

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

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552642	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED C 10/01/2010
NAME OF PROVIDER OR SUPPLIER WESTLAKE DALY CITY DIALYSIS CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2201 JUNIPERO SERRA BOULEVARD, SUITE A DALY CITY, CA 94014		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
V 000	INITIAL COMMENTS The following reflects the findings of the California Department of Public Health during an investigation of Complaint CA00244424 regarding Infection Control. The inspection was limited to the specific complaint and does not represent the findings of a full inspection of the facility. Representing the California Department of Public Health: Artemis Tumaneng, Health Facilities Evaluator 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: Based on observation, interview, and record review, the facility failed to ensure that two staff practiced hand hygiene after transporting used dialyzers in the reuse room. This practice increased the risks for cross-contamination and spread of infections. Findings: During an observation on 9/29/10 at 9:40 AM, PCT 2 (Patient Care Technician) came in to the	V 113			

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	Continued From page 1 Reuse Room with a used dialyzer wrapped in a red plastic bag. He was wearing gown, gloves and faceshield. After he affixed the label on the dialyzer, he put the dialyzer in the refrigerator. He did not take his gloves off after handling the used dialyzer and then opened the Reuse Room door to go back to the patient treatment area. During an observation on 9/29/10 at 10:00 AM, PCT 2 came in to the Reuse Room with a used dialyzer wrapped in a red plastic bag. He was wearing gown, gloves and faceshield. After he affixed the label on the dialyzer, he put the dialyzer in the refrigerator. He took his gloves off but did not do hand hygiene and then he opened the Reuse Room door to go back to the patient treatment area. In an interview on 9/29/10 at 10:30 AM, the Clinical Services Specialist said the staff considered Reuse as dirty area so they did not do hand hygiene before leaving the Reuse Room but they washed their hands when they returned to the treatment area. Review of the facility's policy and procedure Infection Control for Dialysis Facilities revised March 2010 indicated, "Hand hygiene is to be performed...after removal of gloves, after contamination with blood or other infectious material..."	V 113			
V 228	494.40(a) MIXING SYSTEMS-LABELING 5.4.4.1 Mixing systems: labeling Labeling strategies should permit positive identification by anyone using the contents of mixing tanks, bulk storage/dispensing tanks, and small containers intended for use with a single hemodialysis machine.	V 228			

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V 228	<p>Continued From page 2</p> <p>Mixing tanks: Prior to batch preparation, a label should be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. This labeling should remain on the mixing tank until the tank has been emptied.</p> <p>Bulk storage/dispensing tanks: These tanks should be permanently labeled to identify the chemical composition or formulation of their contents.</p> <p>Concentrate jugs: At a minimum, concentrate jugs should be labeled with sufficient information to differentiate the contents from other concentrate formulations used at the facility.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview and record review, the facility failed to change the label on the storage/dispensing tank to indicate the tank contains 3K (potassium) and 2.5 Ca (Calcium) dialysates. Failure to label the storage/dispensing tank with the correct composition or formulation of the contents could lead to administration of wrong dialysate which could compromise patients' safety.</p> <p>Dialysate refers to fluid used during dialysis to remove waste products in the body that kidneys cannot excrete.</p> <p>Findings:</p> <p>During an observation on 10/1/10 at 10:20 AM, the Dialysate Preparation/Storage Area had a storage/dispensing tank with small red label of 1K 2.5Ca on the bottom part of the tank.</p>	V 228			

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V 228	<p>Continued From page 3</p> <p>Review of the Granuflo (dialysate mixing machine) Batch Production Record indicated, "9/22/10 Granuflo batch transferred to Storage Tank."</p> <p>In an interview on 10/1/10 at 10:20 AM, the Reuse Technician said the tank with label 1K 2.5Ca had a 3K 2.5Ca dialysate contents. He said the label 1K 2.5 Ca on the tank was not taken off eventhough the contents of the tank was 3K 2.5 Ca. He added that when he mixed the dialysate, it was checked and verified by the Registered Nurse that it was the right 3K 2.5Ca concentration. He said he did not remove the label or made a new label for the 3K because the Biomed was the person in-charge of the labeling.</p> <p>In an interview on 10/1/10 at 10:30 AM, the Biomed Technician said the facility changed the dialysate concentrate from 1K to 3K but did not change the labels. He acknowledged the storage/dispensing tanks should be labeled with the correct concentration or formulation of the dialysate contents to positively identify the contents of the tank.</p> <p>In an interview on 10/1/10 at 11:00 AM, the Administrator said the facility's dialysate P&P was not specific for a certain dialysate but it covered the general mixing of dialysate.</p> <p>Review of the facility's Granuflo Concentrate Dissolution Unit policy and procedure revised March 2007, did not indicate the storage tank should be labeled with the correct concentration of dialysate after it was mixed from the dissolution unit. The P&P did not include safety measures to follow when changing the contents or</p>	V 228			

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V 228	Continued From page 4	V 228			
V 245	<p>concentration of the storage tank.</p> <p>494.40(a) ACID CONC DIST-CONC LABELED & COLOR-CODED RED</p> <p>5.5.3 Acid concentrate distribution systems: labeled & color-coded red Acid concentrate delivery piping should be labeled and color-coded red at the point of use (at the jug filling station or the dialysis machine connection).</p> <p>All joints should be sealed to prevent leakage of concentrate. If the acid system remains intact, no rinsing or disinfection is necessary.</p> <p>More than one type of acid concentrate may be delivered, and each line should clearly indicate the type of acid concentrate it contains.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to label the dialysate delivery piping and the dialysis machine connection port connected to the storage tank of dialysate 3K 2.5Ca. Failure to affix a label on these areas of the dialysate delivery system could lead to patients receiving the 3K 2.5 CA dialysate instead of the right concentration prescribed for them and therefore compromise patients' safety.</p> <p>Findings:</p> <p>During an observation on 10/1/10 at 9:25 AM, Station 6 had a hemodialysis machine connected to an unlabeled and unidentified dialysate port. It was also observed that the remaining 23 stations including the Isolation Room had dialysate ports which were unlabeled and unidentified.</p>	V 245			

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V 245	Continued From page 5 In an interview on 10/1/10 at 9:45 AM, the Administrator said the facility switched the dialysate 1K 2.5Ca to 3K 2.5Ca recently so the 1K ports were changed to 3K. He said the Biomed was aware of it and on the process of ordering the labels.	V 245			
V 319	494.50(b)(1) ENVIRONMENTAL SAFETY REGARDING CHEMICALS 8.5 Environmental safety: regarding chemicals The dialysis facility shall have written procedures for safe storage and handling of chemicals used in reprocessing (see National Institute for Occupational Safety and Health [NIOSH]/OSHA, 1980; Sax, 1979; material safety data sheets [MSDS]). This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure all staff were aware of how to handle large spills of chemical (Renalin). Failure to properly handle chemical spills could expose the patients and staffs to unsafe environmental conditions. Findings: In an interview on 9/29/10 at 9:35 AM, the Reuse Technician was not able to state the proper way of handling large spills of Renalin.	V 319			

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V 319	Continued From page 6 Review of the facility's Peracetic Acid Concentrate Spill Procedure revised on March 2008 stated, "NOTE: Large spills of > 1 quart of concentrate, call Fire Department and Hazardous Materials Personnel.	V 319			