

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: 552559	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 01/07/2009
NAME OF PROVIDER OR SUPPLIER SATELLITE DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 1860 MILMONT DRIVE MILPITAS, CA 95035	
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V 000	INITIAL COMMENTS Surveyor: 05189 The following represents the findings of the Department of Public Health during an investigation of Complaint Intake Number: CA0014207 Representing the Department of Public Health: Dorothy Rice, HFEN. The inspection was limited to the specific complaint being investigated and does not represent the findings of a full inspection of the facility.	V 000		
V 726	494.170 MEDICAL RECORDS 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. This STANDARD is not met as evidenced by: Surveyor: 05189 Based on staff interview and record review, the facility failed to maintain accurate and complete records for one (Patient 1) of one patients reviewed. The clinical record lacked documentation of the calculations utilized in fluid removal, documentation regarding sodium modeling and PUF (pure ultrafiltration). This failure placed Patient 1 at risk for medical and clinical decision be made on inaccurate or incomplete information.	V 726		3/25/09

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 726	<p>Continued From page 1</p> <p>Findings:</p> <p>The record review on 12/23/08 showed that Patient 1 was admitted to the facility on 3/6/07. The preadmission History and Physical record, dated 2/14/07, showed that Patient 1 was previously cared for in an acute care hospital for congestive heart disease. The record also showed that Patient 1 had "very advanced kidney failure", requiring hemodialysis. (Hemodialysis is the procedure whereby excess body wastes and fluid are removed from the blood. This treatment procedure requires a route [blood access] in order to remove blood to and from the bloodstream.) On 3/6/07, orders showed the following: "NA [sodium] modeling, every treatment.</p> <p>A. On 12/24/08, the review of facility policy for "Dialysate Sodium Modeling" showed that the treatment was "to enhance fluid removal during dialysis while preventing hypotension and muscle cramping by altering the sodium concentration of the dialysate [a solution used in hemodialysis]". The policy further instructed that sodium modeling was to be done only upon the order of a physician and was to include the following elements:</p> <ul style="list-style-type: none"> - The method (e.g., step, linear, exponential), if applicable to the machine. (Step=increases sodium to a set percent; Linear=Offers a high sodium in the beginning with gradual decline; exponential= Gives high sodium at the beginning of treatment and drop the sodium in a more dramatic curve.) - The point in the treatment at which the sodium level was to be returned to baseline; - The sodium was to be returned to the baseline level at least 30 minutes prior to the end of the 	V 726			

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V 726	<p>Continued From page 2 dialysis treatment.</p> <p>The review of the above procedure for the Fresenius 2008 H (machines utilized by facility and capable of delivering all three method of treatment identified above) usage included the following: "Please note that all programs with the exception of 'STEP' should run the full treatment time. 'STEP' should be set to return to 'normal' level at least the 30 minutes of treatment.</p> <p>On 2/4/08, the Hemodialysis Treatment Log showed that Patient 1's treatment order included: - Treatment duration of 3 hours; - Dry weight (weight after excess fluid removal) at 64.5 Kg(kilogram); and - Sodium modeling- every treatment.</p> <p>However, the order did not include the specific elements in accordance with the above policy and procedure. For example, the method (e.g., step, linear, exponential) applicable to the Fresenius 2008H machines utilized by the facility, was not included. Without this information, it was difficult to determine at what point in the treatment the sodium level was to be returned to baseline.</p> <p>The Hemodialysis Treatment Log , dated 2/4/08, showed that Patient 1 developed complications. During treatment, Patient 1's blood pressure lowered to 99/45 (from 118/86), ultrafiltration rate was turned off, Patient 1 "c/o [complained of] headache, neck tightness...", and treatment was subsequently discontinued thirty three minutes prior the scheduled time.</p> <p>On 12/23/08, Staff A stated that the order should have included the specifics as indicated in the policy, and that staff should have documented the</p>	V 726			

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V 726	<p>Continued From page 3</p> <p>time the sodium modeling was started and ended in the correlating "Time Given" and "Time Ended" sections of the Hemodialysis Treatment Log.</p> <p>Additionally, on 2/6/08 review of the treatment log and the progress notes showed that Patient 1 had severe cramping. Again, the documentation in the log showed only that the sodium modeling "to enhance fluid removal during dialysis while preventing hypotension and muscle cramping" was "Done".</p> <p>There was no documentation of the method (step, linear, exponential) utilized.</p> <p>On 2/11/08, 2/13/08, 2/15/08, 2/20/08, 2/22/08, the treatment logs showed no documentation that the sodium modeling order was implemented for Patient 1.</p> <p>B. On 12/24/08, the review of facility "Calculating Fluid Removal Goal" policy/procedure, showed the method of calculating as follows: "Subtract patient's ordered dry weight from the current weight. The difference is the amount of body water that needs to be removed that treatment. Add to that amount the volume of normal saline prime and rinse back that will be used (.5 kilo grams/500 cc)."</p> <p>On 2/4/08, the treatment log showed that Patient 1's weight prior to treatment was 70.1 Kg. In accordance with the facility's policy, staff was directed to subtract patient's ordered dry weight (64.5 Kg. from the current weight (70.1 Kg). The difference was the amount of body water that needed to be removed during treatment. The procedure also directed staff to add to that amount the volume of normal saline prime and</p>	V 726			

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V 726	<p>Continued From page 4</p> <p>rinse back that will be used (.5 kilo grams/500 cc). i.e.,</p> <ul style="list-style-type: none"> - 70.1 Kg. - 64.5 Kg. = 5.6 Kg/5600 cc - 5.6 Kg. + 0.5 Kg. = 6.1 Kg/6100 - 6.1 Kg/6100 cc Total Fluid Removal <p>On 2/4/08, the "Fluid to Remove" designated area on the Hemodialysis Treatment Log showed only a proposal of 5.6 Kg of fluid to be removed instead of the 6.1 Kg volume calculated using the policy's directions.</p> <p>However, the documented actual total fluid removal (TFR) of 4.0 Kg., and the post treatment weight was 68.7, together (4.0 + 68.7= 72.7) did not correlate and add up to the pre treatment weight of 70.1 Kg. This practice made it difficult to determine which parameter (fluid removal, post treatment weight, other possible variable) lead to the discrepancy. Moreover, the difference of the post weight (68.7) and the dry weight (64.5) or (68.7 - 64.5 = 4.2) indicated that Patient 1 left the facility 4.2 kilos over the dry weight.</p> <p>On 12/24/08 at approximately 11:10 am, Staff A stated that nurses should notify the physician when a patient was leaving the facility 2.0 Kilos (kg.) over the dry weight.</p> <p>C. On 12/24/08, the review of facility policy for "Pure Ultrafiltration (PUF)" showed that ultrafiltration (removal of fluid) was prescribed for patients who displayed fluid overload equal or greater than 3 kg., and that the "treatment must be in conjunction with at least 15 minutes of hemodialysis following the treatment so that there is not a hemoconcentration of potassium or electrolytes."</p> <p>The procedure showed the following:</p>	V 726			

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V 726	<p>Continued From page 5</p> <p>"a. Determine whether PUF is to be done prior to the initiation of a full hemodialysis treatment and the prescribed PUF timeframe (sequential Ultrafiltration), or whether PUF is to be done without hemodialysis treatment (Isolated PUF)</p> <p>b. If sequential PUF is ordered, initiate PUF at onset of treatment by placing machine in bypass (a feature that cuts off the flow of dialysate through the dialyzer and shunts it to the drain) for the prescribed duration of the PUF treatment. Once the prescribed treatment time for PUF has ended, remove hemodialysis machine from bypass and reset machine for prescribed hemodialysis treatment time.</p> <p>c. If isolated PUF is ordered, initiate PUF at onset of treatment by placing dialysis machine in bypass for duration of prescribed PUF treatment time. "</p> <p>On 2/6//8, the log showed that Patient 1 had a pre-treatment weight of 74.4 Kg. The difference from the dry weight (64.5 Kg.) and the pre weight (74.4 Kg) was 9.9 Kg. The total amount of fluid actually removed was 3.8 Kg. However, once again the total fluid removed (3.8 Kg) plus the post weight (67.0 Kg) for a total of 70.8 Kg did not add up to the pre weight of 74.4 Kg: This practice made it difficult to determine which parameter (fluid removal, post treatment weight, other possible variable) lead to the inaccurate documentation.</p> <p>On 2/7/08, the Patient 1's orders included the following:"PUF, x[times] 2 hrs for fluid overload". The order did not clarify between Sequential or Isolated PUF treatment.</p> <p>On 2/7/08, the Hemodialysis Treatment Log showed a prescription of 3:00 hour duration.</p>	V 726			

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V 726	<p>Continued From page 6</p> <p>On 2/7/08, the log documentation showed that treatment "Expected Time On" was 1247 (12:47 PM), and "Expected Time Off" was 1547 (3:27 PM) which indicated a planned treatment for 3.0 hour duration (as opposed to the two hour PUF treatment order). Subsequent documentation showed treatment was initiated at 12:47 PM, but actually discontinued at 1527 (3:27 PM) and Patient 1 cramping. i.e., "TX [treatment] ended; off 20 minutes early due to cramping." There was no documentation that determined what kind or if any PUF treatment was done. Moreover, there was no documentation recorded in the "PUF" section on the Hemodialysis Treatment Log.</p> <p>On 12/24/08, Staff A acknowledged the deficient documentation practice and stated that the physician order should have included the type (Sequential or Isolated) of PUF treatment to be done. Staff A stated that staff should have clearly checked the corresponding "PUF" designated section of the log, when the PUF procedure started, as well as when the treatment was discontinued .</p>	V 726			