

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

PRINTED: 10/29/2009
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 052845	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 03/05/2009
NAME OF PROVIDER OR SUPPLIER SOUTH HAYWARD DIALYSIS CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 254 JACKSON STREET HAYWARD, CA 94544	
(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 Surveyor: 05189 The following represents the findings of the Department of Public Health during the investigation of one complaint and one entity reported event. Complaint Intake Number: CA00147229. Entity reported event number: CA00147802 Representing the Department of Public Health: Dorothy Rice, HFEN. The inspection was limited to the specific complaint and entity reported event being investigated and does not represent the findings of a full inspection of the facility. The complaint and entity reported event were substantiated. One deficiency was issued as a result of the investigation of Complaint CA00147229 and Entity reported event CA00147802.	V 000		
V 715	494.150(c)(2)(i) POLICIES AND PROCEDURES The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; This STANDARD is not met as evidenced by: Surveyor: 05189 Based on staff interview and record review, the medical director failed to ensure that the facility policies for Dialysate Culture/Endotoxins testing	V 715		

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 715	<p>Continued From page 1</p> <p>and Water Culture/Endotoxins testing were implemented. When results of the dialysate and water cultures, and endotoxins tests showed action and unacceptable levels (levels that required corrective actions), the facility failed to inform the medical director to obtain further action guidance. This failure placed the patients at an increased risk for complications related to unsafe water/dialysate.</p> <p>Findings:</p> <p>A. Record review during an onsite visit on 3/4/09 and 3/5/09, showed that for the samples collected on 4/16/08, the facility dialysate endotoxin testing reports showed high levels of 5.55 EU/ml (endotoxin unit/milliliter) and 2.39 EU/ml respectively, for two different testing sites. The water endotoxin testing reports, collected on 4/16/08, also showed high levels ranging from 1.99 EU/ml to 12.10 EU/ml for nine sampled sites.</p> <p>According to the facility policy for Endotoxin Water/Dialysate Testing the goal was to ensure that the quality of water and dialysate met or exceeded the AAMI (Advancement of Medical Instrumentation) recommendations for endotoxin levels. The policy showed: a. Acceptable level: Below 1 EU(Endotoxin Unit)/ml; b. Action Level (requiring interventions/actions), 1 E U/ml or greater, but less than 2 EU/ml; c. Unacceptable Level: 2 EU/ml or greater.</p> <p>The policy instructed the staff to notify the medical director when more than one site tested for endotoxins was at, or above the unacceptable level, or at the action level. The facility had no documented evidence that the staff informed the</p>	V 715			

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V 715	<p>Continued From page 2</p> <p>medical director as soon as the tests results showed abnormal levels.</p> <p>B. The record review on 3/4/09 also showed that on 4/18/08, the water cultures identified unacceptable levels of bacterial growth for two testing sites: 360 cfu/ml (colony forming unit/milliliter) and 530 cfu/ml.</p> <p>The facility policy for Water Culture , reviewed on 3/5/09, had the goal of ensuring that the water used to prepare dialysate met or exceeded the current AAMI recommendations: a. Acceptable Level: below 50 cfu ; b. Action level: 50-199 cfu/ml; c. Unacceptable Level: 200 cfu/ml or greater.</p> <p>The policy instructed the staff to notify the medical director when the water cultures for more than one site had results at the unacceptable or action level. Facility records showed no evidence that the medical director was notified as soon as the culture results were reported and were found and required corrective actions.</p> <p>Moreover, further record review on 3/4/09 showed that on 4/18/08, repeated tests for water endotoxin levels at three testing sites showed unacceptable and actionable levels: 1.5 EU/ml, 3.01 EU/ml, and 5.95 EU/ml respectively.</p> <p>C. On 4/21/08, repeated tests for water cultures and endotoxin levels showed again abnormal results:</p> <p>a. Two testing sites had unacceptable levels of bacterial growth: 360 cfu/ml and 530 cfu/ml (Unacceptable Level at 200 cfu/ml or greater)</p> <p>b. The endotoxin levels were even higher than those obtained on 4/18/08. The endotoxin levels</p>	V 715			

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V 715	<p>Continued From page 3</p> <p>increased from 1.5 to 13.3 EU/ml, from 3.01 to 17.60 EU/ml, and from 5.95 to 8.06 EU/ml. (Actionable level at 2 EU/ml or greater). Furthermore, there were other eight sites tested that showed abnormal levels of endotoxins in the water.</p> <p>On 3/5/09 the facility staff was unable to produce any evidence that the medical director was informed of the high water and dialysate testing results as directed by the facility policies. On 4/21/08 the staff reported to the medical director that there were patients who experienced chills, and some even had fever while receiving treatment.</p> <p>On 3/5/09 at approximately 10:45 am, Staff F stated (in presence of Staff C, Staff G, and Staff E) that she had not notified and involved the Medical Director prior to 4/21/08.</p>	V 715			