

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 052673	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 12/27/2010
NAME OF PROVIDER OR SUPPLIER BAKERSFIELD DIALYSIS CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 5143 OFFICE PARK DRIVE BAKERSFIELD, CA 93309		
(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 Jean Chiang, HFES Janet Parmelee, HFEN Census: 403 hemodialysis patients 33 peritoneal dialysis patients Sample size: 13 hemodialysis patients 2 peritoneal dialysis patients.	V 000			
V 110	494.30 CFC-INFECTION CONTROL This CONDITION is not met as evidenced by: Based on observation, interview and record review, it was determined the facility did not meet the Condition for Coverage (CFC) for infection control by failing to: 1. Provide and monitor a sanitary environment to minimize the potential transmission of infectious disease as evidenced by the dirty computer stands and keyboards in patient treatment areas, peritoneal dialysate fluid boxes on the floor, supply carts containing needles placed directly on the floor, dirty vents in the green unit, broken and dirty blinds in the red room. (See V111) 2. Ensure staff were performing proper hand hygiene while providing patient care and touching	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 equipment. (See V113) 3. Ensure staff wore appropriate personal protective equipment (PPE) while providing care in the treatment area. (See V115) 4. Ensure staff maintained separate areas for clean and dirty items. (See V117) 5. Ensure staff and patients' vaccinations for hepatitis B were current. (See V126) 6. Ensure laboratory testing was done for staff and patients after vaccinations for hepatitis B were completed and annually to determine immunity status. (See V127) 7. Monitor compliance with infection control policies. (See V142) 8. Ensure staff observed aseptic technique in medication preparation. (See V143) 9. Identify and report infection control issues. (See V144) The cumulative effect of these systemic practices had the potential to transmit infectious diseases to all 403 hemodialysis patients and staff. The facility failed to ensure compliance with Federal Regulations for the Condition for Coverage: Infection Control.	V 110			
V 111	494.30 IC-SANITARY ENVIRONMENT The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.	V 111			

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V 111	<p>Continued From page 2</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to provide and monitor a sanitary environment by allowing ventilation louvers to be dirty, broken and dirty equipment, and sterile supplies placed directly on the floor. These unsanitary conditions had the potential to transmit infectious disease to a universe of 403 hemodialysis patients and all staff.</p> <p>Findings:</p> <p>During a concurrent observation and interview on December 20, 2010 at 1:15 PM, the ventilation louvers above the nurse's station in the green unit were discolored with a black substance. Patient Care Technician (PCT) 4 stated, "I think that's dust" when asked what the substance was.</p> <p>During an observation on December 21, 2010 at 4:25 PM, the window blinds by Station 40 were broken and dirty. An IV pump used to administer medications was located by Station 37 and a red rust colored substance was on the back of the pump and the stand was dirty. Acid and bicarbonate tubing lines extending from the wall for Stations 7, 42 and 46 were observed on the floor. Computer stands at Stations 1, 6, 7, 11, 18, 19, 22, 24 55, and 56 contained rust and a white crusted substance. The computer keypads at Stations 18, 19, 22, and 24 were discolored with a beige colored crusted substance.</p> <p>During an observation on December 21, 2010 at 6:50 PM, two plastic storage containers were directly on the floor. A staff member opened the bottom drawer of one container and pulled out two needles for accessing a dialysis site. This</p>	V 111			

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V 111	Continued From page 3 drawer was approximately one half inch up from the floor surface. The staff member placed the needles on the chair at Station 25 in preparation for beginning dialysis.	V 111			
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 and interview, the facility failed to ensure staff were performing proper hand hygiene while providing patient care and touching equipment which had the potential to spread infection to a universe of 403 hemodialysis patients. Findings: 1. During an observation on December 20, 2010 at 9:35 AM, Patient Care Technician (PCT) 1 was accessing the patient's vascular access at Station 38 wearing gloves. PCT 1 then used the gloved hands to search for something while moving paper on the computer stand next to the machine. After removing the gloves, PCT 1 used hand	V 113			

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V 113	<p>Continued From page 4</p> <p>sanitizer and with her bare hands reset a hemodialysis machine alarm at Station 38 and went to Station 41 and reset the hemodialysis machine alarm without donning gloves or using hand sanitizer. Both hemodialysis machines were in use and had patient blood in the tubing.</p> <p>During an observation on December 20, 2010 at 12:30 PM, PCT 5 was wiping the empty patient chair in the hepatitis isolation room. The patient called out his weight to PCT 5 and she removed her gloves and typed the weight into the computer using her bare hands while still in the isolation room.</p> <p>During an interview on December 23, 2010 at 4:15 PM, the Infection Control Nurse 1 was asked how often the "Clean Sweep" audit for infection control was performed. She stated, "I try to do it monthly, but it doesn't always get done. I watch one or two staff and if they don't follow procedures, we copy the policy and give them a copy."</p> <p>2. During an observation of patient care in the Red Unit on December 21, 2010 the following was observed:</p> <p>At 7:50 PM, PCT 5 was holding a latex glove in the palm of her hand and used the tip of one finger of the glove to push the alarm button on the dialysis machine at Station 39 while the patient was receiving dialysis.</p> <p>At 8 PM PCT 6 was also seen holding a latex glove in the palm of her hand and used the tip of one finger of the same glove to push the buttons on the dialysis machines at Stations 51, 56, and 55 while patients were receiving dialysis. She</p>	V 113			

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V 113	Continued From page 5 also used an un-gloved hand to remove a clamp from the top of the dialysis machine at Station 54 and then used it to clamp the tubing attached to the machine while a patient was receiving dialysis. At 8:10 PM, Charge Nurse (CN) 1 was setting up an intravenous pump (a pump used to infuse medication into a vein) at Station 54 wearing gloves. While wearing the same gloves, she moved the computer located between Station 53 and 54, plugged in the IV pump to an electrical strip attached to the computer stand, and pushed a button on the dialysis machine at Station 54. The facility policy and procedure titled "Infection Control For Dialysis Facilities" dated September 2010 read, "Teammates will wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station, and will remove gloves and wash hands or perform hand hygiene between each patient and/or station. Gloves should be changed when going from a "dirty area or task to a "clean" area or task, and after touching one patient or their dialysis delivery system and before arriving to care for another patient or touch another patient's dialysis delivery system. Hand hygiene is to be performed upon entering the facility, prior to gloving, after removal of gloves, after contamination with blood or other infectious material, after patient and dialysis delivery system contact, between patients even if the contact is casual."	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	V 115			

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V 115	<p>Continued From page 6</p> <p>procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on observation, and record review, the facility failed to ensure all staff were wearing protective cover garments in the treatment area during hemodialysis which had the potential to expose staff to infectious blood.</p> <p>Findings:</p> <p>During an observation upon entry into the facility on December 20, 2010 at 9:15 AM, four staff members, providing patient care in the treatment area, were seen hurriedly putting on protective gowns.</p> <p>During an interview with the Group Facility Administrator (GFA) on December 22, 2010 at 1:20 PM, she stated staff was required to wear protective gowns while inside any of the dialysis units.</p> <p>During an interview with the Infection Control Nurse (ICN) on December 23, 2010 at 3:50 PM, she stated when she does monthly audits, she checks to make sure staff are using protective gowns while in the treatment area.</p> <p>The facility policy and procedure titled "Infection Control For Dialysis Facilities" with revision date of September 2010 read, "Appropriate lab coats or gowns will be worn at all times when on the treatment floor."</p>	V 115			

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V 117	<p>494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS</p> <p>Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.</p> <p>When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.</p> <p>Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to separate clean and dirty areas which had the potential to result in cross contamination and risk of transmission of infection to all patients and staff.</p> <p>Findings:</p> <p>1. During the observation of the facility's patient treatment area named the Gold Unit with the Clinical Coordinator (CC) on December 20, 2010 at 10 AM, the medication preparation area was located on the same counter with a sink with a sign that read "Dirty Area." On the counter was</p>	V 117			

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V 117	<p>Continued From page 8</p> <p>an open box of unused milliliter (ml) syringes, and an open box of multiple use Heparin 10 ml vials with six capped vials and three uncapped vials. Between these two boxes was a roll of red bags (bags used to for contaminated medical waste) on a metal dispenser. In the cabinet above this counter was three re-processed dialyzers in clear plastic bags, a bag of intravenous normal saline, four pre-drawn medications for Patient 16, and multiple plastic bins containing newly filled medication bottles for multiple patients. In the three drawers below this counter were numerous intravenous tubing, 1 ml syringes, and 10 ml syringes. This observation was verified with the CC and when asked which side she considered a clean area and which side was the dirty area, she pointed to an area at the half way mark of the counter, which left the drawer with the syringes under the dirty side and the intravenous medication approximately two inches from the dirty side of the counter.</p> <p>2. During an observation of the facility's patient treatment area named the Red Unit on December 21, 2010 at 5:50 PM, a dirty sink was located by number 52 treatment station. The words "Dirty Area" was posted by the sink and on the counter was a large plastic container with clamps soaking in clear fluid. Patient Care Technician (PCT) 7 was observed removing a set of tubing, used for dialysis, from a cabinet located below the dirty area. She opened the package and placed the tubing on the machine located at treatment station number 56. When this cabinet was opened and observed with PCT 8, she confirmed it contained multiple sets of new tubing, one case unopened intravenous normal saline in one liter bags, and the container on the counter contained used clamps soaking in disinfectant. PCT 8</p>	V 117			

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V 117	Continued From page 9 stated these items were being used on the clean dialysis machines before the start of patients treatments. During an interview with Charge Nurse 1 on December 21, 2010 at 6:25 PM, she verified the clean tubing and saline bags were in the dirty area. She stated she was unaware the items had been placed there and were being used by the staff. She stated, "These items should not be in the dirty area." 3. During an observation of the supply room on with Inventory Technician (IT) on December 20, 2010 at 1 PM, 11 cases of dialysate for peritoneal dialysis was on the floor. The IT stated those cases were waiting for a patient to pick up and take home. Also, on the floor was 19 other cases of peritoneal dialysate in the opposite corner. The IT stated the boxes should not be on the floor, but there was not room for more wooden pallets to stack the boxes. The facility policy and procedure titled "Infection Control For dialysis Facilities" with revision dated September 2010 read, "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. Teammates will 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."	V 117			
V 126	494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF Hepatitis B Vaccination	V 126			

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V 126	<p>Continued From page 10</p> <p>Vaccinate all susceptible patients and staff members against hepatitis B.</p> <p>This STANDARD is not met as evidenced by: Based on interview, and record review, the facility failed to provide two of 15 sampled patients (14 and 15) and eight random patients (19, 20, 21, 22, 23, 24, 25, and 26) with the hepatitis B (a disease that infects the liver) vaccination series (a total of four shots given at 0, 1, 2, 6 months), which resulted in their continued exposure to potential hepatitis B virus infection and had the potential to be infected and infect other patients, staff, and visitors who are susceptible to hepatitis B.</p> <p>Findings:</p> <p>The following clinical records were reviewed on December 23, 2010 at 2:15 PM:</p> <p>1. For Patient 14, the Patient Summary of Information Sheet (PSIS) indicated he started dialysis at the facility on October 19, 2010. The facility's form titled "Audit, Hepatitis Status and Compliance with CDC Recommendations for Hepatitis B Testing on ESRD Patients" (AHSC) indicated Patient 14 was <1 on the HBsAb test (a test for hepatitis B antibodies, (a number >10 reflects an immunity to hepatitis B infections at the time of testing) and negative on the HBsAB Core test (a test used to detect the first antibody to appear following an acute hepatitis B infection) done on November 11, 2010. The hepatitis B vaccine patient consent (HBVPC) form, signed by Patient 14 on November 11, 2010, indicated Patient 14 had chosen to receive the hepatitis B vaccination. The vaccination report dated January 1, 2010 through December 23, 2010</p>	V 126			

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V 126	<p>Continued From page 11 indicated Patient 14 had not received a vaccination for hepatitis B.</p> <p>2. For Patient 15, the PSIS indicated she started dialysis at the facility on July 2, 2010. The AHSC indicated Patient 15 was <1 on the HBsAB test and negative on the HbsAB Core test done on July 2, 2010. The HBVPC, signed by Patient 15 on July 29, 2010, indicated she had chosen to receive the hepatitis B vaccination. The vaccination report dated January 1, 2010 through December 23, 2010 indicated Patient 15 had not received a vaccination for hepatitis B.</p> <p>3. For Patient 19, the facility's patient census form (PCF) indicated she started dialysis at the facility on June 26, 2010. The AHSC indicated Patient 19 was <1 on the HBsAB test and negative on the HbsAB Core test done on July 8, 2010. The HBVPC, signed by Patient 19 on July 9, 2010, indicated she had chosen to receive the hepatitis B vaccination. The vaccination report dated January 1, 2010 through December 23, 2010 indicated Patient 19 had received one shot of the hepatitis B vaccine on August 26, 2010. No other shots for the hepatitis B vaccine were charted.</p> <p>4. For Patient 20, the PCF indicated she started dialysis at the facility on February 11, 2009. The AHSC indicated Patient 20 was <1 on the HBsAB test and negative on the HbsAB Core test done on February 17, 2009. The HBVPC, signed by Patient 20 on February 17, 2009, indicated she had chosen to receive the hepatitis B vaccination and this form also read "needs to restart series." The vaccination record indicated Patient 20 received her first hepatitis B shot on May 26, 2009 and one month later on June 23, 2009 she</p>	V 126			

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V 126	<p>Continued From page 12</p> <p>received the second shot. The third shot was recorded over a year later on July 13, 2010 and the fourth on October 7, 2010.</p> <p>5. For Patient 21, the PCF indicated he started dialysis at the facility on February 9, 2010. The AHSC indicated Patient 21 was <1 on the HBsAB test and negative on the HbsAB Core test done on February 9, 2010. The HBVPC with Patient 21's name printed on the top and found in his chart was not signed or dated by him. This form did not indicate his decision for or against the vaccine. This form did read "HBsAB <1 2/9/10." The vaccination report indicated Patient 21 had not received the hepatitis B vaccine.</p> <p>6. For Patient 22, the PCF indicated he started dialysis at the facility on August 27, 2010. The AHSC indicated Patient 22 was <1 on the HBsAB test and negative on the HbsAB Core test done on September 2, 2010. The HBVPC with Patient 22's name printed on the top and found in his chart was not signed or dated by him. This form did not indicate his decision for or against the vaccine. This form did read "HBsAB <1 9/2/10." The vaccination report indicated Patient 22 had not received the hepatitis B vaccine.</p> <p>7. For Patient 23, the PCF indicated she started dialysis at the facility on August 27, 2010. The AHSC indicated Patient 23 was <1 on the HBsAB test and negative on the HbsAB Core test done on September 30, 2010. The HBVPC, signed by Patient 23 on September 30, 2010, indicated she had chosen to receive the hepatitis B vaccination. The vaccination report indicated Patient 23 did not receive her first shot of the series until December 7, 2010.</p>	V 126			

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V 126	<p>Continued From page 13</p> <p>8. For Patient 24, the PCF indicated he started dialysis at the facility on September 24, 2008. The AHSC indicated Patient 24 was <1 on the HBsAB test and negative on the HbsAB Core test done on September 29, 2008. The HBVPC, signed by Patient 24 but not dated, indicated he had chosen to receive the hepatitis B vaccine. This HBVPC read "Needs to start series over." The vaccination report indicated Patient 24 received one shot of hepatitis B vaccine on September 29, 2008. No other dates or shots for hepatitis B were documented.</p> <p>9. For Patient 25, the PCF indicated she started dialysis at the facility on May 20, 2009. The AHSC indicated Patient 25 was <1 on the HBsAB test and negative on the HbsAB Core test done on May 29, 2009. The HBVPC, signed by Patient 25 but not dated, indicated she had chosen to receive the hepatitis B vaccine. The vaccination record indicated Patient 25 received one hepatitis B vaccine shot on February 12, 2010 and there was no documentation the series was completed. The AHSC indicated another HBsAB test was done on May 3, 2010 with a level of 32. On October 13, 2010, another HBsAB test was drawn with a level of 3. The vaccination record indicated Patient 25 was given a shot of the hepatitis B vaccine on December 22, 2010.</p> <p>10. For Patient 26, the PCF indicated she started dialysis at the facility on December 4, 2008. The AHSC indicated Patient 26 was <1 on the HBsAB test and negative on the HbsAB Core test done on December 9, 2008. Another HBsAB test was done on February 10, 2009 with a result of <1. The HBVPC, signed by Patient 26 on December 9, 2008 indicated he had chosen to receive the vaccine. The vaccination report indicated Patient</p>	V 126			

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V 126	<p>Continued From page 14</p> <p>26 received three of the four required shots (on May 26, 2009, July 28, 2009, and August 25, 2009) in the series. The fourth shot or another HBsAB test to check for immunity was documented on the vaccination report.</p> <p>During an interview with the Infection Control Nurse 1 (ICN) on December 23, 2010 at 3:50 PM, she stated since she took over the Infection Control position in June 2010, she has been trying to be current with the hepatitis B vaccination series for all the patients. She stated, "I didn't start every one because I'm only one person and a lot of patients are behind." She stated the Inventory Technician (IT) ordered the vaccines and he had a cap on how many he was allowed to order. She stated the facility uses the pediatric doses in vials that were cheaper and those were on back order. She stated the adult prefilled syringes were usually available but were more expensive. At this time, a review of the above patients was done with the ICN 1 and she verified the information listed above. ICN 1 was asked if it was a danger to have patients without hepatitis B immunity near hepatitis B antigen positive patients. ICN 1 stated, "I would expect staff to wash their hands. I would like to start new patients as soon as they come in, but we don't have the medications."</p> <p>During an interview with the IT on December 23, 2010 at 4:35, he stated the vaccine was hard to get from the current vendor contracted by the facility's corporate office and he confirmed the adult dose was usually available but more expensive.</p> <p>During an interview with the Administrator on December 27, 2010 at 11:30 AM, he stated the</p>	V 126			

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V 126	<p>Continued From page 15</p> <p>pediatric dose was often on back order and he verified the adult dose was usually available but sometimes it was on back order also. He stated most facilities use the pediatric doses because they were cheaper. He confirmed the facility did not attempt to find another vendor to purchase the needed vaccine.</p> <p>The hepatitis B vaccine manufacturer's recommendations titled "(name of company) Prescribing Information" dated 2010 and supplied by the facility was reviewed on December 27, 2010 at 11:45. This document read "Immunization is recommended in persons of all ages, especially those who are, or will be, at increased risk of exposure to hepatitis B, for example: Selected Patients and Patient Contacts: Patients and staff in hemodialysis units and hematology/oncology units." Under Table 1 this document read "Recommended Dosage and Administration Schedules: Adult hemodialysis - 40 mcg (micrograms)/2.0 ml (milliliters) - 0, 1, 2, 6 months (one dose then another one month later, third dose two months from the first, and the fourth dose 6 months from the first)."</p> <p>The facility policy and procedure titled "Hepatitis Surveillance, Vaccination and Infection Control Measures" revision date December 2008, read "Hepatitis B vaccination is recommended for all susceptible chronic dialysis patients and should be offered upon admission with physician order. The patient will sign a consent form and receive the Vaccination Information Sheet. If the vaccination series is interrupted after the first dose, the second dose should be administered as soon as possible. The second and third dose should be separated by an interval of at least one month, while making effort to maintain the</p>	V 126			

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V 126	Continued From page 16 recommended vaccine specific dosing intervals. Test all vaccinated patients for HBsAB one to two months after the last dose of the full vaccine series."	V 126		
V 127	494.30(a)(1)(i) IC-HBV-TEST PTS/STAFF POST LAST DOSE Hepatitis B Screening: Patients and Staff Test all vaccines [patients and staff] for anti-HBs 1-2 months after last primary vaccine dose. -- If anti-HBs is <10 mIU/mL, consider patient or staff member susceptible, revaccinate with an additional three doses, and retest for anti-HBs. -- If anti-HBs are =10 mIU/mL, consider immune, and retest patients annually. -- Give booster dose of vaccine to patients if anti-HBs declines to <10 mIU/mL and continue to retest patients annually. This STANDARD is not met as evidenced by: Based on interview and personnel file review, the facility failed to: 1. Test two of 27 staff members' responses (Registered Nurse 3 and Reuse Technician 1) to the hepatitis B vaccine (a vaccine developed for the prevention of hepatitis B virus infection) periodically; this had the potential to expose its staff to hepatitis B infection. 2. Test one out of 15 sampled patients (11) for continued immunity to hepatitis B (a disease that infects the liver), which had the potential for her to be infected with hepatitis B and infect other patients, staff, and visitors who are susceptible to hepatitis B.	V 127		

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V 127	<p>Continued From page 17</p> <p>Findings:</p> <p>1. On December 22, 2010 at 2:20 PM, during a concurrent interview and personnel file review with the Assistant Facility Administrator (AFA), the following were found:</p> <p>a. The AFA could not locate any documentation to indicate Registered Nurse (RN) 3, hired on December 9, 2008, had ever had a test completed for hepatitis B vaccine. RN 3 was initially hired to provide dialysis services to patients in an acute care setting.</p> <p>b. On December 22, 2010 at 2:40 PM, during a concurrent interview and personnel file review with the AFA. The AFA could not locate any documentation to indicate Reuse Technician (RT) 1, transferred from another dialysis center on March 16, 2009, had a test completed for hepatitis B vaccine since his transfer date.</p> <p>On December 22, 2010 at 4 PM, during an interview, the AFA stated she had been in charge of the Hepatitis Vaccination Program, and that the dialysis center's policy to test employees was annually.</p> <p>2. The clinical records for Patient 11 was reviewed on December 23, 2010 at 9:25 AM. The Audit: Hepatitis status and Compliance document indicated Patient 11 was immune to hepatitis B on July 8, 2009 with a HBsAB level of >150 (a test for hepatitis B antibodies (a number >10 reflects an immunity to hepatitis B infections at the time of testing) and she had not been re-tested for immunity in 2010.</p> <p>During an interview with the Group Facility Administrator (GFA) on December 23, 2010 at</p>	V 127			

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V 127	Continued From page 18 10:30 AM, she stated she could not find a HBsAB level drawn for Patient 11 in 2010. She stated the test should be drawn one year from the last test. The facility policy and procedure titled "Hepatitis Surveillance, Vaccination and Infection Control Measures" revised December 2008, read "If the hepatitis B surface antibody (HBsAb or anti-HBs) is (greater than or equal to) 10 mIU/mL (milli-international units per milliliter), consider patient immune, and retest annually for HBsAB." The manufacturer's recommendations titled "Engerix - B, Prescribing Information"(a vaccination used for immunization for hepatitis B) and supplied by the facility, read "For hemodialysis patients, in whom vaccine-induced protection is less complete and may persist only as long as antibody levels remain above 10 mIU/mL, the need for booster doses should be assessed by annual antibody testing."	V 127			
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: Based on interview and personnel file review, the facility failed to follow its annual tuberculosis (TB) screening practice to three of 27 random sampled staff which had placed its patients and staff at risk for TB exposure. Findings:	V 142			

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V 142	Continued From page 19 On December 22, 2010 at 2:20 PM, during a concurrent interview and personnel file review, accompanied by the Assistant Facility Administrator (AFA), the following were found: 1. The Facility Administrator (FA) had his last TB screening completed on January 24, 2008. The AFA was unable to locate any more recent screening after that date. The FA was hired on May 31, 2005. 2. Registered Nurse (RN) 3 was hired on December 9, 2009 as a per-diem Registered Nurse to serve patients needing dialysis in acute care settings. The FA was also unable to locate his TB screening results from his hire date. 3. A Reuse Technician (RT) 1 who was transferred to this facility from another sister facility in March 2009 also did not have a TB screening in his personnel records. The FA stated that this could have been missed as a result of his transfer. She verified with the sister facility but was unsuccessful to locate a TB screening that was completed in the past year. On December 22, 2010 at 4 PM, the facility's policy and procedure on "TUBERCULOSIS MONITORING AND FOLLOW-UP" was reviewed. Under "Baseline and Annual TST (Tuberculin Skin Testing/test)," read in part, "All new teammates including paid volunteers, per-diem teammates ...will receive baseline tuberculin skin testing (TST) using ... Follow up TB screening using TST will occur on an annual basis, from the date of the last TST using ..."	V 142			
V 143	494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS	V 143			

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V 143	<p>Continued From page 20</p> <p>[The facility must-]</p> <p>(2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility staff failed to observe aseptic techniques for medication preparation. This had the potential to place patients at risk for acquired infectious illnesses.</p> <p>Findings:</p> <p>1. On December 20, 2010 at 9:55 AM, during an initial tour of the Gold Room, seven one-millimeter (ml) syringes, out of original package, were placed in an emesis basin. Eight 3-ml syringes, also out of original package, were placed in a second emesis basin.</p> <p>On December 20, 2010, at 10:15 AM, during an interview, Registered Nurse (RN) 5 stated she came in early this morning and had to take these syringes out of the manufacturers' package in order to get ready for patients coming in for dialysis later. At 10:20 AM, the Clinical Coordinator (CC) 1 was informed of the above finding. The CC 1 stated these syringes should not be taken out of packages until ready for use.</p> <p>2. On December 20, 2010 at 9:55 AM, during an initial tour of the Gold Room, observed Patient Care Technician (PCT) 10 removing some supplies from a cabinet. In these supplies, were two 10-ml syringes, one was labeled "2 cc (ml)</p>	V 143			

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V 143	Continued From page 21 Heparin" and the other one was Lidocaine (a medication used topically to relieve pain). Both syringes did not have patient name, date, time of preparation, or dosage on the label. The Association for Professionals in Infection Control and Epidemiology (APIC) strongly recommends to "Never store needles and syringes unwrapped as sterility cannot be assured." The facility's Policies and Procedures & Guidelines on "MEDICATION POLICY," revised on September 2009, read in part, "14. If medications are prepared and administered immediately, by the same licensed nurse teammate, the medications do not need to be labeled. If the medication is not immediately administered or is to be administered by another teammate, the medication must be labeled with the patient name, name of medication, date, time prepared, dose and initials of teammate preparing the medication."	V 143			
V 144	494.30(b)(3) IC-STAFF REPORT IC ISSUES [The facility must-] (3) Require all clinical staff to report infection control issues to the dialysis facility ' s medical director (see § 494.150 of this part) and the quality improvement committee. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to demonstrate an effective reporting system for infectious diseases which had the potential to inadequately protect a universe of 403 hemodialysis patients from contamination by drug	V 144			

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V 144	<p>Continued From page 22 resistant organisms.</p> <p>Findings:</p> <p>During a record review on December 20, 2010 at 2 PM, the facility's infection log identified 16 cases of methicillin resistant staphylococcus aureus (MRSA) since July 1, 2010. MRSA is an infectious bacteria which is resistant to most antibiotics.</p> <p>During a record review on December 21, 2010 at 2:15 PM of the Quality Improvement and Facility Management Meeting Minutes dated October 29, 2010, the page titled "Incenter HD (hemodialysis) -Infection Tracking and Vaccinations" identified no drug resistant organism follow-up and did not identify a desirable goal for infection rate. April 2010 read 9.7% total infection rate and June read 9.3% total infection rate.</p> <p>During an interview with the Infection Control Nurse (ICN) 1 on December 23, 2010 at 4:15 PM, she stated she had been to one Quality Improvement meeting and she will be tracking infections "as soon as I'm shown. I don't know who is doing that now."</p> <p>During an interview on December 27, 2010 at 11:15 AM, the Facility Administrator (FA) 1 stated the infection rate goal was 5% and it was not being accurately reported because they were tracking antibiotics instead of infections. FA 1 stated, the ICN 1 was still training and was not involved with tracking infections.</p> <p>During an interview on December 27, 2010 at 12:30 AM, FA 1 stated the facility had "Zero" MRSA infections in the 18 months since he had</p>	V 144			

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V 144	Continued From page 23 been administrator. He stated he was responsible for reviewing the Quality Improvement data and the infection log and indicated he did not remember getting reports of MRSA.	V 144			
V 400	494.60 CFC-PHYSICAL ENVIRONMENT This CONDITION is not met as evidenced by: Based on observation, interview and record review, it was determined that the facility did not meet the Condition for Coverage (CFC) for physical environment by failing to: 1. Provide emergency call lights for patients in the peritoneal dialysis exam rooms. (See V402). 2. Ensure staff performed daily calibration testing for the conductivity meters and daily quality control on the glucose meters. (See V403) 3. Ensure patients' vascular accesses remained visible during hemodialysis treatment. (See V407) 4. Conduct emergency preparedness drills for the nocturnal shift of hemodialysis patients. (See V408) 5. Ensure emergency crash carts were properly maintained. (See 413)	V 400			

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V 402	<p>494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to provide a patient call system in the peritoneal dialysis training examination rooms which had the potential to prevent the patient from calling for help in an emergency.</p> <p>Findings:</p> <p>During a concurrent observation and interview of the peritoneal dialysis training examination rooms on December 21, 2010 at 9:30 AM, no patient call lights were observed in either of the two rooms. Peritoneal Dialysis Nurse (PDN) 1 stated there was no call light system in the room for patients and if staff needed help, they used the telephone intercom system.</p>	V 402			
V 403	<p>494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU</p> <p>The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record</p>	V 403			

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V 403	<p>Continued From page 25</p> <p>review, the facility failed to ensure the controls for the blood sugar testing device were completed before using it to measure the blood glucose for one of 15 sampled patients (11). The facility also failed to ensure the Myron L Meters (a meter that tests dialysis fluid for the correct conductivity) were calibrated daily and correctly before testing the dialysis machines for conductivity. Both failures had the potential to adversely affect the facility's diabetic and hemodialysis patients.</p> <p>Findings:</p> <p>1. During an observation of the Red Unit on December 22, 2010 at 1:10 PM, the blood sugar monitor control log was requested from the Unit Secretary (US). She stated the patient care technicians (PCTs) kept the log for the blood sugar testing monitor in a binder, which was kept on the Red Unit.</p> <p>The blood sugar test monitor log for the Red Unit was reviewed on December 22, 2010 at 1:20 PM with the Group Facility Administrator (GFA). The log indicated from June 7, 2010 to December 22, 2010, the controls were performed 26 times. She stated the controls should be done daily.</p> <p>The clinical record for Patient 11 was reviewed on December 22, 2010 at 1:40 PM. The Patient Progress Notes dated December 1, 2010 indicated Patient 11's blood sugar was tested in the Red Unit before she was sent to the hospital. At this time, the same date was reviewed on the Red and Green Unit's blood sugar test monitor logs. The logs for both the Red and Green Units indicated the controls for the blood sugar test monitors were not done between the dates of November 29 through December 13, 2010.</p>	V 403			

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V 403	Continued From page 26 During an observation of the Green Unit on December 22, 2010 at 3:20 PM, the Green Unit's binder containing the blood sugar testing monitor log was located at the nurses station. The log indicated since March 8, 2010 to December 22, 2010, the blood sugar testing monitor had the controls performed 14 times. At this time, Registered Nurse 1 (RN) 1 was asked who was responsible for the controls being performed on the blood sugar testing monitor, she stated, "I don't know, I think Biomed (the department that performs maintenance on medical equipment) does the checks everyday." During an interview with PCT 2 from the Green Unit on December 22, 2010 at 3:30 PM, she stated the controls for the blood sugar monitor log should be done daily by the PCTs but she was unaware the control test should be documented on a log. She stated, "I didn't do them today." The manufacturer's user guide, provided by the facility, was reviewed on December 27, 2010 at 10:05 AM. On page 55 of this manual, it read "The control solution test tells you that your monitor and test strips are working correctly." The facility's policy and procedure titled "Blood Glucose Testing" revised September 2009, read "Quality control (QC) testing is completed prior to the first use of the day when the monitor is used for patient blood glucose testing. QC procedures are performed and documented every day the monitor is used. The Quality Control Log is completed at the time of each QC test." The same policy and procedure under procedure, read "In addition to the required daily control tests, glucose controls are used: Before using	V 403			

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V 403	<p>Continued From page 27</p> <p>the meter for the very first time. . . "</p> <p>2. During an interview with PCT 2 and PCT 3 on December 22, 2010 at 3:20 PM, PCT 2 stated the calibration of the Myron L Meter should be done daily, but she was unaware she should chart the test in the calibration log. She stated, "I did the test today on number 2 and it was 13.7." When asked what the control test number should be she stated, "Plus or minus 5%." PCT 3 stated meter number 3 was up in the cabinet, which she opened and it was sitting on the shelf. She stated, We don't use it very often."</p> <p>During an interview with PCT 11 in the Purple Unit, while reviewing the Myron L meter calibration log, on December 22, 2010 at 3:40 PM, she verified the log indicated the calibration had not been done for meter number 17 since August 5, 2010, for meter number 13 since August 9, 2010, for meter number 18 since July 19, 2010, and for meter number 15 since July 10, 2010. She stated, "The calibrations haven't been done today."</p> <p>During an interview with the GFA on December 22, 2010 at 4 PM, she stated the Myron L Meters should be calibrated every morning before the first dialysis machine was tested for conductivity and the test should be charted in the calibration log on each unit.</p> <p>The Myron L meter calibration log for the Red and Green Units were reviewed on December 22, 2010 at 4:30 PM. The Red Unit log indicated meter number nine was calibrated 16 times in March 2010, 4 times in April 2010, 9 times in May 2010, 6 times in June 2010, 4 times in July 2010, zero times in August 2010, 1 time in September</p>	V 403			

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V 403	Continued From page 28 2010, and 7 times in October 2010. The last documentation of meter number nine being calibrated was October 18, 2010. For the Green Unit, the calibration log indicated meter number 2 was tested 12 times since January 25, 2010 to December 22, 2010. Six of the 12 times meter 2 was tested, it did not test at exactly 14.0 mS (a measure of electric conductance). The last date charted was July 22, 2010. A second calibration log for meter number 3, indicated it had been calibrated 4 times from March 1, 2010 to December 22, 2010, with the last calibration on April 15, 2010. The facility policy and procedure titled "Myron L Dual Range Conductivity Meter Quality Control" revised March 2010, read "The Quality Control (QC) testing procedure is performed daily on each Myron L meter prior to use. The meter should read exactly 14.0 mS, the known value of the control solution. If the meter dose NOT match the value of the control solution, the test must be repeated. If results continue to vary from known control solution value, the meter cannot be used to test delivery system dialysate. . ." The manufacturer's operation manual titled "Dual Range Dialysate Meter Operation Instructions, User Manual for Models D-2" undated, read "Before measuring dialysate samples, check the calibration of your meter. . . If the D-2 meter does not indicate the 14.0 millimhos (mS) shown on the Standard Solution bottle's label., first clean the cell. . . and test the Standard Solution again. If the D-2 meter still does not indicate the correct value, re-calibrate it as described below."	V 403			
V 407	494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS	V 407			

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V 407	<p>Continued From page 29</p> <p>Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement).</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure multiple patients receiving dialysis treatments had their vascular access (method used to gain access to the blood stream) sites exposed and able to be seen by staff members during dialysis treatments which had the potential to result in undetected accidental needle or blood line disconnection which could result in massive blood loss and death in minutes.</p> <p>Findings:</p> <p>During a concurrent observation and interview on December 20, 2010 at 10:30 AM, a patient was seated at Station 42 and his arm was wrapped with a blue plastic pad. Hemodialysis tubing containing blood was seen leading from the arm to the hemodialysis machine. Registered Nurse (RN) 1 stated his access was covered because he pulls at his needles and family sits with him. The male family member sitting in a chair in front of the patient was asked if he knew what to look for if the patient is bleeding, the man looked confused and stated "No hablo ingles (I don't speak English)".</p> <p>During an observation of the Red Unit on December 21, 2010 at 2 PM, Patient 17 had his vascular access and dialysis blood tubing wrapped with a Chux (a blue and white pad used to absorb fluid). During this same observation, Patient 18 was covered from his feet to under his</p>	V 407			

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V 407	Continued From page 30 chin with a blanket. To his right side dialysis blood tubing could be seen going to and under the blanket. His vascular access was not visible. During an interview with Charge Nurse (CN) 1 on December 21, 2010 at 2:15 PM, she stated Patient 17 should not have his vascular access covered. She stated all patients should have their vascular access visible during dialysis. During the continued observation of the Red Unit on December 21, 2010 at 2:30 PM, Patient 15 was receiving dialysis. She also was covered with a blanket. Her vascular access and dialysis blood tubing were not visible. At 2:40 PM, Patient 18's vascular site was still covered with a blanket. At 3:15 PM, Patient Care Technician 9 asked Patient 15 to remove her arm from under the blanket so it could be visible. The facility policy and procedure titled "Arteriovenous Fistula and Arteriovenous Graft Vascular Access Care" dated September 2007 read, "Cannulation sites and blood tubing connections will be verified for accurate, patent, and secure connections, and remain visible throughout the treatment."	V 407			
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			

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V 408	Continued From page 31 This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to follow their policy and procedure to have each shift participate in quarterly emergency and evacuation drills, which had the potential for causing harm to patients and staff. The facility also failed to ensure the emergency supplies were checked monthly per the facility's policy and procedure. Findings: 1. During an interview with the Group Facility Administrator (GFA) on December 20, 2010 at 4:20 PM, she stated the facility has three shifts of patients receiving dialysis which included a nocturnal (between 7 PM and 4 AM) shift that starts around 7 PM on Tuesdays, Thursdays, and Sundays. The fire and disaster drill documentation for the facility was reviewed on December 21, 2010 at 10:45 AM. The documentation did not include night shift staff and patient participation in a fire or disaster drill. During an interview with Patient 13 on December 21, 2010 at 7 PM, he stated he has been a patient of the facility for the past two years. He stated he had never participated in a fire or disaster drill since he had gone to the nocturnal shift, which was 6 months ago. During an interview with the GFA on December 22, 2010 at 1:20 PM, she stated the facility does not have fire or disaster drills on the nocturnal shift.	V 408			

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V 408	Continued From page 32 The facility policy and procedure titled "Disaster and Emergency Preparedness Business Continuity Policy" revised March 2010 read, "Patients and teammates on each shift will participate in quarterly emergency and evacuation drills. 2. During an observation of the Red Unit with the Clinical Coordinator (CC) on December 20, 2010 at 9:35, a large black suitcase covered in a layer of a powder-like substance was located on the ledge behind station 44. During an observation of the Green Unit with the CC on December 20, 2010 at 9:50 AM, a large black suitcase covered in a layer of brown powder was on the ledge behind station 24. The CC stated the suitcases were the emergency supplies. During an observation of the Red and Green Units on December 21, 2010 at 8:45 AM, both units had new plastic bins on wheels containing emergency supplies. Registered Nurse (RN) 2 stated, "The emergency kits were changed yesterday." During an interview with Clinical Service Supervisor 1 on December 21, 2010 at 9 AM, she stated the emergency kits should be checked every month and documented on a check list but the last documentation of them being checked was January 2010. The facility policy and procedure titled "Emergency Equipment Checks" revised December 2008, read "To ensure the designated equipment is available and functional, the	V 408			

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V 408	Continued From page 33	V 408			
V 413	<p>following equipment checks will be performed by a licensed nurse teammate: Monthly: Evacuation kit is complete and supplies have not expired."</p> <p>494.60(d)(3) PE-ER EQUIP ON PREMISES-02, AED, SUCTION</p> <p>Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the facility failed to ensure the emergency crash carts (supplies and medications used in medical emergencies) were properly maintained. This had the potential to result in failure to deliver appropriate care to patients.</p> <p>Findings:</p> <p>During an inspection of the Green Unit's crash cart with the Clinical Services Supervisor (CSS) 1 on December 21, 2010 at 9 AM, the contents located on top of the crash cart located and the emergency equipment checklist (a record of when the crash cart was checked for expired and used items that needed to be replaced) were reviewed. The oxygen tank air meter indicated the tank was empty and the CSS 1 verified this when she turned it on and no oxygen was released. The artificial resuscitator (a bag with a mouth piece used to force air into the lungs) mouth piece was hard and discolored and the CSS 1 verified it should be replaced. The checklist indicated the crash cart was last checked on December 20, 2010. A check mark was placed by all the areas</p>	V 413			

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V 413	<p>Continued From page 34</p> <p>including the oxygen tank and artificial resuscitator indicating they were operational. The area under "Action if necessary" was blank. This was verified by the CSS. She stated the crash carts should be checked daily and documentation done on the emergency equipment checklist. While reviewing the emergency equipment checklist, she confirmed no checks were done between December 7 and December 18, 2010.</p> <p>During a review of the Red Unit's emergency equipment located on top of the crash cart and checklist for the crash cart with the CSS on December 21, 2010 at 9:15 AM, she verified the crash cart was checked two times in July 2010 (7/09, 7/10, 2010), three times in August 2010 (8/14, 8/17, 8/25, 2010), one time in August 2010 (9/26/2010), one time in September 2010 (9/26/2010), and one time in October 2010 (10/27/2010). Between November 8 and November 10, 2010 this checklist indicated the suction machine (a machine used to suction secretions from the mouth, and throat during a medical emergency) was not operational and on November 10, 2010 it read "Will be checked by Biomed (a department that repairs medical equipment)."</p> <p>While entering the Purple Unit on December 21, 2010 at 9:30 AM, Registered Nurse (RN) 4 was checking the contents of the crash cart drawers. During this time the emergency equipment and checklist was reviewed with her. The emergency equipment checklist indicated the crash cart contents located on top and the oxygen had not been checked since December 13, 2010. The form titled "Monthly Crash Cart Check - First Drawer" read "Check monthly & after each use. Date & Initial after checking. Check expiration</p>	V 413			

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V 413	<p>Continued From page 35</p> <p>dates. Replace stock as necessary." This form indicated drawer one had been checked four times in 2010 (3/18, 5/26, 6/3, 7/28, 2010) and indicated the expiration dates on 10 emergency medications had not been checked since July 28, 2010. The form titled "Monthly Crash Cart Check - Second Drawer" read "Check monthly & after each use. Date & Initial. Restock as necessary." This form indicated the drawer was checked five times in 2010 (3/18, 5/26, 6/3, 7/28, and 12/21, 2010). The drawer contained medical supplies used to place an artificial airway in patients who can not breathe on their own. The form titled "Monthly Crash Cart Check - Bottom read "Check monthly & after each use." The bottom contained normal saline (a solution used intravenously during a medical emergency), Chux (an large absorbant pad), pediatric kit (supplies used for children), and a suction catheter (a hard plastic hollow wand used to suction fluid from the mouth and throat). The form indicated the bottom was checked three times in 2010 (3/18, 6/3, 7/28, 2010). RN 4 verified all the above and stated the facility does have pediatric patients.</p> <p>The facility policy and procedure titled "Emergency Equipment Checks" revised December 2008, read "Purpose: To ensure that emergency equipment is maintained in a ready-to-use condition. The emergency checklist will be developed by the facility based on Medical Director input as to the supplies needed on the emergency crash cart and will be used to verify that the cart has been checked. A list of all dated supplies will be posted, with the expiration dates, on the cart and is to be checked weekly by licensed nurse teammate assigned to check the emergency cart." This policy and procedure indicated the contents of the top of the crash cart</p>	V 413			

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V 413 V 470	Continued From page 36 and the oxygen tank was to be checked weekly. 494.70(c) PR-RIGHTS POSTED,STATE/NW 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 interview, the facility failed to post the telephone number for the State survey agency which had the potential to prevent patients from voicing complaints to the appropriate State agency. Findings: During an observation on December 20, 2010 at 9:15 AM, a poster was on a bulletin board in the Green Unit waiting room. This poster contained patient rights information and the phone numbers to call complaints i.e., the ESRD network and the Department of Health and Human Services. The phone number listed was not the phone number for the CDPH District Office. During a concurrent observation and interview with the Facility Administrator (FA) 1 on December 27, 2010 at 3:45 PM, the bulletin board was no longer on the wall. FA 1 stated they had taken the bulletin board down but the bulletin board in the Red Unit waiting room had been updated. Upon observation of the State Agency phone number posted on the Red Unit bulletin board, it was determined it was the voice mail	V 413 V 470			

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V 470	Continued From page 37 telephone number of a district office supervisor and not the main phone number for the CDPH District Office. FA 1 was unable to provide additional information.	V 470			
V 501	494.80 PA-IDT MEMBERS/RESPONSIBILITIES The facility's interdisciplinary team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the facility failed to ensure the instability status for one out of 15 sampled patients (11) was addressed during the IDT (interdisciplinary team) meetings in order to develop a plan of care to address her frequent hospitalizations and medical conditions, which had the potential for Patient 11 to continue to be unstable and to continue to experience frequent hospitalizations. Findings: The clinical record for Patient 11 was reviewed on December 23, 2010 at 10:50 AM. The care plan printed from the facility's computer indicated Patient 11 had been hospitalized nine times in 2010 (1/22, 2/7, 3/16, 4/26, 7/5, 9/17, 10/3, 10/8, 12/1, 2010) and three of those times were within	V 501			

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V 501	<p>Continued From page 38</p> <p>30 days (9/17, 10/3, 10/8, 2010). This care plan also indicated it was generated on March 3, 2010 and no revisions of the plan of care had be done since April 23, 2010.</p> <p>During an interview with the Clinical Coordinator (CC) on December 27, 2010 at 11 AM and concurrent review of Patient 11's care plan, she verified Patient 11's care plan had not been revised since April 23, 2010. She verified Patient 11's three hospitalizations between September 17 and October 8, 2010 should have changed her to an unstable status and her care plan should have been reviewed by the IDT. Then, an updated care plan should have been generated in the computer system and reviewed monthly until she was stable per CC.</p> <p>The facility policy and procedure titled "Patient Assessments and Plan of Care" revised September 2009, read "A comprehensive re-assessment of each patient and a revision in the plan of care will be conducted: At least monthly for unstable patients including, but not limited to, patients with the following: extended or frequent hospitalizations. The facility's interdisciplinary team will develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patients' condition, and will include measurable and expected outcomes and estimated timetables to achieve these outcomes. Subsequent interdisciplinary re-assessments and adjustments to the patient's plan of care should be completed within the 30 days following the initiation of the re-assessment. This process would occur monthly for unstable patients and annually for</p>	V 501			

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V 501	Continued From page 39 stable patients."	V 501			
V 506	494.80(a)(3) PA-IMMUNIZATION/MEDICATION HISTORY The patient's comprehensive assessment must include, but is not limited to, the following: Immunization history, and medication history. This STANDARD is not met as evidenced by: Based on interview and record review, the facility administered an antibiotic to a patient (9) without verifying the patient's allergy. This had the potential to cause serious adverse reactions to patients who had allergies to medications. Findings: On December 22, 2010, Patient 9's "IDT (interdisciplinary team) Assessment and Plan of Care Report" was reviewed. The baseline data dated July 8, 2010, read, "ALLERGIES: codeine (a pain medication), Vancomycin (an antibiotic)." During further review of Patient 9's record, Patient 9 had been on Vancomycin since December 13, 2010, four times a week. There was no documentation to indicate the patient had any adverse reaction during this period. On December 23, 2010 at 3:40 PM, the Group Facility Administrator stated Patient 9 was not allergic to Vancomycin. She added the nursing staff, when entering the order and prior to administering the medication, should have checked the allergy history and notified the physician.	V 506			

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V 520	<p>494.80(d)(2) PA-FREQUENCY REASSESSMENT-UNSTABLE Q MO</p> <p>In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted-</p> <p>At least monthly for unstable patients including, but not limited to, patients with the following: (i) Extended or frequent hospitalizations; (ii) Marked deterioration in health status; (iii) Significant change in psychosocial needs; or (iv) Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the facility failed to ensure the instability status for one out of 15 sampled patients (11) was addressed during the IDT (interdisciplinary team) meetings in order to develop a plan of care to address her frequent hospitalizations and medical conditions, which had the potential for Patient 11 to continue to be unstable and to continue to experience frequent hospitalizations.</p> <p>Findings:</p> <p>The clinical record for Patient 11 was reviewed on December 23, 2010 at 10:50 AM. The care plan printed from the facility's computer indicated Patient 11 had been hospitalized nine times in 2010 (1/22, 2/7, 3/16, 4/26, 7/5, 9/17, 10/3, 10/8, 12/1, 2010) and three of those times were within 30 days (9/17, 10/3, 10/8, 2010). This care plan</p>	V 520			

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V 520	<p>Continued From page 41</p> <p>also indicated it was generated on March 3, 2010 and no revisions of the plan of care had been done since April 23, 2010.</p> <p>During an interview with the Clinical Coordinator 1 on December 27, 2010 at 11 AM and concurrent review of Patient 11's care plan, she verified Patient 11's care plan had not been revised since April 23, 2010. She verified Patient 11's three hospitalizations between September 17 and October 8, 2010 should have changed her to an unstable status and her care plan should have been reviewed by the IDT. Then, an updated care plan should have been generated in the computer system and reviewed monthly until she was stable per CC 1.</p> <p>The facility policy and procedure titled "Patient Assessments and Plan of Care" revised September 2009, read "A comprehensive re-assessment of each patient and a revision in the plan of care will be conducted: At least monthly for unstable patients including, but not limited to, patients with the following: extended or frequent hospitalizations. The facility's interdisciplinary team will develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patients' condition, and will include measurable and expected outcomes and estimated timetables to achieve these outcomes. Subsequent interdisciplinary re-assessments and adjustments to the patient's plan of care should be completed within the 30 days following the initiation of the re-assessment. This process would occur monthly for unstable patients and annually for stable patients."</p>	V 520			

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V 628	<p>494.110(a)(2) QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS</p> <p>The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops 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 identify appropriate indicators for quality assurance in the areas of infection control, adequacy, and accesses which had the potential to provide patients with optimal hemodialysis outcomes.</p> <p>Findings:</p> <p>1. During a record review on December 21, 2010 at 2:30 PM, the facility Quality Improvement and Facility Management Meeting Minutes (QIFFM) dated October 29, 2010 were reviewed. The facility's goal for fistula (a vein and artery connection for hemodialysis access) was 52%. The goal established by Centers for Medicare and Medicaid Services (CMS) for 2010 was 66%. The facility's goal for central vascular catheter (CVC) was 25%. The goal established by CMS for 2010 was less than 10%.</p> <p>During an interview with Facility Administrator (FA) 1 on December 27, 2010 at 11:15 AM, he stated the facility's goal of 25% was decided by the corporate office.</p> <p>2. During a record review on December 21, 2010</p>	V 628			

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V 628	Continued From page 43 at 2:30 PM, the facility QIFFM minutes dated October 29, 2010 were reviewed. The facility's goal since March 2010 for adequacy was a Kt/V (a measurement of hemodialysis adequacy) of ">1.2" was 95% and "<1.2" was 90%. During an interview with FA 1 on December 27, 2010 at 11:20 AM, he stated these goals were in error and the Clinical Services Supervisor was responsible for checking the goals. FA 1 acknowledged the error occurred for seven months without correction. 3. During a record review on December 21, 2010 at 2:40 PM, the facility QIFFM dated October 29, 2010, July 23, 2010, May 21, 2010, and April 23, 2010 were reviewed. The facility's goal for infection rate was not identified and no evaluation of the data was documented. During an interview with FA 1 on December 27, 2010 at 11:15 AM, he stated the facility's infection rate goal was 5% and he and the Assistant Facility Administrator were reporting the infections. When questioned about the rate of 9.7% in April and 9.3% in June, he stated the data was not correct because they had reported antibiotic use instead of infection rate and since the antibiotics were given prophylactically, the data was wrong. During an interview on December 27, 2010 at 3:45 PM, the Medical Director 1 was unable to provide the target goal for the infection rate and stated the Facility Administrator was responsible.	V 628			
V 634	494.110(a)(2)(vi) QAPI-INDICATOR-MEDICAL INJURIES/ERRORS The program must include, but not be limited to,	V 634			

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V 634	<p>Continued From page 44</p> <p>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 staff failed to ensure a medication error was recorded timely which left no opportunity for the management to investigate and prevent recurrence.</p> <p>Findings:</p> <p>On December 22, 2010, Patient 9's dialysis run sheets for December 16, 2010 were reviewed. Patient 9 had been on vancomycin (an antibiotic used to treat infections) for infection. The medication was prescribed to be given at the end of the dialysis treatment. A nurse documented the vancomycin was "missed" and the notes read, "due to short staffing unable to give antibiotic pt (patient) refused to stay longer in order to get (1)00 mi (milliliter) 0.9 NS (normal saline) flush for medication."</p> <p>On December 23, 2010 at 3:30 PM, during an interview, the Group Facility Administrator (GFA) stated this incident was not recorded in the facility's adverse event and it should have been reported to the management as a medication error. She reviewed the staffing for that day and stated there were two registered nurses on duty at the time and was unable to confirm short staffing was the cause.</p> <p>On December 23, 2010, the facility's "Medication Policy," last revised in September 2009, was reviewed. It read in part, "30. All medication</p>	V 634			

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V 634	Continued From page 45 errors are reported to the Facility Administrator/Designee. She/he will then notify the patient's physician of the event and of any adverse changes in the patient's condition. Examples of medication errors include... A prescribed medication not administered to the patient ..."	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 information on infection incidence; (B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and (C) Take actions to reduce future incidents. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to accurately tract and trend infection control data which prevented the facility from identifying infection trends and developing prevention plans. Findings: During a record review on December 21, 2010 at 2:40 PM, the facility Quality Improvement and Facility Management Meeting Minutes (QIFFM) dated October 29, 2010, July 23, 2010, May 21, 2010, and April 23, 2010 were reviewed. The facility's goal for infection rate was not identified and no evaluation of the data was documented.	V 637			

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V 637	Continued From page 46	V 637			
V 681	<p>During an interview with Facility Administrator (FA) 1 on December 27, 2010 at 11:15 AM, he stated the facility's infection rate goal was 5% and he and the Assistant Facility Administrator were reporting the infections. When questioned about the rate of 9.7% in April and 9.3% in June, he stated the data was not correct because they had reported antibiotic use instead of infection rate and since the antibiotics were given prophylactically the data was wrong.</p> <p>During an interview on December 27, 2010 at 3:45 PM, the Medical Director 1 was unable to provide the target goal for the infection rate and stated the Facility Administrator was responsible.</p> <p>494.140 PQ-STAFF LIC AS REQ/QUAL/DEMO COMPETENCY</p> <p>All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure staff had adequate infection control training to perform assigned duties which had the potential to expose patients to infectious diseases and suboptimal outcomes.</p>	V 681			

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V 681	<p>Continued From page 47</p> <p>Findings:</p> <p>During a record review on December 20, 2010 at 2 PM, the facility's infection log identified 16 cases of methicillin resistant staphylococcus aureus (MRSA) since July 1, 2010. MRSA is an infectious bacteria which is resistant to most antibiotics.</p> <p>During a record review of the Quality Improvement and Facility Management Meeting Minutes on December 21, 2010 at 2:15 PM, the page titled "Incenter HD (hemodialysis)-Infection Tracking and Vaccinations identified no drug resistant organism follow-up and did not identify a desirable goal for infection rate. April 2010 read 9.7% total infection rate and June read 9.3% total infection rate.</p> <p>During an interview with the Infection Control Nurse (ICN) 1 on December 23, 2010 at 4:15 PM, she stated she was assigned the duties in July 2010 and her training consisted of previous staff showing her "some minimal stuff like hepatitis B reports and vaccination reports." ICN 1 stated she had been to one Quality Improvement meeting and she will be tracking infections "as soon as I'm shown. I don't know who is doing that now."</p> <p>During an interview on December 27, 2010 at 11:15 AM, the Facility Administrator (FA) 1 stated the infection rate goal was 5%. FA 1 stated he and the Assistant Facility Administrator were reporting and it was not being accurately reported because they were tracking antibiotics instead of infections. FA 1 stated the ICN 1 was still training and was not involved with tracking infections.</p>	V 681			

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V 681	Continued From page 48 During an interview on December 27, 2010 at 12:30 AM, FA 1 stated the facility had "Zero" MRSA infections in the 18 months since he had been administrator. He stated he was responsible for reviewing the Quality Improvement data and the infection log and indicated he did not remember getting reports of MRSA.	V 681			
V 750	494.180 CFC-GOVERNANCE This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the facility's governing body failed to provide oversight to ensure compliance by failing to: 1. Provide and monitor a sanitary environment to minimize the potential transmission of infectious disease as evidenced by the dirty computer stands and keyboards in patient treatment area, peritoneal dialysate fluid boxes on the floor, supply carts containing needles placed directly on the floor, dirty vents in the green unit, broken and dirty blinds in the red room. (See V111) 2. Ensure staff were performing proper hand hygiene while providing patient care and touching equipment. (See V113) 3. Ensure staff wore appropriate personal protective equipment (PPE) while providing care in the treatment area. (See V115) 4. Ensure staff maintained separate areas for clean and dirty items. (See V117) 5. Ensure staff and patients vaccinations for hepatitis B were current. (See V126)	V 750			

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V 750	Continued From page 49 6. Ensure laboratory testing was done for staff and patients after vaccinations for hepatitis B were completed and annually to determine immunity status. (See V127) 7. Monitor compliance with infection control policies. (See V142) 8. Ensure staff observed aseptic technique in medication preparation. (See V143) 9. Identify and report infection control issues. (See V144) 10. Provide emergency call lights for patients in the peritoneal dialysis examination rooms. (See V402) 11. Ensure staff performed daily calibration testing for the conductivity meters and daily quality control on the glucose meters. (See V403) 12. Ensure patients' vascular accesses remained visible during hemodialysis treatment. (See V407) 13. Conduct emergency preparedness drills for the nocturnal shift of hemodialysis patients. (See V408) 14. Ensure emergency crash carts were properly maintained. (See V413) The cumulative effect of these systemic problems resulted in the facility's inability to ensure the provision of quality health care in a safe environment.	V 750			

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