

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

PRINTED: 09/30/2010
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 052305	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 04/22/2010
NAME OF PROVIDER OR SUPPLIER SANTA CLARA VALLEY MEDICAL CENTER - ESRD			STREET ADDRESS, CITY, STATE, ZIP CODE 2220 MOORPARK AVENUE SAN JOSE, CA 95128	
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V 000	<p>INITIAL COMMENTS</p> <p>Surveyor: 05189 The following reflects the findings of the California Department of Public Health during a recertification survey from 4/19/2010 to 4/22/2010.</p> <p>Representing the Department of Public Health: Dorothy Rice HFEN, Doina Vlasache HFES, Lutgarda Sturms HFEN and Nikki Kratt HFEN.</p> <p>The census at the start of the survey was 277 patients (239 Hemodialysis and 38 Peritoneal).</p> <p>Acronyms and Abbreviations commonly used in this report:</p> <p>ESRD-end-stage renal disease. Treatment options include hemodialysis [using a manufactured artificial kidney to remove fluid and waste]; peritoneal dialysis [using the patient's peritoneal membrane in their abdominal cavity as a filter to remove fluids and waste]; or kidney transplant.</p> <p>EDW - estimated dry weight. The weight of a person when all excess weight was removed.</p> <p>Dialyzer - an artificial kidney using a membrane to filter and remove excess fluid and waste from the body.</p> <p>Dialysate - specific mixture of treated water, acidified concentrate with variable ratios of potassium (K) and calcium (Ca), and bicarbonate.</p> <p>Dialysis machine - the delivery system for hemodialysis.</p>	V 000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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V 000	<p>Continued From page 1</p> <p>Cross-contamination - spread of infection from a patient to another through breaks in infection control practices.</p> <p>Measurements of Dialysis Adequacy: Kt/V = kinetic modeling for dialysis adequacy reflecting clearance, time and volume URR = Urea reduction ratio (percentage of urea reduction)</p> <p>Vascular Access - the site on patient's body where blood is removed and returned during dialysis. AVF - arteriovenous fistula-surgically created direct connection between an artery and vein in the patient's body, usually on the lower or upper arm. AVG - arteriovenous graft: a synthetic type material utilized to create a connection between an artery and vein. Catheter- a synthetic tube outside the body that goes into a large vessel: a tunneled catheter is tunneled beneath the skin usually through the internal jugular vein or into the subclavian vein.</p> <p>Hepatitis B - a serious disease affecting the liver caused by Hepatitis B virus.</p> <p>Antigen - a substance that prompts the generation of antibodies and could cause an immune response. Used in Hepatitis B testing to denote a person who has been exposed to Hepatitis B.</p> <p>Antibody - particle generated by the body in response to an antigen. Used in Hepatitis B testing and vaccination to measure the degree of immunity to Hepatitis B.</p>	V 000			

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V 000	Continued From page 2 Two types of Peritoneal Dialysis (PD) methods: - CAPD continuous ambulatory peritoneal dialysis (done manually) - CCPD continuous cycling peritoneal dialysis (done with machine) PPE - personal protective equipment QAPI - quality assurance performance improvement Venous Pressure - a measurement of the extracorporeal (outside the body) blood circuit at some point after the dialyzer and before the blood enters the patient's body. A sudden drastic increase in the venous pressure from 50 to 150 mm Hg (mercury) could indicate clotting conditions. MSW-Social worker RN-Registered Nurse CHT-Certified Hemodialysis Technician, also called PCT, Patient Care Technician HSA-Hospital Services Assistant CDC - Centers for Disease Control mm - millimeter mg. - milligrams mcg. - micrograms ml. - milliliter cc - cubic centimeter F - Farenheit C - celsius	V 000			
V 110	494.30 CFC-INFECTION CONTROL	V 110		6/3/10	

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V 110	<p>Continued From page 3</p> <p>This CONDITION is not met as evidenced by: Surveyor: 21174</p> <p>Based on observation of care delivery, interview with staff, family members and patients, and record review, the facility failed to comply with the Condition for Coverage for Infection Control as demonstrated by:</p> <p>Failure to ensure that a family member was provided impervious cover garments while in the isolation treatment room and while one (Patient 2, who was Hepatitis B positive) of 15 sampled patients was receiving hemodialysis treatment. This failure placed the family member at risk for blood borne illness. (Refer to V 115).</p> <p>Failure to vaccinate a newly admitted and susceptible patient against the Hepatitis B virus, placing the patient at risk for hepatitis (Refer to V 126).</p> <p>Failure to provide quantitative Hepatitis B Antibody results for patients and staff members to determine whether they were immune or susceptible to hepatitis B virus and to allow the staff to monitor for potential decline in antibodies response and for need to revaccinate. This failure placed the facility's 277 patients and all staff at risk for infection. (Refer to V127)</p> <p>Failure to revaccinate patients who did not develop antibodies after receiving one vaccine series, leaving them susceptible to Hepatitis B viral infection as evidenced by random review of three (Patients 5, 1, 7) of 15 sampled patients and two (Patients 26 and 27) randomly selected patients. (Refer to V127)</p>	V 110			

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V 110	<p>Continued From page 4</p> <p>Failure to annually retest all immune patients for Hepatitis B antibodies to determine if the level of immunity continued to provide the patients with protection against infection for one (Patient 7) of 15 sampled patients. This failure placed the patients at increased risk for infection. (Refer V127)</p> <p>Failure to develop a system that would ensure that Hepatitis B susceptible patients (randomly selected Patients 18, 20, 26, and 27) were not cared for by staff (such as CHT's L and Q) simultaneously caring for Hepatitis B positive patients. This failure increased the potential for transmission of Hepatitis B to patients not immune to the Hepatitis B virus (Refer to V131).</p> <p>Failure to reeducate staff regarding infection control practices at least annually as recommended by the Center for Disease Control and evidenced by seven (RN N, RN D, Staff O, CHT L, RN C, MSW A, and Nurse Manager) of ten staff files reviewed not having evidence of such training. This failure placed staff and patients (a total of 277 patients) at risk of infections. (Refer to V132)</p> <p>Failure to implement infection control policies by: a) Lacking a system to ensure that the patients' status of vaccination against pneumonia was determined and addressed for two (Patients 3 and 6) of 15 patients sampled; b) Provide one (Patient 2) of 15 sampled patients with pneumococcal vaccine; and c) Test for tuberculosis one (Patient 10) of 15 sampled patients. These failures placed the patients at risk for infectious diseases. (Refer to V 142). Failure to ensure the catheter care policy and procedure followed CDC's "Guidelines for the</p>	V 110			

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V 110	Continued From page 5 Prevention of Intravascular Catheter-Related Infections" for maintaining aseptic technique. This failure increased the potential for catheter-related infections for the 35 patients with catheters receiving hemodialysis treatments at the facility. (Refer to V146) Failure to ensure that staff practiced rigorous hand hygiene during catheter care for two (Patients 12 and 6) of two patients observed, placing the patients at risk for catheter related infections. (Refer to V 146).	V 110			
V 115	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. 494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. This STANDARD is not met as evidenced by: Surveyor: 16558 Based on observation, interview, and record review, the facility failed to ensure that a family member was provided impervious cover garments while in the isolation treatment room and while one (Patient 2, who was Hepatitis B positive) of 15 sampled patients was receiving hemodialysis treatment. This failure placed the family member at risk for blood borne illness.	V 115		6/3/10	

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V 115	<p>Continued From page 6</p> <p>Findings:</p> <p>Clinical record review on 4/19/10 showed Patient 2 started receiving hemodialysis treatments at the facility on 10/20/04. The comprehensive assessment, dated 8/24/09, indicated Patient 2 had cognitive impairment and needed assistance with the activities of daily living due to her mentation. Patient 2 tested positive for Hepatitis B and received treatments in the isolation room.</p> <p>During an interview on 4/21/10 at 12:40 p.m., Medical Social Worker A stated that due to her cognitive loss, Patient 2 required the presence of a family member during treatments to calm her down. Medical Social Worker A stated that Patient 2 would become agitated, would pull the lines out of the vascular access during treatment and would attempt to leave the facility. The presence of a family member helped Patient 2 cope with the hemodialysis treatment.</p> <p>On 4/21/10 at 2:41 p.m., while PCT L was initiating Patient 2's treatment, a family member was seated in a chair, about one and a half feet away from the dialysis chair. The family member was wearing gloves, but no other protective garment. PCT L had a face shield and goggles, gloves and a gown covering his clothing. During interview, the family member stated he had to be present during treatment at all times because Patient 2 could unexpectedly attempt to pull the lines or get off the chair. Patient 2 was observed rocking back and forth continuously. The family member reported during the interview, that recently, Patient 2 pulled the lines and that "there was blood everywhere and I had to hold her".</p>	V 115		

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V 115	Continued From page 7 In an interview on 4/22/10 at 9:35 a.m., Nurse Manager stated the family member should wear a gown while in the treatment area as splashing of blood would be expected if Patient 2 would pull out the lines.	V 115		
V 126	494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF Hepatitis B Vaccination Vaccinate all susceptible patients and staff members against hepatitis B. This STANDARD is not met as evidenced by: Surveyor: 21174 Based on interview and record review, the facility failed to initiate Hepatitis B vaccination for one (Patient 12) of 15 sampled patients. Patient 12 was admitted to the facility on 2/4/10, and had yet to receive the first injection of the four injection vaccine series, leaving him susceptible to Hepatitis B infection. Findings: Review of Patient 12's medical record on 4/19/10 indicated he was admitted to the facility on 2/4/10. Review of Patient 12's Initial Comprehensive Patient Assessment, dated 2/23/10, showed staff evaluated his Hepatitis B vaccination history and marked "Needs Vaccine". During an interview on 4/21/10 at 8:50 a.m., RN H confirmed Patient 12's admission date and his negative Hepatitis B antibody results, showing Patient 12 was susceptible to Hepatitis B infection. RN H stated "They've yet to start his series."	V 126		6/3/10

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V 126	Continued From page 8 Review of the facility policy "Hepatitis B Virus", revised 3/10, indicated, "Based on the results of the testing of non vaccinated patient the following should be done: Susceptible patients will receive the Engerix B Vaccine immediately upon admission."	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: Surveyor: 21174 Based on interview and record review, the facility failed to: Provide quantitative Hepatitis B Antibody results for 277 patients and all staff members that would allow staff to determine whether the patients and the staff were immune or susceptible to hepatitis B virus. By not reporting a numeric value, the staff was not able to closely monitor for a decline in antibodies response and to timely evaluate the need for revaccination. This failure placed the facility's 277 patients and all staff at risk for infection.	V 127		6/3/10

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V 127	<p>Continued From page 9</p> <p>Revaccinate patients who did not develop antibodies after receiving one vaccine series, leaving them susceptible to Hepatitis B viral infection as evidenced by random review of three (Patients 5, 1, 7) of 15 sampled patients and two (Patients 26 and 27) randomly selected patients.</p> <p>Annually retest all immune patients for Hepatitis B antibodies to determine if the level of immunity continued to provide the patients with protection against infection for one (Patient 7) of 15 sampled patients. This failure placed the patients at increased risk for infection.</p> <p>Findings:</p> <p>1. On 4/19/10, review of Patient 5's record indicated he was "negative" for Hepatitis B antibodies . Review of Patient 14's record indicated she was "positive". On 4/21/10, review of Patient 18's record indicated he was "borderline." There were no numbers accompanying these results that would explain how the facility determined whether the patient had developed immunity to Hepatitis B or was susceptible.</p> <p>During an interview on 4/20/10 at 9 a.m., the facility's Senior Health Care Program Analyst stated that in March (2010), "We reviewed the Condition for Coverage and asked the lab to provide quantitative results (expressing the antibody result numerically)." The Senior Health Care Program Analyst produced an e-mail written by the Clinical Biochemist on 4/20/10 at 9:12 a.m. According to the biochemist, the lab used an assay method that gave results in quantitative terms, but "prior to mid-March we were converting that number to the qualitative responses Positive,</p>	V 127			

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V 127	<p>Continued From page 10</p> <p>Borderline, or Negative. These three gradations come from the (manufacturers's) package insert." . The package insert defined a Positive result as a result >12.0 mIU/mL (mili-international units/milliliter)/test or two tests with a value between 8.0-12.0; a Borderline value was one or two test of 8.0-12.0 or one > 12.0 and one < 8.0; Negative results were given to tests that were both <8.0. There was no explanation why the quantitative terms were not used.</p> <p>2. Record review on 4/19/10 showed Patient 5 was admitted to the facility on 5/6/06 with end stage kidney disease due to diabetes. According to his annual Comprehensive Patient Assessment, dated 11/11/09, his Hepatitis B antibodies status was negative with a comment "Engerix (Hepatitis B vaccine) series complete."</p> <p>During an interview on 4/21/10 at 8:40 a.m., RN H confirmed Patient 5 received his four shot vaccine series at the proper intervals and completed the series on 2/07. She stated "After the series, if they didn't respond (develop antibodies after receiving the Hepatitis B vaccine series, indicating immunity to Hepatitis B) we called them primary nonresponders." RN H confirmed Patient 5 was considered by the facility to be a non-responder and received monthly Hepatitis antigen tests to ensure he had not contracted Hepatitis B. She stated Patient 5, as a non-responder, also received a Hepatitis B antibody test every six months, and if Patient 5 had a positive result (indicating antibody response) "I'll do a booster (extra vaccine dose)." She confirmed Patient 5 never received a second vaccine series.</p> <p>3. Record review on 4/19/10 showed Patient 1</p>	V 127			

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V 127	<p>Continued From page 11</p> <p>was admitted to the facility on 7/23/07 with a diagnosis of end stage renal disease, requiring dialysis. According to his immunization record, Patient 1 was considered susceptible to Hepatitis B infection, testing negative every six months for Hepatitis B antibodies.</p> <p>On 4/21/10 at 8:48 a.m., RN H stated that the facility considered Patient 1, "a non-responder." She reviewed her vaccination log and stated Patient 1 completed his Hepatitis B vaccine series on 4/08 and received no further vaccinations. Review of the facility policy "Hepatitis B", revision 3/10, indicated "Primary vaccine dose to see if they responded to the vaccine a). If anti-HBs (Hepatitis B antibodies) is < (less than) 10 mU/ml consider patient or staff member susceptible, revaccinate with a second series which includes three doses given at 0, 1, 6 month schedule, and retest for anti-HBs 1-2 month after completion of the series per CDC recommendations. (If their titer (antibody level) is still less or negative, patient is considered to be a non responder and given no more vaccine."</p> <p>Surveyor: 05189</p> <p>4. The record review (paper and electronic) on 4/20/10 with RN A showed that Patient 7 was admitted to the facility on 8/17/07. The electronic medical record showed that on 5/20/08, Patient 7 tested "Negative" for Hepatitis B antigen and "Positive" for Hepatitis B antibodies (indicating immunity to the Hepatitis B infection).</p> <p>On 4/20/10, RN A stated that the facility's practice and policy was to retest annually patients with positive results for Hepatitis B antibodies. However, further review showed that Patient 7 was not re-tested until 7/21/09 (as opposed to 5/20/09) and that the result was "Negative" (indicating susceptibility to Hepatitis B infection).</p>	V 127			

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V 127	<p>Continued From page 12</p> <p>On 8/20/09, Patient 7 received a Hepatitis B vaccine booster (one dose of vaccine) and on 10/20/09, the Hepatitis B antibodies level was again, "Positive", but no numerical value, that would allow staff to determine the level of protection, was reported.</p> <p>Patient 7 was re-tested on 2/9/10 and the Hepatitis B antibodies test read, "Negative" (no value given). The lack of reporting the test results in a quantitative format, made it difficult to the facility staff to determine when the level of antibodies declined, placing the patients at risk to become susceptible to hepatitis B infection.</p> <p>On 4/21/10, during a telephone conversation, RN H stated that she was aware that Patient 7 was susceptible and required additional Hepatitis B vaccination. RN H stated that she was out on sick leave and had not had the opportunity to "get caught up".</p> <p>According to the CDC's Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients (April 27, 2001 / Vol. 50 / No. RR-5), "Among hemodialysis patients who respond to the vaccine, protection against hepatitis B is not maintained when antibody titers fall below protective levels. " Surveyor: 16558</p> <p>5. Record review on 4/22/10 with RN A showed Patient 26 tested negative for Hepatitis B immunity on 12/14/09. According to RN A, Patient 26 received a Hepatitis B vaccination series between 3/9/07 and 9/7/07. Despite the fact that Patient 26 did not achieve immunity against Hepatitis B infection, the facility did not administer a second vaccine series to Patient 26.</p>	V 127		

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V 127	Continued From page 13 6. On 4/22/10, review of the clinical record with RNA showed Patient 27 was not immune to Hepatitis B infection. Patient 27 tested negative for Hepatitis B antibodies on 1/12/10. According to the records, Patient 27 received a full series of vaccination between 2/24/05 and 8/25/05, but no other series since.	V 127			
V 131	494.30(a)(1)(i) IC-HBV-ISOLATION-STAFFING Isolation of HBV+ Patients Staff members caring for HBsAg positive patients should not care for HBV susceptible patients at the same time, including during the period when dialysis is terminated on one patient and initiated on another. This STANDARD is not met as evidenced by: Surveyor: 16558 Based on observation, interview, and record review, the facility failed to develop a system that would ensure that Hepatitis B susceptible patients (randomly selected Patients 18, 20, 26, and 27) were not cared for by staff (such as CHT's L and Q) simultaneously caring for Hepatitis B positive patients. This failure increased the potential for transmission of Hepatitis B to patients not immune to the Hepatitis B virus. Findings: Record review on 4/19/10 showed that Patient 6 started hemodialysis treatments at the facility on 10/20/04 and that the patient tested positive for Hepatitis B infection. On 4/21/10 at approximately 2:40 p.m., CHT L was observed initiating Patient 6's hemodialysis treatment in the isolation room. CHT L stated he was assigned to the care of three other patients. Review of the patient schedule and staff assignment on 4/22/10 at 9:50 a.m. with RN F,	V 131		6/7/10	

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V 131	<p>Continued From page 14</p> <p>showed that on 4/21/10, while CHT L took care of Patient 6, he also provided treatment to Patients 18, 19, and 20. The Hemodialysis Runsheets, dated 4/21/10, pertaining to Patient 6, 18, 19, and 20 confirmed same staff (CHT L) took care of susceptible patients at the same time he was caring for a Hepatitis B positive patient. Laboratory results for Hepatitis B antibodies showed that Patient 18 tested "Borderline" on 2/8/10, Patient 19 tested "Positive" on 6/15/09, and Patient 20 tested "Negative" on 1/18/10. In an electronic communication, dated 4/22/10 at 11:38 a.m., the Clinical Biochemist from the laboratory processing the blood tests, indicated that those with Borderline results should be treated as susceptible. Both Patients 18 and 20 were susceptible to Hepatitis B infection. According to RN F, interviewed on 4/22/10, there were five other patients receiving care at the facility that tested positive for Hepatitis B infection : Patients 21, 22, 23, 24, and 25. Further patient schedule and runsheets review showed the following: On 4/20/10, CHT L cared for Patient 21 (Hepatitis B positive) and Patient 26, who's laboratory results, dated 12/14/09, showed Patient 26 tested Negative for the presence of Hepatitis B antibodies. Patient 26 was susceptible to infection with Hepatitis B virus. CHT Q was assigned and cared for Patient 23 on 4/20/10, beginning at 3:04 p.m. till 6:43 p.m. CHT Q was also assigned to Patient 27, who's laboratory results, dated 1/12/10 showed Negative results for the Hepatitis B antibodies. Patient 27 was susceptible to infection with Hepatitis B virus. Patient 27 treatment started at 3:44 p.m. and ended at 7:46 p.m. During an interview on 4/22/10 at 10:40 a.m., RN F (charge nurse) stated it was her duty as a</p>	V 131			

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V 131	Continued From page 15 charge nurse to assigned staff to the care of patients. RN F also stated that the assignment sheets have the patients names preprinted and that she adds the staff's name at the beginning of the treatment day. According to RN F, it was the facility's practice to rotate staff from a pod (section of treatment stations) to a different pod in a quarterly basis, but patients remained assigned to the same station. RN F continued to say that she did not check the patient's Hepatitis B immune status prior to assigning their care to a staff who was also assigned to care for a Hepatitis B positive patient (in the isolation room) during the same time. At approximately 2 p.m., Senior Health Care Program Analyst confirmed the practice and stated the Hepatitis B immune status of patients assigned to the same staff caring for a patient with Hepatitis B infection was not verified prior to assigning a patient to a certain treatment station, and consequently to a certain staff member.	V 131			
V 132	494.30(a)(1)(i) IC-TRAINING & EDUCATION Infection Control Training and Education Infection control practices for hemodialysis units: intensive efforts must be made to educate new staff members and reeducate existing staff members regarding these practices. This STANDARD is not met as evidenced by: Surveyor: 16558 Based on interview and record review, the facility failed to reeducate staff regarding infection control practices at least annually as recommended by the Center for Disease Control and evidenced by seven (RN N, RN D, Staff O,	V 132		5/20/10	

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V 132	Continued From page 16 CHT L, RN C, MSW A, and Nurse Manager) of ten staff files reviewed not having evidence of such training. This failure placed staff and patients (a total of 277 patients) at risk of infections. Findings: On 4/22/10 at 9:30 a.m. during an interview, the facility Nurse Manager stated that the staff was to receive annual infection control training, such as prevention of exposure to bloodborne infections, screening and prevention of tuberculosis, prevention of viral hepatitis, and hand hygiene. Ten personnel files reviewed on 4/22/10 showed the following: RN N did not receive infection control training since June 2008. Staff O and CHT L did not receive infection control training since July 2008. RN D and RN C did not receive infection control training since September 2008. MSW A's personnel file did not have evidence of infection control training in the last three years. The Nurse Manager confirmed the findings on 4/22/10 at 12:30 p.m..	V 132		
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;	V 142		6/3/10

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V 142	<p>Continued From page 17</p> <p>This STANDARD is not met as evidenced by: Surveyor: 16558</p> <p>Based on interview and record review, the facility failed to implement infection control policies by:</p> <p>Lacking a system to ensure that the patients' status of vaccination against pneumonia was determined and addressed for two (Patients 3 and 6) of 15 patients sampled.</p> <p>Provide one (Patient 2) of 15 sampled patients with pneumococcal vaccine.</p> <p>Test for tuberculosis one (Patient 10) of 15 sampled patients.</p> <p>These failures placed the patients at risk for infectious diseases.</p> <p>Findings:</p> <p>1. Record review on 4/19/10 showed Patient 3's comprehensive assessment, dated 6/3/09 showed under "Vaccinations", Pneumovax (vaccine against a bacteria causing severe pneumonia), "Pt. (patient) does not know if he had this vaccine." The patient plan of care for Immunizations, dated 7/21/09, indicated that Patient 3 should receive a pneumococcal vaccine every 10 years. Under "Interventions" the plan of care read, "Not completed-will follow up. Unknown if pt. has received in past 5 years." Further record review showed no evidence that Patient 3's pneumococcal immunization status was followed-up on or that vaccine was offered.</p>	V 142			

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V 142	Continued From page 18 During an interview on 4/21/10 at 10:55 a.m., RN A stated the facility did not have a system for following up on patients' Pneumovax status. 2. The care plan for Immunizations, dated 4/13/10 and reviewed on 4/20/10, showed Patient 6 did not have pneumococcal vaccination done at the facility and that the plan was to follow-up. Further record review with RN A on 4/20/10 at 1 p.m., showed no evidence that the patient's vaccination history for pneumovax was determined and recorded. 3. Patient 2's record was reviewed on 4/19/10. The patient's comprehensive assessment, dated 8/24/09 showed Patient 2 needed pneumococcal vaccination. Further record review showed no evidence that the vaccine was administered to Patient 2. RN A stated on 4/20/10 at 1:20 p.m., after reviewing Patient 2's electronic and paper record, that she could not find any evidence that Patient 2 received a Pneumovax dose. 4. On 4/20/10, record review showed Patient 10 received hemodialysis treatments at the facility on 3/30/10, 4/1/10 and on 4/3/10. Further review showed no evidence that Patient 10 was tested for tuberculosis. The facility policy for "Tuberculin Skin Tests", dated 4/10, indicated that each patient would have a tuberculin skin test during admission, unless the patient "had an adequate negative test within the previous three months." There was no evidence of a tuberculin test in Patient 10's record.	V 142			
V 146	494.30(c)(2) IC-CATHETERS:GENERAL (2) The "Guidelines for the Prevention of Intravascular Catheter-Related Infections" entitled	V 146		5/5/10	

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V 146	<p>Continued From page 19</p> <p>"Recommendations for Placement of Intravascular Catheters in Adults and Children" parts I - IV; and "Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients," Morbidity and Mortality Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection as the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html</p> <p>This STANDARD is not met as evidenced by: Surveyor: 21174 Based on observation, interview, and record review, the facility failed to: Ensure the catheter care policy and procedure followed CDC's "Guidelines for the Prevention of Intravascular Catheter-Related Infections" (MMWR August 9, 2002/Vol. 51/No. RR-10) for maintaining aseptic technique. This failure increased the potential for catheter-related infections for the 35 patients with catheters receiving hemodialysis treatments at the facility. Ensure that staff practiced rigorous hand hygiene during catheter care for two (Patients 12 and 6) of two patients observed, placing the patients at risk for catheter related infections.</p>	V 146			

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V 146	Continued From page 20 Findings: 1. Review of the CDC "Guidelines for the Prevention of Intravascular Catheter-Related Infections" showed that aseptic technique and scrupulous hand hygiene was to be performed while providing catheter exit site care to lessen the potential for catheter related infections. 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 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. On 4/20/10, review of the facility policy "Dialysis Catheter Care and Dressing Change", dated 7/09, showed that the policy instructed the staff to remove the old catheter dressing with clean gloves, inspect the site, discard the gloves and place sterile gloves on. The policy did not direct the staff to perform hand hygiene after removing	V 146			

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V 146	<p>Continued From page 21</p> <p>the gloves used to remove potentially contaminated dressing.</p> <p>2. On 4/20/10 at 4:02 p.m. RN J was observed performing catheter exit site care for Patient 12. After removing the old dressing, Staff J examined the site for redness, then removed her gloves and donned sterile gloves. Without any hand hygiene, RN J proceeded to clean the catheter insertion site and to place a new dressing over the exit site. Following the dressing change on 4/20/10 at 4:08 p.m., RN J was informed that she did not perform hand hygiene after removing the old dressing and her gloves. She stated, "It's because it's his? (implying that the microorganisms were Patient 12's, so therefore not an infection issue). She was informed hand hygiene needed to be performed after removal of the old dressing and prior to donning new gloves to clean the exit site because she was going from a "dirty" activity to a "clean" activity. Separating "dirty" activity from "clean" activity decreases cross-contamination and therefore the risk that microorganisms would enter the patient's blood.</p> <p>The Medical Director was informed on 4/21/10 at approximately 4 p.m. that the facility policy did not include hand hygiene after removing the old dressing and gloves and prior to donning sterile gloves. He stated he was not aware of the omission and agreed the policy needed to be changed.</p> <p>Review of the facility policy "Hand Hygiene Guidelines", last revised 8/06, indicated "Hand hygiene is required after gloves are removed."</p> <p>Surveyor: 16558</p> <p>3. Record review on 4/19/10 showed Patient 6 started receiving hemodialysis treatments at the facility on 12/21/06. Patient 6 had a central</p>	V 146		

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V 146	Continued From page 22 venous right jugular (vein going up the front of the neck) permacatheter for the vascular access. On 4/20/10 at 10:35 a.m., RN P provided catheter care for Patient 6. After RN P positioned Patient 6 for comfort, she used alcohol lotion for less than three seconds and placed clean gloves on her hands. Then, RN O removed the dressing covering the catheter site, removed the gloves, and again rubbed her hands for 2-3 seconds with alcohol lotion. Immediately after, RN O put on sterile gloves and proceeded to disinfect the site. While disinfecting the catheter site and the skin surrounding it, RN O used her sterile gloved left hand to hold the patient's garment away from the site, then applied the sterile dressing. RN O discarded the gloves, rubbed alcohol lotion on her hands for about three seconds and put on new gloves. For at least three consecutive instances, RN O did not perform a rigorous hand hygiene as recommended by CDC for prevention of catheter related infections. In its "Guidelines for the Prevention of Intravascular Catheter-Related Infections", CDC recognizes "direct contamination of the catheter or catheter hub by contact with hands or contaminated fluids or devices", as one of the four routes for catheter contamination.	V 146		
V 208	494.40(a) H2O STORAGE & DISTRIBUTION-DESIGN 5.3 Water storage and distribution 5.3.1 General: Design A water storage and distribution system should be designed specifically to facilitate bacterial control, including measures to prevent bacterial colonization and to allow for easy and frequent disinfection.	V 208		6/11/10

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V 208	Continued From page 23 This STANDARD is not met as evidenced by: Surveyor: 21174 Based on observation and interview, the facility failed to ensure that purified water connections to one (Station A4) of 25 dialysis stations was properly tightened, creating exposed surfaces that increased the potential for contamination of the water supply to that dialysis machine. Findings: During the initial tour on 4/19/10 at 10:17 a.m., observation showed a fast, steady leak of a clear fluid behind treatment station A4. The leak appeared to come from the connection from the wall to the tubing that delivered purified water to the dialysis machine. The facility's Senior Health Care Program Analyst was present at the time of the observation. He stated "It (connector) needs to be tightened. I can get it right away." The patient receiving dialysis at the time of the observation was the second patient scheduled that day to be dialyzed at treatment station A4. It was unknown how long the water connector had been loose or how many patients had been potentially affected.	V 208			
V 403	494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. This STANDARD is not met as evidenced by: Surveyor: 21174	V 403		5/20/10	

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NAME OF PROVIDER OR SUPPLIER SANTA CLARA VALLEY MEDICAL CENTER - ESRD			STREET ADDRESS, CITY, STATE, ZIP CODE 2220 MOORPARK AVENUE SAN JOSE, CA 95128	
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V 403	Continued From page 24 Based on observation and interview, the facility failed to maintain in good repair one treatment chair (A5) of 25 treatment chairs, increasing the potential for cross-contamination or patient injury. Findings: While waiting for Patient 5 to arrive for his scheduled treatment, observation on 4/20/10 at 10:06 a.m. showed the treatment chair contained a large tear in the vinyl seat, leaving an approximate three inch gash with jagged edges and exposing the chair's stuffing. CHT I present during the observation, stated "It's an old chair. We're replacing them one at a time." On 4/21/10 at 10:25 a.m., HSA K was observed cleaning treatment chair A5 with a disinfectant wipe. She stated she thought the chair had been torn for a few months. She stated "We're replacing the chairs, one at a time", and added "Would you like to sit there?"	V 403		
V 409	494.60(d)(1) PE-ER PREP STAFF-INITIAL/ANNUAL/INFORM PTS The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following: (i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of- (A) What to do; (B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated; (C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This	V 409		6/3/10

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V 409	<p>Continued From page 25</p> <p>contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and</p> <p>(D) How to disconnect themselves from the dialysis machine if an emergency occurs.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 16558 Based on interview and record review, the facility failed to:</p> <ol style="list-style-type: none"> 1. Ensure that all staff received annual training in emergency procedures as evidenced by seven (RN N, RN D, Staff O, CHT L, RN C, MSW A, and Nurse Manager) of ten staff files reviewed not having evidence of annual emergency training. This failure placed the staff and the patients receiving treatment at the facility (a total of 277 patients) at risk for not being able to handle emergencies, such as fires, earthquakes, severe bleeding). 2. Ensure that one (Patient 17) randomly selected patient was informed of procedures in case an emergency occurred while the patient was not in the facility. This failure increased the risk that the patient will not know what to do during an emergency. <p>Findings:</p> <ol style="list-style-type: none"> 1. The facility "Emergency Management Program, revised in 6/08 and reviewed on 4/22/10, indicated that staff would be provided emergency procedures training annually. 	V 409			

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V 409	Continued From page 26 On 4/22/10, ten personnel files reviewed showed the following staff did not receive emergency procedures training yearly: RN N and Nurse Manager had received last emergency training in June 2008. Staff O and CHT L did not receive emergency training since July 2008, and RN D and RN C since September 2008. MSW A's personnel file had no evidence of emergency training in the past three years. Nurse Manager confirmed during an interview on 4/22/10 at approximately 11:30 a.m. that emergency training should be provided annually and acknowledged the findings. Surveyor: 05189 2. On 4/21/10 during an interview, Patient 17 adequately explained the emergency procedures while in the facility. When the surveyor asked about emergency procedures when not in the facility, such as an earthquake, Patient 17 stared at the surveyor with a quizzical expression and stated, "I don't remember anyone talking about a disaster, like an earthquake." Review of Patient 17's record (both hard and electronic record) with RN A on 4/20/10, showed no documented evidence that Patient 17 was informed what to do and who to call in case of an emergency that occurred outside the facility. RN A confirmed the findings.	V 409		
V 466	494.70(a)(15) PR-INFORMED OF EXTERNAL	V 466		5/21/10

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V 466	<p>Continued From page 27 GRIEVANCE PROCESSES</p> <p>The patient has the right to-</p> <p>(15) Be informed of external grievance mechanisms and processes, including how to contact the ESRD Network and the State survey agency;</p> <p>This STANDARD is not met as evidenced by: Surveyor: 21174 Based on interview and record review, the facility failed to provide two (Patients 1 and 12) of 15 sampled patients with the correct contact information of the State survey agency in the event they needed help in resolving grievances. This failure could result in delay for patients seeking assistance from the appropriate State survey agency.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. On 4/19/10, record review for Patient 12 who was admitted on 2/4/10, showed a form signed by the patient on 2/4/10, indicating that if the patient requested external assistance to resolve a problem or grievance, he should call his "State Survey Agency at (510) 540-2417". Upon calling the phone number given to the patient, the message heard was, "This phone number has been disconnected or is no longer in service." No forwarding phone number was included in the message that might assist a caller who required help from the State Agency. 2. On 4/19/10, record review for Patient 1, who was admitted on 4/23/07, showed a form signed by the patient on 4/27/07 that indicated if he 	V 466			

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V 466	Continued From page 28 requested external assistance to resolve a problem or grievance, he could be referred to his State Survey Agency, by calling 1-800 MEDICARE (1-800-633-4227) .	V 466			
V 503	494.80(a)(2) PA-APPROPRIATENESS OF DIALYSIS RX The nurse manager was interviewed on 4/19/10 at 2:58 p.m. She acknowledged the phone numbers listed were incorrect. The patient's comprehensive assessment must include, but is not limited to, the following: (2) Evaluation of the appropriateness of the dialysis prescription, This STANDARD is not met as evidenced by: Surveyor: 21174 Based on interview and record review, the facility failed to follow the physician's dialysis orders for one (Patient 5) of 15 sampled patients. Patient 5's dialysis prescription was changed during his dialysis treatment, and staff did not extend the treatment time as ordered by the physician, increasing his potential for an adverse outcome. Findings: On 4/21/10, review of Patient 5's medical record indicated he was admitted to the facility on 5/6/06 for renal failure due to diabetes. Review of Patient 5's treatment record for 4/13/10 showed physician orders for dialysate bath of 3 K+/2.5 Ca, indicating he did not require much potassium to be removed through dialysis, and a treatment run time of three hours and 15 minutes. On 4/13/10,	V 503		5/5/10	

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V 503	<p>Continued From page 29</p> <p>Patient 5's treatment began at 10:46 a.m. using the 3 K/2.5 Ca dialysate bath. At 1 p.m., a documented therapy incident from the treatment record showed "K 6.6 (a dangerously high potassium level; normal potassium level is 3.5 to 5.5). Dr. -- ordered to change to 1 K (a dialysate bath that will remove more potassium) and run pt (patient) for extra 30 minutes. Review of the computerized treatment sheet showed the bath was changed to 1 K/2.5 Ca at 1 p.m., but no increased run time noted. Staff documented Patient 5's treatment was stopped at 2 p.m., three hours and 14 minutes after his treatment was started; his normal run time.</p> <p>RN E was interviewed on 4/22/10 at 11:15 a.m. She reviewed the electronic treatment record and confirmed she was the nurse who received the physician's order to change the potassium level of the dialysate and increase the treatment run time by 30 minutes. She stated "I told him (CHT I, the CHT for Patient 5 that day) the patient needed another 30 minutes." CHT I was not available for interview. RN E stated she thought the additional 30 minutes of run time was not added to the treatment time because Patient 5 started his treatment late and staff did not want to delay treatment for the next patient scheduled for that treatment station. Review of the schedule showed the next patient was not due until 3:15, one hour and 15 minutes after CHT I ended Patient 5's treatment. RN E agreed Patient 5's treatment should have been extended until 2:30 p.m.</p> <p>The medical director stated in interview on 4/22/10 at 1 p.m., "They should have notified the physician if they were not going to run the extra 30 minutes."</p>	V 503			

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V 504	<p>494.80(a)(2) PA-ASSESS B/P, FLUID MANAGEMENT NEEDS</p> <p>The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>Blood pressure, and fluid management needs.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 16558 Based on interview and record review, the facility failed to ensure that patient's comprehensive assessment included blood pressure parameters for the administration of Mannitol to be administered when the patient experienced a decrease in blood pressure for one (Patient 2) of 15 sampled patients. This failure placed patients at risk for delay in receiving the prescribed treatment in case they experienced low blood pressure, which could cause lack of tissue oxygenation to the main body organs and systems.</p> <p>Findings:</p> <p>Record review on 4/19/10 showed Patient 2 had a physician order, dated 1/26/10, for Mannitol 12.5 g (50 ml) to be given intravenously as needed for hypotension (low blood pressure). Patient 2's treatment was ordered for three hours and 45 minutes. Review of the "Hemodialysis Runsheets" showed that Patient 2 experienced low blood pressure during treatments and that the nursing staff did not implement the order for Mannitol in a consistent manner. For instance, on 3/10/09, Patient 2's blood pressure at 2:50 p.m., when treatment was started, was 156/79. By 5:20 p.m. the patient's blood pressure dropped to 97/56.</p>	V 504		6/3/10

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V 504	Continued From page 31 Patient 2 did not receive a dose of Mannitol. However, on 4/9/10, Patient 2's blood pressure was 127/74 at 2:43 p.m. when the treatment was initiated. At 5:13 p.m., the patient's blood pressure dropped to 90/47 and at 5:27 p.m., Patient 2 received a dose of Mannitol.	V 504		
V 541	494.90 POC-GOALS=COMMUNITY-BASED STANDARDS The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards. This STANDARD is not met as evidenced by: Surveyor: 22301 Based on observation, interview, and record review, the facility failed to develop a complete and accurate plan of care for one random patient (Patient 16). Failure to do so, prevented the IDT (interdisciplinary team) to implement interventions to address the specific needs of Patient 16.	V 541		5/27/10

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V 541	<p>Continued From page 32</p> <p>Findings:</p> <p>Patient 16's medical records were reviewed on 4/21/10 and showed Patient 16 was admitted to the facility on 6/2/04 with diagnosis that included diabetes, and end stage kidney disease. Patient 16's initial assessment included "slow to comprehend".</p> <p>Patient 16's comprehensive assessment dated 5/28/09 was reviewed. The nurse manager presented this surveyor with an incomplete and undated Plan of Care (POC) based from assessments dated 5/28/09.</p> <p>The latest POC that had no date and was not verified by anyone of the IDT was reviewed. It was not updated for most of the assessment criteria. The following criteria were not complete or accurate:</p> <ol style="list-style-type: none"> 1. Although the documentation indicated vascular access plan of care goal was met, it did not addressed Patient 16's current condition. When CHT G uncovered the patient's access, Patient 16's left arm and left hand were swollen. The access was located in Patient 16's upper left arm. CHT G said the hand and arm were swollen because of blockage in the access. CHT G said the MD and vascular access coordinator were aware. There was no provided documentation about care given or plan of care for the swollen arm. 2. Psychosocial needs. There was no social worker input noted for the 5/28/09 assessments. The social worker (MSW A) assigned to the patient was interviewed on 4/22/10 at 10 a.m. MSW A said the patient was assigned to her on 	V 541			

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V 541	Continued From page 33 10/09 after the prior social worker left on 8/09. MSW A said she was aware that Patient 16 was at one time living in a nursing home but was now back at home living with family members. MSW A also said that she was aware of the recent hospitalization of Patient 16 and that she needed to evaluate the patient's present living conditions. Patient 16's clinical record did not reflect his current living situation. At 10:40 am, of 4/22/10, the Nurse Manager confirmed that the latest POC was not accurate, completed or verified by anyone of the IDT. The Medical Director acknowledged on 4/22/10 that the facility was behind in updating the POC for some of the patients.	V 541			
V 589	494.100(c)(1)(i) H-MONITOR HOME ADAPT;HOME VISIT=POC Services include, but are not limited to, the following: (i) Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care. This STANDARD is not met as evidenced by: Surveyor: 22301 Based on interview and record review, the facility staff failed to provide home visits to 38 of 38 patients on home peritoneal dialysis, as evidence by a random review of Patient 15's record. Failure to monitor patients' home adaptation of their peritoneal dialysis regimens could result in increased complications.	V 589		6/3/10	

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V 589	<p>Continued From page 34</p> <p>Findings:</p> <p>1. During an interview on 4/19/10 at approximately 2 p.m., RN C stated that there were 38 peritoneal dialysis patients plus three patients who were still in training, who did the treatment in their own home. RN C further stated that she had been working at the facility since 1994 as a peritoneal dialysis nurse. When asked if the peritoneal dialysis nurses did home visits before initiation of the patient's home treatment and then periodically to monitor the patient's progress, RN C stated that the facility staff did not do home visits.</p> <p>During an interview on 4/21/10 at 12:15 p.m., the nephrologist overseeing the peritoneal dialysis patients, stated the hospital-based facility had contacted the County Public Health to send nurses to the facility to be trained to provide home visits, but because of "separation" between the County Public Health and the county hospital, the nurses did not come. The nephrologist added that the facility's peritoneal dialysis nurses would have to get transportation certificates before they could go on home visits. There was no time table for staff obtaining the transportation certificates.</p> <p>2. A review of the medical records for Patient 15 who finished training and started home treatment on 4/6/10, revealed that there was no home visit done by the facility staff.</p> <p>Surveyor: 21174</p> <p>3. During an interview on 4/19/10 at 3 p.m., RN C stated "We don't make home visits." She was asked how the facility determined a patient could</p>	V 589			

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V 589	Continued From page 35	V 589			
V 726	<p>safely perform peritoneal dialysis at home. She stated "Patients are screened for their ability to do PD (peritoneal dialysis) at home."</p> <p>494.170 MR-COMPLETE, ACCURATE, ACCESSIBLE</p> <p>The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 05189 Based on interview and record review, the facility failed to maintain complete and accurate records for two (Patients 7 and 11) of 15 sampled patients. Staff failed to document pertinent assessment and treatments given Patients 7 and 11 that would reflect the actual care they received during their treatments.</p> <p>Findings:</p> <p>1. The facility's policy, entitled "Saline Flush Heparin Free Dialysis" showed that its purpose was "to prevent extracorporeal circuit clotting in heparin free dialysis". (Heparin is a medication that prevents blood clotting.) The procedure included the following:</p> <p>"A. Initiate hemodialysis eliminating the heparinization process. B. Initiate flushes if the following: 1) Fibrin or clots in the dialyzer 2) Dark blood in the header. 3) Increasing venous pressure 4) History of</p>	V 726		5/5/10	

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V 726	<p>Continued From page 36</p> <p>dialyzer clotting problems</p> <p>C. If flushes needed, flush with 100 ml NS (normal saline)15 minutes into the treatment and every 30 minutes thereafter..."</p> <p>D. Document reason for flush, document each flush. e.g., appearance of dialyzer. If flush is not needed, document why not.</p> <p>E. Check with the physician regarding continuation of heparin free treatment."</p> <p>Record review on 4/20/10 and 4/21/10 showed that Patient 11 was admitted to the facility on 1/5/10 with diagnoses that included Type II Diabetes and End Stage Renal Disease. The admission order record sheet, dated 1/4/10, showed a "Right forearm A/V fistula" access placement, and "Heparin free/No heparin administration" order.</p> <p>On 2/23/10, the treatment record showed staff started Patient 11's treatment at 10:05 am. At 11:11 am, staff documented that 100 ml of normal saline was administered "to flush dialyzer". There was no documentation of any additional 30 minute flushes (if needed) or the reason for the initial flush. e.g. the appearance of the dialyzer indicating the presence of fibrin, clots, or dark blood in the dialyzer header.</p> <p>On 3/2/10, the treatment record showed staff started Patient 11's treatment at 10:05 am. The record further showed an increase in the venous pressure readings during the treatment. i.e., At 10:36 a.m. =130 (mm Hg) At 11:06 a.m. =140 At 11:25 a.m. =150 At 11:36 a.m. =180 At 12:06 p.m. =220 At 12:35 p.m. the record showed the following</p>	V 726		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 052305	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 04/22/2010
NAME OF PROVIDER OR SUPPLIER SANTA CLARA VALLEY MEDICAL CENTER - ESRD			STREET ADDRESS, CITY, STATE, ZIP CODE 2220 MOORPARK AVENUE SAN JOSE, CA 95128		
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V 726	<p>Continued From page 37</p> <p>documentation, "Venous Chamber Clot; blood returned, resumed Tx (treatment) with new system." There was no documented assessment of the increasing venous pressure readings for potential clotting conditions. There was indication that the flushes were initiated (or why they were not needed). There was no documentation as to time interval between returning the blood, preparing a new setup, and resuming treatment. The record showed only continued routine thirty-minute monitoring checks with the start time at 10:05 a.m. and the scheduled ending time at 1:41 (the approximate 3.5 hours as prescribed). This practice made it difficult to determine if the patient received the actual 3.5 hour completed treatment time since the disruption time frame was not documented during treatment.</p> <p>On 3/12/10, the record showed that Patient 11 had facial edema (swelling) prior to the start of treatment at 3:09p.m. The record further showed an increase in the venous pressure readings during the treatment, as follows: At 3:39 p.m. =190 (mm Hg) At 4:10 p.m. =220 At 5:09 p.m. =270 At 5:39 p.m. =440</p> <p>At 5:43 p.m., the record showed the following: "Clotted Dialyzer. Re-set up machine. tx (treatment) resumed, using 1 cath for arteril [arterial] and 1 arm access for venous [needle] due to high venous pressure." There was no documented assessment of the post treatment facial edema. There was no documentation of the increasing venous pressure readings for potential clotting conditions. There was no indication that the flushes were initiated (or why they were not needed). There was no</p>	V 726			

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V 726	<p>Continued From page 38</p> <p>documentation of the time needed to prepare a new set up prior to resuming treatment. (The record showed that the treatment was started at 3:09 p.m. and ended at 6:45 p.m.; three hours 36 minutes. This practice made it difficult to determine if the patient received the actual 3.5 hour completed treatment after the disruption in treatment.</p> <p>On 3/19/10, the record showed that staff started the patient's treatment at 2:59 p.m. and ended at 6:29 p.m. The record further showed an increase in the venous pressure readings during the treatment. i.e., At 3 p.m. = 120 (mm Hg) At 3:30 p.m. = 250 At 4 p.m. = 280 At 4:30 p.m. = 310</p> <p>The record also showed showed the following information: At 3:46 p.m., "100 cc NS Flush. both chambers clear post flush." At 4:02 p.m., "100 cc NS Flush. both chambers clear post flush." At 4:31 p.m., "200 cc NS Flush. slight clotting at both headers post flush."</p> <p>There was no documentation that showed why a 200 cc normal saline flush was administered (instead of 100 cc), nor any 30 minute additional flushes(or why they were not needed) thereafter, especially with a clotted dialyzer history.</p> <p>On 4/7/10, the record showed that staff started the patient's treatment at 2:46 p.m. and ended at 6:07 p.m.; 3.5 hours. According to physician orders, the treatment time had been extended to four hours. At 2:44 p.m., the record showed the</p>	V 726			

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V 726	<p>Continued From page 39</p> <p>following documentation, "flush dialyzer 100 cc ns [normal saline] doe [due] to no hep[heparin]." There was no explanation as to why the treatment was shortened or why flushes were administered.</p> <p>On 4/9/10, the record showed that staff started the patient's treatment at 2:36 p.m. and ended at 6:07 p.m.; 3.5 hours. There was no documentation explaining the shortened treatment, or that flushes were initiated and administered every 30 minutes. Further review of the record showed , "Post dialyzer Rating: Clotted".</p> <p>On 4/12/10, the record showed that staff started the treatment at 2:45 p.m. and ended the treatment at 6:46 p.m. There was no documentation that showed that flushes were initiated and administered every 30 minutes. Further review of the record showed , "Post dialyzer Rating: Clotted".</p> <p>Additionally, there was no documentation in any of the treatment records that indicated staff notified the physician of the frequent clotted dialyzers or whether the heparin free treatment order should be continued.</p> <p>RN A acknowledged the deficient practice and stated that she did not know why staff did not include the documentation in accordance with the facility's policy and procedure.</p> <p>2. On 4/21/10, the Nurse Manager stated that the facility's practice was to complete a PSN (Patient Safety Net computerized system) occurrence/event report for "clotted dialyzer" incidents in regards to the clotted incident for Patient 11. However, after intensive research by</p>	V 726			

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V 726	Continued From page 40 the Nurse Manager there were none found and available for review. 3. On 4/20/10, the record review showed that Patient 7 was admitted to the facility on 8/16/07. According to the treatment record dated 4/17/10, Tylenol (pain medication) was given at 10:43 a.m. during treatment for "Chronic right shoulder" pain. There was no follow-up assessment documented whether Patient 7 achieved pain relief.	V 726		