

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

PRINTED: 05/31/2011  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>552618</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>01/07/2011</b>
NAME OF PROVIDER OR SUPPLIER  <b>SAN MARCOS DIALYSIS CENTER</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2135 MONTIEL ROAD BLDG B SAN MARCOS, CA 92069</b>		
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V 000	INITIAL COMMENTS  The following represents the findings of the Department of Public Health during a recertification survey conducted January 4th 2011 to January 7th 2011. The facility census at the time of the survey was 60 hemodialysis patients and 72 peritoneal dialysis patients. The sample size was 13 patients.  Representing the Department were, HFEN 22383 and HFEN 17130.  Glossary of Abbreviations: °C degree Celsius °F degree Fahrenheit CCHT Certified Clinical Hemodialysis Technician CN Charge Nurse PD peritoneal dialysis PPE Personal Protective Equipment P&P Policy and Procedure RN Registered Nurse	V 000			
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: 2. During observations on 1/5/11 at 3:15 P.M., one non-sterile glove was noted on the top of the dialysis machines in stations 8, 9, and 11. At 3:17 P.M., RN 1 typed on the computer keyboard in	V 113		2/18/11	

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 113	<p>Continued From page 1</p> <p>station 9 with clean, bare hands. RN 1 then picked up the glove on top of the machine in station 9 and used the tip of the glove as a barrier while making changes on the dialysis machine (the machine was considered a dirty area and when touched by the glove rendered the glove dirty). RN 1 did not don the glove. After using the glove as a barrier, RN 1 placed the soiled glove back on top of the machine in station 9.</p> <p>During an interview on 1/5/11 at 3:25 P.M., the CN stated that gloves should not be placed on top of the machine. She stated that re-use of the gloves and using the tip, as a barrier was not appropriate infection control procedure.</p> <p>On 1/6/11, the facility provided the P&amp;P titled, "Infection Control for Dialysis Facilities," which was approved by the governing body on 10/27/10. The policy specified that, "Appropriate PPE will be worn whenever there is the potential for contact with body fluids, hazardous chemicals, contaminated equipment and environmental surfaces, for example, reuse room, patient care areas."</p> <p>Based on observation and interview, the facility failed to ensure that 2 staff members (CCHT 3, RN 1) appropriately used clean, nonsterile gloves while providing care to patients and when moving between clean tasks and contaminated areas.</p> <p>Findings:</p> <p>1. On 1/5/11 at 11:41 A.M., CCHT 3 picked up 1 of 2 gloves from a patient's chairside table at station 7. CCHT 3 used the glove as a barrier to reset the machine (the machine was considered a dirty area and when touched by the glove</p>	V 113			

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V 113	Continued From page 2 rendered the glove dirty), than replaced it onto the chairside table. CCHT 3 then moved to the chairside charting keyboard to enter patient information. After typing with bare hands, CCHT 3 picked up the same gloves put them on and started to provide patient care.	V 113			
V 122	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL  [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.  This STANDARD is not met as evidenced by: Based on observations, interview, and record review, the facility failed to adequately disinfect the point of care glucometer (a device to measure blood sugars) used on multiple patients against blood borne pathogens, according to accepted standards of practice and manufacturer's guidelines. In addition, the facility failed to ensure that 2 staff members (CCHT 2, CCHT 3) wiped down the prime buckets between patient treatments, according to facility P&P.  Findings:  1. During an interview on 1/05/11 at 9:14 A.M., the Charge Nurse (CN) stated that the facility used 1 glucometer to check blood sugar levels on multiple patients. According to the Charge Nurse, staff took the glucometer to the chairside to	V 122		2/18/11	

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V 122	<p>Continued From page 3</p> <p>perform the test. The Charge Nurse stated that staff members "clean the device with alcohol between patients because that is all that can be used on the meter." She stated that the facility would prefer to use bleach.</p> <p>During an interview on 1/05/11, LVN 1 stated that she took the glucometer to the chairside and cleaned it with alcohol after use.</p> <p>In 2009, APIC (Association for Professionals in Infection Control and Epidemiology) published the "APIC Position Paper: Safe Injection, Infusion and Medication Vial Practices in Healthcare." The paper specified that the exterior surfaces of a glucometer should be disinfected after each use with an Environmental Protection Agency (EPA) -registered disinfectant effective against HBV, HCV, and HIV, or a 1:10 bleach solution (one part bleach to 9 parts water).</p> <p>On 1/05/11 at 2:26 P.M., the glucometer manufacturer's website specified guidelines for cleaning the facility's glucometer. According to the manufacturer's guidelines, the glucometer could be disinfected with a 10% bleach solution, contrary to staff interview.</p> <p>On 1/06/11, the facility provided the P&amp;P titled, "Infection Control for Dialysis Facilities," which was approved by the governing body on 10/27/10. The purpose of the policy was "to prevent the spread of infections or bloodborne pathogens in the dialysis facility environment." The policy specified that, if blood glucose meters are used, measures will be taken to prevent cross contamination between patients, and "If the potential for contamination exists, the device</p>	V 122			

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V 122	<p>Continued From page 4</p> <p>outercasing is wiped with an appropriate disinfectant before being returned to clean area or using on another patient."</p> <p>2. During observations on 1/05/11 at 2:43 P.M, CCHT 2 disinfected the dialysis machine in Station 11 with a cloth soaked in 1:100 bleach solution in preparation for a patient treatment. CCHT 2 removed previously used tubing from machine and discarded it. At 2:52 P.M., CCHT 2 removed the prime bucket from the side of the dialysis machine. The prime bucket is a plastic container that holds discarded fluid used to "prime" the dialysis machine at the beginning of a treatment. CCHT 2 carried the prime bucket to the soiled sink, emptied the prime fluid, and rinsed out the bucket with tap water. CCHT 2 did not wipe the inside or the outside of the soiled prime bucket with disinfectant. Then, CCHT 2 carried the prime bucket back to Station 11 and re-attached the soiled bucket to the clean, disinfected dialysis machine.</p> <p>During an interview on 1/06/11 at 10:15A.M., the Administrator stated that she expected staff to empty prime bucket into the dirty sink, rinse with water, and then wipe out (disinfect) with the a wipe soaked in 1:100 bleach solution. She expected that staff wipe out the prime bucket with the same concentration of bleach solution used to wipe down the dialysis machines (1:100 bleach solution).</p> <p>On 1/07/11, the facility provided the P&amp;P titled, "Infection Control for Dialysis Facilities" which was approved by the governing body on 10/27/10. The policy specified, "Teammates will thoroughly wipe down all non-disposable items and</p>	V 122			

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V 122	<p>Continued From page 5</p> <p>equipment such as the blood pressure cuff, the inside and outside of the prime container,...with an appropriate disinfectant after every treatment."</p> <p>3. On 1/5/11 at 11:49 A.M., CCHT 2 cleaned the machine at station 9 between patients. CCHT 2 did not empty or wipe the prime bucket or wipe the patient's TV. CCHT 2 placed new lines on the machine. She connected bloodlines to the prime bucket to flush the lines. The prime bucket still had fluid in it from the previous patient.</p> <p>On 1/5/11 at 11:55 A.M., CCHT 2 stated the policy for cleaning the prime bucket was that staff were to dump the contents of the prime bucket in the sink and then rinse the prime bucket with water.</p> <p>4. On 1/5/11 at 11:51 A.M., CCHT 3 cleaned the machine at station 7 between patients. CCHT 3 did not empty or wipe the prime bucket or wipe the patient's TV.</p> <p>On 1/5/11 at 12:23 P.M., the administrator stated the staff were to empty the prime bucket and wipe it out with a bleach solution. Staff were also to wipe the patients' TV between patients with the same bleach solution.</p> <p>The facility's P&amp;P Infection Control for Dialysis Facilities revised on 9/10, read in part "...44. ...Use an appropriate disinfectant such as 1:100 bleach solution for environmental surfaces...45. Equipment including the dialysis delivery system the interior and exterior pf the prime container, the dialysis chair and side tables ...television</p>	V 122			

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V 122	Continued From page 6 arms and control knobs or remote control devices if accessible to patients and teammates ..."	V 122			
V 142	494.30(b)(1) IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P  The facility must- (1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit;  This STANDARD is not met as evidenced by: Based on observations, staff interview and P&P review, the facility failed to maintain the required temperature range for the storage of medications in the peritoneal dialysis medication refrigerator.  Findings:  On 1/4/11 at 12:03 P.M., the PD medication refrigerator contained vials of Epogen®. The documented temperature for that morning was 32.7° F. During the period of October 1, 2010, through January 4, 2011, staff documented on the "Medication Refrigerator Temperature log" that the refrigerator temperatures were out of range 42 times. The log indicated that the temperature range was to be (36°- 46°). The log had a column to indicate the, "Action taken if out of range." There was no documented action for any of the dates the temperature was out of range.  On 1/4/11 at 12:03 P.M., the PD Manager stated that the PD tech was responsible for documenting the temperatures.  The facility's P&P, "Medications Requiring	V 142		2/18/11	

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V 142	Continued From page 7 Refrigeration", revised 10/09, read in part ..."2. The refrigerator is checked twice daily, during facility normal operating hours, to ensure that the temperature remains between 36°F and 46°F. The refrigerator temperature is to be checked by a licensed nurse teammate at the beginning and end of the day. "	V 142			
V 196	The facility's P&P, "Administration of Intravenous Epogen", dated 9/07, read in part ..."4. Epogen® is refrigerated at 2°C to 8°C (36°F to 46°F)." 494.40(a) CARBON ADSORP-MONITOR, TEST FREQUENCY  6.2.5 Carbon adsorption: monitoring, testing freq Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours.  Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet.  Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N.N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L]. Samples should be drawn when the system has	V 196		2/18/11	

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V 196	Continued From page 8 been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly.  This STANDARD is not met as evidenced by: Based on observations and staff interview the facility failed to ensure staff ran the water system the required 15 minutes prior to testing for chlorine.  Findings:  On 1/5/11 9:57 A.M., CCHT 1 was assigned to do the chlorine testing. He stated the water needed to run 5 min prior to testing for chlorine. The CCHT did the testing after the water system had been on approximately 5 minutes.	V 196			
V 300	494.50 CFC-REUSE OF HEMODIALYZERS & BLOODLINES  This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure that staff members documented the absence of germicide in a reuse dialyzer prior to starting a treatment (refer 352). The facility failed to ensure that staff members documented the presence of germicide in a reuse dialyzer prior to rinsing and priming (refer 350). The facility failed to ensure that staff verified and accurately documented the correct dialyzer in use (refer 348). The facility failed to ensure that the dialyzers for patients with the same last name were labeled to indicate there were dialyzers with similar names (refer 330). The facility failed to	V 300		2/18/11	

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V 300	Continued From page 9 label the germicide used to disinfect dialyzer blood port caps (refer 339). The facility failed to ensure that a Reuse Technician wore adequate PPE while pre-processing a dialyzer (refer 320).	V 300			
V 320	<p>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.</p> <p>494.50(b)(1) PERSONNEL PROTECTIVE GEAR</p> <p>8.4 Personnel protection: gear Personnel shall wear durable gloves and protective clothing when handling the dialyzer during initiation and termination of dialysis and during the reprocessing procedure. Standard Precautions shall be observed. Personnel shall wear eye protection when performing steps that may result in spills or splashes of substances of known or suspected toxicity. These agents shall be handled only in areas with adequate ventilation, washing facilities, eyewash stations, appropriate respirators, and spill control materials. When personnel are handling concentrated toxic substances, they shall wear aprons impervious to these substances.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure that 1 of 2 Reuse Technicians (1) wore full face protection while pre-processing a dialyzer, according to regulatory requirement and facility P&amp;P. This failure had the potential to expose Reuse Technician 1 to toxic substances.</p> <p>Findings:</p>	V 320	2/18/11		

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V 320	Continued From page 10 During observations of the reuse procedure on 1/5/11 at 12:05 P.M., Reuse Technician 1 wore a long sleeve gown, gloves, and personal eye glasses while pre-processing a dialyzer.  Technician 1 removed the dialyzer from Renatron 1 (a machine used to clean and disinfect dialyzers), rotated the dialyzer 180 degrees, and placed caps on the dialyzer ports. Technician 1 did not have a full face shield on. Technician 1's face and eyes were not protected against potential spills or splashes.  During an interview on 1/5/11 at 12:06 P.M., Reuse Technician 1 stated that he should be wearing a face shield when in that area of the room. He stated, "That is something I need to work on."	V 320			
V 330	494.50(b)(1) INFORMATION REC ON LABEL/SIMILAR NAME WARN  10.3 Information recorded on label/similar name warning The dialyzer shall be labeled with the patient's name, the number of previous uses, and the date of the last reprocessing. Dialyzers of patients with	V 330		2/18/11	

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V 330	<p>Continued From page 11</p> <p>similar last names should have a warning to the user to take extra care in ensuring that the name or other identifying information on the label corresponds to that of the patient. If there is sufficient room, the dialyzer may also be labeled with the results of tests, the signature or other unique means of identifying the person performing the various steps in the reprocessing procedure, and the reference values for performance parameters. If this information appears on the label, a permanent record should also be kept (see [AAMI] 4.2) Electronic records are acceptable. If records are electronic, the test results should be available to the user.</p> <p>Home dialysis patients are exempted from the recommendation that the patient's name appear on the label, unless the dialyzers are taken to a dialysis facility for reprocessing.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure appropriate labeling on a reprocessed dialyzer for 1 of 2 non-sampled patients (15) with the same last name, according to regulatory requirement and facility P&amp;P.</p> <p>Findings:</p> <p>On 1/4/11, the facility provided a census of all patients who received in-center hemodialysis. The census showed that Patients 15 and 16 had the same last name.</p> <p>During the initial tour of the reuse room on 1/5/11 at 10:09 A.M., the reuse refrigerator contained</p>	V 330			

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NAME OF PROVIDER OR SUPPLIER  <b>SAN MARCOS DIALYSIS CENTER</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2135 MONTIEL ROAD BLDG B SAN MARCOS, CA 92069</b>		
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V 330	<p>Continued From page 12</p> <p>Patient 15's used dialyzer which was stored for reprocessing later that morning. Patient 15's dialyzer lacked an orange, "name alert" tag and an orange, "similar name" label.</p> <p>On 1/5/11 at 10:20 A.M., the storage area for clean reprocessed dialyzers (dialyzers that were used, cleaned and reused by the same patient for multiple treatments) was inspected. Multiple, small, individual cubby holes contained each patient's clean, reprocessed dialyzer. Patient 16's dialyzer was labeled and stored in one of these cubby holes. Patient 16's dialyzer had both an orange, "name alert" tag and an orange "similar name" label.</p> <p>During an interview on 1/5/11 at 10:34 A.M., the Reuse Technician stated that the reason Patient 15's dialyzer was not labeled with the orange, "name alert" tag and an orange "similar name" label was because Patient 16 was, "New to reuse." The Technician stated that he had, "Not touched" Patient 15's dialyzer since Patient 16 had started reuse. He did not have a chance to place similar name alert tags on Patient 15's dialyzer.</p> <p>During an interview on 1/5/11 at 11:15 A.M., the Administrator stated that any hemodialysis patient in the facility with similar or the same last names should have the name alert tag and similar name tag on their dialyzer, whether or not the patient was, "New" to reuse. The Administrator stated that Patient 16 was admitted to the facility on 12/15/10, approximately 2 1/2 weeks prior. She agreed that the potential existed for staff to mix up the dialyzers and give either Patient 15 or 16 the incorrect dialyzer.</p>	V 330			

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V 330	Continued From page 13	V 330			
V 339	<p>On 1/6/11, the facility provided the P&amp;P titled, "Reuse Hemodialyzer Labeling". The policy provided guidelines for the labeling of reuse hemodialyzers. The policy specified, "An additional distinctive warning label is placed on the dialyzer jacket of patients with the same or similar last names."</p> <p>494.50(b)(1) GERM PROCESS=HIGH-LEVEL DISINFECT</p> <p>11.4.1 Interior (blood/dialysate compartment) 11.4.1.1 Germicidal process: high-level disinfection achieved Chemical germicides or other procedures used for disinfecting of hemodialyzers shall have been shown to accomplish at least high-level disinfection when tested in dialyzers artificially contaminated with appropriate microorganisms.</p> <p>If the germicide has an expiration date from the manufacturer, staff members should be sure that the chemical is not outdated. Some germicides have recommendations for maximum storage time after dilution or activation and before usage. If this is the case, the expiration date of the prepared germicide solution should be marked on the outside of the germicide solution container, and that date should be checked at the beginning of each day, before reprocessing begins.</p> <p>The disinfection process shall not adversely affect the integrity of the dialyzer. Germicides shall be rinsed from the dialyzer to below known toxic levels within a rinse-out period established for the particular germicide (see AAMI 12.4). To prevent injury, staff members shall take care not to mix reactive materials such as sodium hypochlorite</p>	V 339		2/18/11	

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V 339	<p>Continued From page 14 and formaldehyde.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure that 1 of 2 Reuse Technicians (1) labeled the solution used to disinfect dialyzer blood port caps, according to facility P&amp;P.</p> <p>Findings:</p> <p>During the initial tour of the reuse room on 1/5/11 at 11:10 A.M., a covered plastic bin located on top of the Renatron machine 2 contained red blood port caps. The removable caps sealed off the blood ports of a dialyzer during storage and transportation. The blood port caps were submerged in a clear liquid. The container did not have an expiration date, expiration time, or staff initials.</p> <p>During an interview on 1/5/11 at 10:41 A.M., Reuse Technician 1 stated that the container held 1% peracetic acid, the solution used to disinfect the ports. He stated that the blood ports could be soaked for 24 hours in the solution. He acknowledged that the container should have been labeled with expiration dates and times.</p> <p>On 1/6/11, the facility provided the P&amp;P titled, "Reuse Hemodialyzer Labeling," which was approved by the governing body on 10/27/10. The policy specified that the disinfectant solution containers should have been labeled with the chemical name, expiration date, time of preparation, and identity of the teammate preparing the solution.</p>	V 339			

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V 348	<p>494.50(b)(1) VERIFY PT ID-2 PEOPLE</p> <p>12.2 Verification of patient identification: 2 people Except in the case of home dialysis, two persons should check that the first and last names on the dialyzer and any other appropriate identifying information correspond to the identifying information on the patient's permanent record. If possible, one of the persons checking identification should be the patient. Completion of this step shall be recorded, along with the signature or other unique means of identifying the person verifying patient identification.</p> <p>NOTE-This step may be done later in the procedure but shall precede initiation of dialysis.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review the facility failed to ensure that 2 staff members documented accurate treatment information when they documented verification of the wrong dialyzer and documented the presence and absence of sterilant when using a single use dialyzer for 1 of 13 sampled patients (9).</p> <p>Findings:</p> <p>On 1/6/11, Patient 9's clinical records were reviewed. On 12/22/10, staff documented on the treatment sheet that the dialyzer was on it's third reuse. The next treatment on 12/24/10, staff documented the dialyzer as at reuse zero and on 12/27/10, the dialyzer was again documented as the third reuse.</p> <p>The treatment, completed on 12/24/10, documented the patient using a reuse dialyzer at</p>	V 348		2/18/11	

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V 348	<p>Continued From page 16</p> <p>zero reuses, the staff documented there was positive sterilant in the dialyzer prior to priming, and that there was a negative residual (the dialyzer had been completely flushed of sterilant) and that the dialyzer documented as used for this treatment was correct.</p> <p>On 1/6/11 at 11:33 A.M., the Administrator stated she did not understand why the reuse number was zero on 12/24.</p> <p>On 1/6/11 at 1:23 P.M., the Administrator stated the patient missed the treatment on 12/22/10 so the dialyzer was not used. On 12/24/10, Patient 9 came in early for dialysis. The RN obtained a physician's order for a single use dialyzer for that treatment, but forgot to enter it into the chairside computer for that treatment.</p> <p>Patient 9 received a treatment on 12/24/10 using a single use dialyzer. The documentation on the treatment sheet was not correct. The Administrator stated that the CCHT assigned to Patient 9 was not aware of how to change the dialyzer used in the computer generated treatment sheet from a reuse dialyzer to a single use dialyzer. The software would not allow the treatment to continue without entering the safety data required for the usual reuse dialyzer. To continue the treatment the computer required the CCHT's to complete the reuse fields for verification and sterilant, even though the information documented was incorrect.</p> <p>On 1/7/11 at 2:55 P.M., the Administrator and the CN both stated that the staff were to tell the nurse if the computer generated treatment sheet was not correct, or if it would not let them input the</p>	V 348			

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V 348	Continued From page 17 correct data. The nurse was able to change the order in the computer at any time during the treatment.	V 348			
V 350	494.50(b)(1) GERMICIDE PRESENCE TEST OF EACH DIALYZER  12.3.1 Presence test of each hemodialyzer Certain germicide manufacturers require testing for the presence of germicide in each hemodialyzer before the rinsing step. These instructions should be followed.  This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure that 3 staff members (CCHT 3, CCHT 4, RN 1) documented the presence of peracetic acid (a germicide used for reuse to ensure disinfection) prior to priming the reuse dialyzer for 1 of 13 sampled hemodialysis patients (4). The failure to check and document the presence of germicide could potentially expose Patient 4 to a dialyzer contaminated with bacteria and/or endotoxins.  Findings:  On 1/7/2011, Patient 4's clinical record was reviewed. The treatment sheets showed that Patient 4 received dialysis on 12/17/10, 12/27/10, 12/29/10, and 12/31/10 using a reuse Polyflux 21R dialyzer.  On 12/17/10, CCHT 3 documented the pre dialysis information for Patient 4. The documentation included checking for the presence of germicide in the reuse dialyzer, prior to priming the dialyzer. The germicide checks were to be done by 2 staff members. There was	V 350		2/18/11	

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V 350	<p>Continued From page 18</p> <p>no documented evidence that CCHT 3 or a second staff member checked the reuse dialyzer for the presence of germicide.</p> <p>During an interview on 1/7/11 at 2:32 P.M., CCHT 3 stated that she did not recall caring for Patient 4 on 12/17/10. CCHT 3 stated that she, "Always checks" for the presence and absence of germicide. She could not explain why she did not document the presence of germicide in the reuse dialyzer for the treatment on 12/17/10.</p> <p>The treatment sheet showed that on 12/27/10 and again on 12/29/10, CCHT 4 documented the pre dialysis information for Patient 4. There was no documented evidence that CCHT 4 or another staff member checked the reuse dialyzer for the presence of germicide.</p> <p>The treatment sheet showed that on 12/31/10, RN 1 documented the pre dialysis information for Patient 4. There was no documented evidence that RN 1 or another staff member checked the reuse dialyzer for the presence of germicide.</p> <p>During an interview on 1/7/11 at 2 P.M., the Administrator stated that the staff members failed to tell the nurse that the germicide checks could not be documented in the chairside computer system. The Administrator stated she expected the staff to notify the nurse.</p> <p>On 1/7/11, the facility provided the P&amp;P titled, "Peracetic acid Concentration Testing Using Perassay 500 Test Strips", which was approved by the governing body on 10/27/10. The policy specified that staff were to check for adequate peracetic acid in the dialyzer prior to priming. The</p>	V 350			

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V 350	Continued From page 19 policy specified, "All dialyzer peracetic acid concentration test results must be signed and documented."	V 350			
V 352	494.50(b)(1) DIALYZER PRIMING/RINSING THE GERMICIDE  12.4 Priming the dialyzer and rinsing the germicide If the manufacturer's instructions so require, a germicide presence test shall be performed before the germicide is rinsed from the dialyzer.  The dialyzer shall be rinsed and primed according to a written procedure that has been documented to produce a reduction in the concentration of germicide to an acceptable level and result in a physiological solution in the blood and dialysate compartments. The dialyzer manufacturer ' s instructions should be considered in developing these procedures.  This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure that 3 staff members ( CCHT 3, CCHT 4, RN 1) documented the absence of peracetic acid (a germicide used for reuse to ensure disinfection) prior to beginning treatment for 1 of 13 sampled hemodialysis patients (4). The failure to check and document the absence of germicide could potentially expose Patient 4 to an unacceptable level of germicide which can cause oxidation and red cell hemolysis (Both cause the destruction of blood cells).  Findings:	V 352		2/18/11	

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V 352	<p>Continued From page 20</p> <p>1. On 1/7/11, Patient 4's clinical record was reviewed. The treatment sheet showed that Patient 4 received dialysis on 12/17/10, 12/27/10, 12/29/10, and 12/31/10 using a reuse Polyflux 21 R dialyzer. On all 4 treatment sheets in the machine setup area staff incorrectly documented "non re-use" where they should have documented the verification for the presence and absence of the germicide. Staff also documented "non-reuse" in the areas for the correct dialyzer verification and the reuse number.</p> <p>The treatment sheet for 12/17/10, showed that CCHT 3 documented the pre dialysis information for Patient 4. The documentation should have included verification of the staff checking for the absence of germicide prior to beginning Patient 4's treatment. The germicide checks were to be done by 2 staff members. There was no documented evidence CCHT 3 or another staff member checked the reuse dialyzer for the absence of germicide prior to the treatment starting.</p> <p>During an interview on 1/7/11 at 2:32 P.M., CCHT 3 stated that she did not recall caring for Patient 4 on 12/17/10. CCHT stated that she, "Always checks" for the presence and absence of germicide. She could not explain why she did not document the absence of germicide in the reuse dialyzer for Patient 4's treatment on 12/17/10.</p> <p>The treatment sheet showed that on 12/27/10 and again on 12/29/10, CCHT 4 documented the pre dialysis information for Patient 4. There was no documented evidence that CCHT 4 or another staff member checked the reuse dialyzer for the absence of germicide prior to the treatment</p>	V 352			

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V 352	Continued From page 21 starting.  The treatment sheet showed that on 12/31/10, RN 1 documented the pre dialysis information for Patient 4. There was no documented evidence that RN 1 or another staff member checked the reuse dialyzer for the absence of germicide prior to the treatment starting.  During an interview on 1/7/11 at 2 P.M., the Administrator stated that the staff members failed to tell the nurse that the germicide checks could not be documented in the chairside computer system and consequently entered inaccurate information into the patient's record. The Administrator stated she expected the staff to notify the nurse.  On 1/7/11, the facility provided the P&P titled, Residual Peracetic Acid Strip Testing of Dialyzer Prior to Patient Use," which was approved by the governing body on 10/27/10. The policy specified that the results of the absence of peracetic acid (germicide) "must be verified and signed off by two teammates" and "Record the results on the patient flowsheet or electronic treatment record."	V 352			
V 413	494.60(d)(3) PE-ER EQUIP ON PREMISES-02, AED, SUCTION  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.  This STANDARD is not met as evidenced by: Based on observation, interview and record	V 413		2/18/11	

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V 413	Continued From page 22 review, the facility failed to ensure the suction machine for use during an emergency was functional.  Findings:  During observation on 1/4/11 at 10:48 A.M., the suction machine located on the emergency crash cart turned on but did not provide suction when plugged into the electrical outlet.  At 11:05 A.M., several staff members determined that the suction tubing from the machine was attached incorrectly. In addition, a staff member determined that a cap was on the end of a portion of the suction tubing. The cap prevented the machine from providing suction.  During an interview on 1/4/11 at 11:07 A.M., staff agreed that valuable time was taken up getting the suction to work when it needed to be operable in an emergency.  On 1/6/11, the facility provided the P&P titled "Emergency Equipment Checks." The policy specified, "To ensure the designated equipment is available and functional, the following equipment checks will be performed by a licensed nurse teammate: Weekly-Suction is operational."	V 413			
V 543	494.90(a)(1) POC-MANAGE VOLUME STATUS  The plan of care must address, but not be limited	V 543		2/18/11	

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V 543	<p>Continued From page 23 to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status;</p> <p>This STANDARD is not met as evidenced by: Based on interview, record review, and P&amp;P review, the facility failed to ensure the staff monitored 8 of 13 sampled patients (4, 6, 7, 8, 9, 10, 12, 13) treatment checks (vital signs and machine parameters) every 30 min for daytime patients and every hour for the nocturnal dialysis patients.</p> <p>Findings:</p> <p>The facility's P&amp;P, "Intradialytic Treatment Monitoring" revised 9/08, read in part "1. Treatment checks should be completed at least every thirty (30) minutes. 2. At a minimum, obtain and document the following: blood pressure Heart rate Blood and dialysate flows, arterial and venous pressures Fluid removal and/or replacement Vascular access status and line connections Patient status and subjective well being."</p> <p>The facility's P&amp;P, "Nocturnal Intradialytic Treatment Monitoring", revised 9/09 read in part ..."3. After the established "lights out" time, treatment checks will remain every 30 minutes with the exception of blood pressure and heart rate.</p> <p>1. On 12/17/10, Patient 4 had no documentation of treatment checks from 8 A.M., to 9:17 A.M.</p> <p>2. On 12/15/10, Patient 6 had no documentation</p>	V 543			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>552618</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>01/07/2011</b>
NAME OF PROVIDER OR SUPPLIER  <b>SAN MARCOS DIALYSIS CENTER</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2135 MONTIEL ROAD BLDG B SAN MARCOS, CA 92069</b>		
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V 543	<p>Continued From page 24</p> <p>of treatment checks from 6 P.M., to 7 P.M. On 12/22/10, Patient 6 had no documentation of treatment checks from 5:49 P.M., to 7:06 P.M. On 12/24/10, there was no documentation of treatment checks from 6:32 A.M., to 7:45 A.M. and again on 1/3/11, there was no documentation of treatment checks from 3:01 P.M., to 4:56 P.M.</p> <p>3. Patient 7's treatment sheets were reviewed. For 12/17/10, Staff documented on hte treatmetn sheet that the patient completed the treatment at 9:39 A.M., yet the the last treatment checks were at 8:30 A.M.</p> <p>4. Patient 8's treatment sheets were reviewed. The treatment sheet for 12/31/10, staff documented treatment checks at 12:03 P.M., and not again until 1:03 P.M.</p> <p>5. Patient 9 had no documentation of treatment checks on 12/27/10, from 5:59 P.M., to 7:03 P.M. On 12/29/10, there was no documentation of treatment checks from 5:38 P.M., to 7:14 P.M., and again on 1/3/11, there were no treatment checks documented from 5:55 P.M., to 6:55 P.M.</p> <p>6. Patient 10 was a nocturnal dialysis (has dialysis overnight) patient. The treatment record for 12/21/10 documented treatment checks at 10:45 P.M., 11:45 P.M., and at 12:45 A.M. On 12/19/11, the treatment checks were done at 11:31 P.M., and at 1:20 A.M. On 12/16/10, treatment checks were documented at 10:44 P.M., 11:45 P.M., and not again until 1:13 A.M.</p> <p>7. Patient 12's treatment sheets were reviewed. The treatment record for 12/15/10, documented the treatment checks were done at 8:27 A.M.,</p>	V 543			

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

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V 543	<p>Continued From page 25</p> <p>and at 9:27 A.M. On 12/17/10, the treatment record indicated Patient 12's treatment was 4 hours and 3 minutes the initial assessment was at 6:04 A.M., and the post assessment was at 10:06 A.M., although the last recorded treatment checks were documented at 8:06 A.M. On 12/31/10, the treatment checks were documented at 5:30 A.M., and not again until 7:10 A.M.</p> <p>8. Patient 13's treatment sheets were reviewed. The treatment record for 12/27/10, did not have documentation to show that the treatment checks were monitored from 11:23 A.M., to 12:25 P.M.</p> <p>On 1/5/11 at 3:12 P.M., the Administrator stated that the patients vital signs were to be monitored every 30 minutes for day time patients and for the nocturnal patients the vital signs should be done once hourly while sleeping.</p>	V 543			