety.</p> <p>Findings:</p> <p>1. During the survey, there were observations of lower blood-filled arterial chambers. For example,</p> <p>a. On 10/26/10 during the orientation tour at 9:32 am, the arterial blood chamber at station 12 was</p>	V 715			

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NAME OF PROVIDER OR SUPPLIER  <b>FMC DS BERKELEY</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2895 SEVENTH STREET BERKELEY, CA 94710</b>		
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V 715	<p>Continued From page 36</p> <p>observed only approximately 1/8 filled with blood (almost emptied). At approximately 9:42 am, the arterial blood chamber at station 14 was approximately only 1/2 filled with blood.</p> <p>b. On 10/27/10 at 8:05 am, the arterial blood chamber at station 15 was observed only 1/3 filled with blood. At 8:10 am, the arterial chamber at station 10 was observed only 2/3 filled with blood.</p> <p>On 10/27/10 at approximately 8:11 am, the lower arterial blood chamber at station 15 was verified by staff. RN D stated that the facility 's practice was for both the venous and arterial chambers to be kept 3/4 filled with blood.</p> <p>c. On 10/28/10 at 7:35 am, arterial blood chambers were further observed at lower blood -filled levels. For example, -The arterial blood chambers at stations 12 and 15 were approximately only 1/3 filled with blood. -The arterial blood chambers at stations 10 and 11 were approximately only 1/2 filled with blood.</p> <p>According to the facility policy "Maintaining Fluid Levels in the Venous and Arterial Drip Chamber" "The fluid level in the venous and arterial drip chambers will be maintained at 2/3 to 3/4 full."</p> <p>"If the fluid level in the arterial chamber is maintained at a low level, there is a possibility of air entering the dialyzer, which will decrease the efficiency of the treatment due to clotting of the fibers. Ultimately, there is a danger of air entering the patient if it is present in the extracorporeal system."</p>	V 715			

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V 715	Continued From page 37  d. On 10/27/10 at 1:40 p.m., observation showed Patient 8 undergoing dialysis and the blood level in the arterial chamber on her dialysis machine was very low, less than one quarter full. Large air bubbles were seen on the top of the blood level in the chamber. An alarm for high arterial pressure sounded, stopping the blood pump. CHT in training T came over to the alarming dialysis machine and adjusted the level in the arterial chamber so it nearly filled the chamber. She stated "I wasn't the one who set her (Patient 8) up. The problem with the high pressure is the arterial chamber is too low, sucking up air. I want to see (arterial pressure) no more than 250 (mm hg)." She agreed air in the line was potentially hazardous for the patient.  2. During the initial tour on 10/26/10 at 10 a.m. inspection of the medication refrigerator showed numerous labeled bundles of syringes with various drawn up medications. Six of the bundles contained 10 cc syringes with a dark fluid. The dark fluid was identified as Venofer, an intravenous iron supplement. The labels indicated Venofer was drawn up at 8:40 a.m. Further observation showed no additional Venofer stored in the refrigerator, but in a cupboard at room temperature. Directions printed on the outside of the box containing the vials of Venofer indicated "Store at 25 degrees C (77 degrees F) Excursions (temporarily out of range) permitted to 15-30 degrees C (59-86 degrees F)." The temperature of the refrigerator was consistently kept in range of 36 to 46 degrees F, colder than acceptable by the manufacturer of Venofer.  During an interview with RN E on 10/26/10 at 10:22 a.m., she opened the medication	V 715			

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V 715	<p>Continued From page 38</p> <p>refrigerator and confirmed the syringes of Venofer were still refrigerated. She stated "We're not supposed to refrigerate them (syringes of Venofer)."</p> <p>3. Observation on 10/29/10 at approximately 10 a.m. showed Patient 3 undergoing a dialysis treatment. During an interview with Patient 3 on 10/29/10 at 10:14 a.m., she stated when she started dialysis treatments in April 2009, she felt okay, but she started having problems with nausea and headaches. She stated because of her nausea she began to lose weight, which she attributed to dialysis, and started missing treatments. She stated she asked if she could decrease the number of treatments and the treatment duration because of her debilitating symptoms but never got a response. She was asked if she ever voiced her concerns during the care conferences the facility held to discuss her plan of care. She stated "Three months ago I had my first conference. Never even heard of one. I've been here for a year and never, ever knew."</p> <p>Review of Patient 3's clinical record on 10/29/10 showed she was admitted to the facility on 4/30/09 for in-center hemodialysis. Review of her dialysis treatment orders indicated Patient 3 was scheduled for three dialysis treatments weekly to run for 3.5 hours. Review of facility records for missed treatments from 5/10 through 9/10 indicated Patient 3 missed eight treatments for the months of May, June, and July, nine treatments for August, and six treatments for September. Review of the past two weeks for October, 2010 showed Patient 3 missed five of the past eight scheduled treatments.</p> <p>Review of Patient 3's initial Patient Plan of Care</p>	V 715			

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V 715	<p>Continued From page 39</p> <p>dated 5/09, indicated Patient 3 had met the goal for dialysis adequacy for the dialysis prescription and a current Kt/V (a measure of how well dialysis is working) value of 1.34 from 6/2/09 was used to determine adequacy. Review of the initial Plan of Care showed no documentation indicating Patient 3 was involved in the plan of care or had participated in the plan of care conference.</p> <p>Review of Patient 3's 90 day Patient Plan of Care, dated 10/09, more than 90 days after her initial plan of care, did not indicate if the goal for dialysis prescription was met or needed to be revised for a specified goal. Staff documented Patient 3 was beginning to miss treatments, identified under psychosocial issues that included "Ability to follow the treatment prescription", "Mental health concerns", and "Coping and adjustment to dialysis". The expected goal was "That pt (patient) will consistently attend TX (treatment) and not become upset with staff on a regular basis" to be re-evaluated 11/2009. Nursing documented on the IDT signature page that Patient 3 "still cont. (continues) misses TX. at least 1 X /week or will request to shorten TX; MD aware, risks of doing this aware (sic)." Again, there was no documentation Patient 3 was involved in her plan or care or had participated in the plan of care conference. There was no plan of care update noted on the 90 day Plan of Care addressing Patient 3's missed treatments or a reevaluation on 11/2009 regarding Patient 3's issues with the dialysis staff.</p> <p>The next Patient Plan of Care for Patient 3 did not occur until 10/10, her annual Plan of Care. This annual review, reserved for stable patients, indicated the dialysis prescription was not meeting goal. There was no adequacy value</p>	V 715			

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V 715	<p>Continued From page 40</p> <p>included; only the explanation "Pt comes 1 X/wk or less" . The "Plan to achieve specified goal" included "Patient education on adequacy principles, treatment adherence" and "MSW working with pt."</p> <p>According to the facility policy "Comprehensive Interdisciplinary Assessment and Plan of Care", "The comprehensive interdisciplinary assessment must include the following ...Evaluation of appropriateness of dialysis prescription (including at least a monthly Kt/V or equivalent measure on HD (hemodialysis) patients."</p> <p>"If the patient is stable, but is not meeting the Plan of Care goals in specific areas, then those areas should be reassessed and the Plan of care revised for those areas, or changes documented in the progress notes or attending physician or physician extender orders."</p> <p>Plan of care requirements" The Plan of Care must include measurable and expected outcomes and an estimated timetable to achieve these outcomes. The patient must be invited and encouraged to participate in this activity. The Plan of Care must be signed by team members including the patient or patient designee. If the patient is unable or chooses not to sign the Plan of Care, this must be documented on the Plan of Care along with the reason the signature was not provided."</p> <p>"Failure to Achieve Plan of Care outcome If the patient is unable to achieve the desired outcomes, the team must adjust the Plan of Care to reflect the patient's current condition, and document in the medical record the reason(s) the patient is unable to achieve the goal. "</p>	V 715			

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V 715	Continued From page 41  The registered dietitian (RD) was interviewed on 11/1/10 at 9:28 a.m. She did not recall Patient 3 attending her care conferences in 2009 or early 2010 and stated the responsibility for notifying patients of care conferences lay with the social worker. Asked why Patient 3 had received an annual Plan of Care and not monthly updates when she was not meeting goals, she stated "She's stable and unstable. We haven't seen a big change."  The facility's social worker (MSW) was interviewed on 11/1/10 at 10:10 a.m. She confirmed Patient 3 did not appear to be a participant in her care conferences, nor was there documentation Patient 3 had been invited to participate at her care conferences.	V 715			