

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552670	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 02/03/2011
NAME OF PROVIDER OR SUPPLIER SATELLITE DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 1040 HAMILTON COURT MENLO PARK, CA 94025		
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V 000	<p>INITIAL COMMENTS</p> <p>The following relects the findings of the California Department of Public Health during an initial certification survey conducted on 2/2/11 through 2/3/11.</p> <p>Representing the Callifornia Department of Public Health: Stella Tannehill, Health Facilities Evaluator Nurse, and Artemis Tumaneng, Health Facilities Evaluator Nurse.</p> <p>The census on 2/2/11 was four.</p> <p>Staff Position Abbreviations: Regional Director- RegDir Clinical Manager- ClinMgr Technical Manager- TechMgr Facilities Supervisor- FS Registered Nurse- RN Technical Aid- TA</p> <p>Definition of Terms commonly used in the deficiencies: Bicarbonate or bicarbonate concentrate- a substance that minimizes change in the acidity of a solution when an acid or base is added to the solution. Bicarbonate jug - a plasic jug for individual use, in which bicarbonate powder (Naturalyte 4000) is mixed with purified water to be added by the dialysis machine to the dialysate being delivered to the patient. Bloodlines - set of tubings that is filled with saline or blood during hemodialysis. Central Venous Catheter or short peripheral</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	Continued From page 1 catheter - a catheter with two lumens inserted under the skin into a large vein in the neck or groin used for hemodialysis treatment. Dialysate - fluid used during dialysis to remove waste products in the body that kidneys cannot excrete. It is composed of purified water, bicarbonate and electrolytes. Dialyzer - an artificial kidney usually composed of hollow fiber which is used in hemodialysis to eliminate waste products from the blood and remove excess fluids from the bloodstream. Dialyzer connectors - tubings with inlet and outlet connectors attached to the dialyzer and the dialysis machine in order for the dialysate to flow in the dialyzer during hemodialysis. Bicarbonate Mixing Areas- where two tanks for mixing bicarbonate with purified water were located and where individual jugs of bicarbonate concentration are mixed. Hemodialysis treatment - a therapy that uses hemodialysis machine and a dialyzer to remove extra fluids and waste products of the body that kidneys could not excrete. Hemodialysis access - three basic kinds of vascular access for hemodialysis are AVF (atrial-venous fistula), AVG (atrial-venous graft), and a central venous catheter. Saline - a bag of sterile solution of sodium chloride or salt. Stations - patient designated treatment area equipped with a chair and a table, a hemodialysis machine, tubings and other equipments.	V 000			
V 235	494.40(a) ADDITIVES-MIXING SPIKES 5.4.5 Additives: mixing spikes Concentrate additives should be mixed with liquid acid concentrates according to the manufacturer's instructions, taking care to ensure	V 235		2/4/11	

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V 235	<p>Continued From page 2</p> <p>that the additive is formulated for use in concentrates of the appropriate dilution ratio. When liquid additives are used, the volume contributed by the additive should be considered when calculating the effect of dilution on the concentration of the other components in the resulting concentrate. When powder additives are used, care should be taken to ensure that the additive is completely dissolved and mixed before the concentrate is used.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure the bicarbonate was mixed according to manufacturer's instructions, when the amount of water added to the mix was estimated rather than measured. This was done for 42 scheduled patient treatments.</p> <p>Failure to accurately measure water when mixing bicarbonate can result in the wrong concentration and inaccurate delivery of bicarbonate. This can affect the acidity of the dialysate.</p> <p>Findings:</p> <p>During observation of the bicarbonate mixing area on 2/2/11 at 11:03 AM, there were two empty, unlabeled, plastic jugs used for mixing individual bicarbonate concentration batches on a floor palate and one placed directly on the floor that were all in the usual upright position of jugs, with the open spout pointing upward. The jugs were unlabeled, and had markings to indicate 8.0 liters and 5.095 liters with no markings in between.</p>	V 235			

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V 235	Continued From page 3 When interviewed on 2/2/11 at 11:03 AM, the TA stated he poured water into the jug to "just below" the 8.0 liter marking on the jug and then added a package of NaturaLyte 4000 (bicarbonate). The TA said he had been mixing bicarbonate in jugs for about a month. Record review of the patient HD treatments schedules for January 2011 and the first 3 days of February, 2011, indicated there were 42 patient treatments scheduled during that time. Review of the manufacturer's instruction for the mixing of NaturaLyte 4000 indicated, "...1. To mix the NaturaLyte 4000 dry pack, add purified water to the container ... Fill to the 7.7 liter mark..." Review of the facility's policy and procedure, Bicarbonate Concentrate Supply, indicated, "2. Follow manufacturer's instructions for proper dilution and mixing procedures..." The TA did not follow the manufacture's instruction to use 7.7 liters of water. The TA filled the jug with water up to an estimated amount that was just below the level of 8 liters.	V 235			
V 244	494.40(a) BICARB JUG MAINTENANCE/DISINFECTION 5.5.4 Bicarbonate concentrate distribution systems: jug disinfection When reusable concentrate jugs are used to distribute bicarbonate concentrate, they should be rinsed free of residual concentrate before disinfection. 6.5 Concentrate distribution	V 244		2/4/11	

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V 244	<p>Continued From page 4</p> <p>When reusable concentrate jugs are used to distribute bicarbonate concentrate, they should be disinfected at least weekly.</p> <p>7 Strategies for bacterial control 7.1 General Following disinfection, jugs should be drained, rinsed, and inverted to dry.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure bicarbonate jugs were disinfected before the next use. Failure to disinfect the jugs could be a potential medium for bacterial growth which could cause infection to 4 patients currently receiving dialysis treatment.</p> <p>According to AAMI (Association for the Advancement of Medical Instrumentation): "Bacteria can multiply very rapidly in bicarbonate concentrate. Therefore, if disinfection is inadequate, one organism can grow into hundreds of thousands-literally overnight." (source Hemodialysis Horizon www.aami.org)</p> <p>Findings:</p> <p>In an observation on 2//2/11 at 11:00 AM, a bicarbonate jug was connected to each dialysis machine in Station 3 and 4</p> <p>In an interview on 2/2/11 at 11:00 AM, the Reuse Technician said that after each patient's treatment, he rinsed the bicarbonate jugs with RO (reverse osmosis - process to purify the water to get rid of chemicals and contaminants) water and let the jugs dry. He added that he used to mix the bicarbonate in the tank but because there was a</p>	V 244			

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V 244	<p>Continued From page 5</p> <p>lot of left-over in the tank, he was told to mix bicarbonate in the jug for each dialysis machine. He said the facility started using the bicarbonate jugs approximately a month ago.</p> <p>During interview on 2/2/11 at 11:03 AM, the TA stated he had been rinsing the plastic jugs used for bicarbonate mixing with water after the mix was used. He said he then made a fresh bicarbonate mix in the same jug without any process of jug disinfection before making the new mix. The TA was not able to state how the plastic jugs used for mixing individual bicarbonate concentration batches should be disinfected.</p> <p>When interviewed on 2/2/11 at 12 noon, the TechMgr said the facility was only using the plastic jugs for mixing bicarbonate temporarily, because there were only a few patients receiving dialysis at that time. The TechMgr said he had not wanted to waste bicarbonate by making it in large batches in the mixing tanks. The TechMgr accepted responsibility for the failure to specifically train and supervise the TA in the individual bicarbonate concentration jug disinfection process.</p> <p>Review of the manufacturer's guidelines for the care of individual containers used for the mixing of bicarbonate (NaturaLyte 4000- the bicarbonate used by the facility), indicated : "...Container must be free of bacterial and chemical contamination..."</p> <p>Review of the facility's policy, Bicarbonate Concentrate Supply, revised 2/9/09, indicated, "...9. When individual concentrate containers are regularly used they are to be disinfected daily</p>	V 244			

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V 244	Continued From page 6 along with the cap and uptake assembly. These containers should be labeled and the disinfection should be documented specific to each container. They should be stored upright, in a manner where any individual fluid can drain from them..."	V 244			
V 676	494.130 LAB-CLIA LABS/MEET NEEDS OF PTS The dialysis facility must provide or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. Any laboratory services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter. This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to check the blood sugar when the hemodialysis treatment was administered as ordered by the physician for 1 of 4 sampled patients (Patient 2). Diabetic patients in ESRD (end stage renal disease) are at greater risk of hypoglycemia, which can occur during hemodialysis. "...ESRD and hemodialysis exert opposing forces on insulin secretion, action, and metabolism, often creating unpredictable serum glucose values..." (Cleveland Clinic Journal Medicine. 11/2009). Findings: Record review on 2/3/11 of Patient 2's physician hemodialysis orders dated 2/2/11 indicated a blood sugar check was to be done every treatment. The order did not specify parameters	V 676		2/4/11	

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CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/27/2011
FORM APPROVED
OMB NO. 0938-0391

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V 676	Continued From page 7 of blood sugar levels when the physician was to be notified, or actions to be taken in response to blood sugar levels. Review of Patient 2's Hemodialysis Treatment Log dated 2/2/11 indicated no blood sugar check was done. When interviewed on 2/3/11 at approximately 10:30 AM, the RegDir reviewed Patient 2's physician orders and his Hemodialysis Treatment Log and verified no blood sugar was obtained when the treatment was administered. During interview on 2/3/11 at approximately 4:30 PM, the RegDir said the nurse did not obtain Patient 2's blood sugar check as ordered because the physician's order did not get transcribed onto the Hemodialysis Treatment Log by the computer as it should have. The RegDir said it was a computer systems problem.	V 676			
V 681	494.140 PQ-STAFF LIC AS REQ/QUAL/DEMO COMPETENCY All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated	V 681		2/2/11	

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V 681	<p>Continued From page 8</p> <p>competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure one of 2 Registered Nurses (RN 2) met the nurse licensure requirements in California before she was allowed to initiate patient's dialysis treatment when her personnel file did not include verification of her RN license.</p> <p>"Verification of current R.N. status -- Every employer of a registered nurse required to hold any board-issued certification, and every person acting as an agent for such a nurse in obtaining employment, shall ascertain that the nurse is currently authorized to practice as a registered nurse pursuant to a board-issued certification within the provisions of this chapter." Business and Professions Code of California 2732.05. (a)</p> <p>Findings:</p> <p>During review of RN 2's personnel file on 2/2/11, there was no record of her RN license verification to check if her license was Active and that she had no records of Disciplinary Actions by the Department of Consumer Affairs Board of Registered Nursing.</p> <p>In an interview on 2/2/11 at 11:30 AM, the Clinical Manager/Administrator said RN 2's license verification was in her home clinic because she was a per diem in the facility. She said she should</p>	V 681			

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V 681	Continued From page 9 have verified RN 2's license before she started working in the facility. During interview with the Clinical Manager (ClinMger) on 2/2/11 at 1:35 PM, she said the facility was still trying to get the RN 2's file in order, since she just started with the facility. The ClinMger said RN 2 was hired at another dialysis facility within the same company on 10/21/10, and should have had her license verified there. Review on 2/2/11, of the facility's policy and procedure (P&P) for lending staff between dialysis facilities within the same corporation, found the P&P did not specify who would be responsible for verification of the license or certification of staff loaned to another facility. The P&P did not specify that licensing verification obtained at one dialysis facility within the same company would be sent to the facility being loaned the staff member.	V 681			
V 760	494.180(b)(3) GOV-GB RESP FOR STAFF ORIENTATION The governing body or designated person responsible must ensure that- (3) All staff, including the medical director, have appropriate orientation to the facility and their work responsibilities; This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure one of 2 Registered Nurses (RN 2) had received proper orientation and demonstrated competency in her assigned duties and responsibilities before she was allowed to independently initiate patient treatment. Failure to orient and test the	V 760		2/4/11	

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V 760	<p>Continued From page 10</p> <p>competency of the RN before allowing her to independently carry out dialysis treatment could lead to errors which could threaten the health and safety of the 4 patients currently receiving treatment in the facility.</p> <p>Level detector module is part of the dialysis machine use to monitor the level of fluid in the venous drip chamber. The parts included in the module are venous drip chamber holder, level detector sensor, blood tubing holder, optical detector and occlusion clamp. It is a safety device (air detector) of the dialysis machine to prevent air from entering the patient's body.</p> <p>Venous drip chamber is part of the bloodlines used during dialysis treatment.</p> <p>Level detector sensors are ultrasonic device inside the venous drip chamber holder which monitors the drip chamber for the presence of air. If the level of the blood in the chamber is too low and air is detected, the machine alarms, the blood pump stops and the clamp occludes the venous tubing. (source: 2008K2 Hemodialysis Machine Operator's Manual)</p> <p>Optical sensor is located below the occlusion clamp which distinguishes whether or not blood is detected in the venous line.</p> <p>Need Blood Sensed - type of machine alarms which required the machine operator to verify the venous bloodline is in the optical detector so the machine could sensed the presence of blood.</p> <p>Dialyzer or artificial kidney is used to filter fluids and wastes from a patient's blood.</p>	V 760			

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V 760	<p>Continued From page 11</p> <p>Peracidin is a chemical disinfectant used for cleaning dialyzers.</p> <p>Reuse dialyzer is used more than once for the same patient after they are cleaned and disinfected.</p> <p>Central Venous Catheter (CVC) is a catheter with two lumens inserted under the skin into a large vein in the neck or groin used for hemodialysis treatment.</p> <p>Air embolism occurs when air enters the vein and travels to the right side of the heart and/or the lungs blocking the blood supply.</p> <p>Findings:</p> <p>Patient 3 was admitted to the facility on 12/17/10 with diagnoses including ESRD (End-Stage Renal Disease) and diabetes. Her dialysis access was a CVC on her right chest.</p> <p>"Venous air embolism is a potentially life-threatening and under-recognized complication of central venous catheterization (CVC), including central lines, pulmonary catheters, hemodialysis catheters..." (source: Venous Air Embolism July 27, 2009 www.emedicine.medscape.com)</p> <p>In an observation on 2/2/11 at 6:35 AM, RN 2 was preparing the dialysis machine in Station 3 for Patient 3. RN 1 approached RN 2 and they both agreed Patient 3's prescription was correct and there was negative residual of the Peracidin on the reuse dialyzer, and then RN 1 left the</p>	V 760			

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V 760	<p>Continued From page 12</p> <p>treatment area. At 6:38 AM, RN 2 proceeded to initiate the dialysis treatment of Patient 3 without the presence of another Registered Nurse or a preceptor. After one minute of initiating the treatment, the dialysis machine alarmed and it showed on the screen "NEED BLOOD SENSED", RN 2 pressed "Reset" button on the dialysis machine to turn off the alarm. After another minute, the machine alarmed again and the screen showed "NEED BLOOD SENSED". RN 2 pressed the "Reset" button again to turn off the alarm the second time without checking what caused the alarm. RN 2 did not recognize why the machine alarmed twice during patient treatment until she was prompted by the surveyor that the machine was not set-up correctly because the venous tubing was not engaged in the blood tubing holder with optical detector and occlusion clamp (parts of the dialysis machine safety device [air detector] to prevent air from entering the patient's body during treatment).</p> <p>In an interview on 2/2/11 at 7:00 AM, RN 2 could not state why the machine alarmed and what was the safety functions of the level detector sensors, optical detector and the clamp. She said it was her first time to use the type of dialysis machine the facility has and she was not oriented to the machine nor she ever practiced in setting up the machine. When asked if she knew what to do if a patient showed signs of air embolism, she said, she will assess the patient, give the patient oxygen, position the patient flat and she will call the doctor.</p> <p>"Management of venous air embolism once suspected, includes identification of the source of air, prevention of further air entry (by clamping or</p>	V 760			

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V 760	<p>Continued From page 13</p> <p>disconnecting the circuit), a reduction in the volume of air entrained ... Immediately place the patient in the left lateral and Trendelenburg position. This helps to prevent air from traveling through the right side of the heart into the pulmonary arteries (lungs)." (source: Venous Air Embolism July 27, 2009, www.emedicine.medscape.com)</p> <p>Review of the facility's Air Emboli policy and procedure revised 6/25/10 indicated, "The staff will prevent an air embolism by adhering to safety standards... Precautionary Measures: Patients with catheters are at increased risk...Check that air detector alarm is properly functioning and engaged prior to initiation of treatment....Attention to detail is essential...Treatment: 1. Immediately stop the blood pump and clamp the bloodlines. 2. Immediately place the patient in the trendelenburg (feet higher than head) on his/her LEFT side until MD (doctor) clears a change of position...9. Initiate CPR (cardiopulmonary resuscitation or cardiac compression) if cardiac arrest occurs and call 911..."</p> <p>In an interview on 2/2/11 at 10:30 AM, RN 1 said she was supposed to supervise RN 2 because it was her second day in the facility but there was a new patient that she needed to admit so she left RN 2 to initiate Patient 3's dialysis treatment. She said that as a preceptor, she should have watched RN 2 while initiating treatment and made sure she was doing all the procedures correctly according to the facility's policy.</p> <p>In an interview on 2/2/11 at 11:00 AM, the Clinical Manager/Administrator said RN 2 was a per diem nurse experienced dialysis nurse and was</p>	V 760			

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

PRINTED: 05/27/2011
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552670	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 02/03/2011
NAME OF PROVIDER OR SUPPLIER SATELLITE DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 1040 HAMILTON COURT MENLO PARK, CA 94025		
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V 760	<p>Continued From page 14</p> <p>competent to initiate patient treatment. When she was told that RN 2 was not able to set-up the machine properly by not engaging all parts of the air detector safety device in the dialysis machine, she said that it was RN 2's second day and she was supposed to continue with the orientation. She acknowledged that if RN 2 was not done with the orientation in the facility and not familiar in using the dialysis machine and have not had her competency checked, she should not initiate patient treatment without supervision to ensure patient safety.</p> <p>Review of the facility's RN & PCT (Patient Care Technician) & Education Program (Experienced) policy and procedure dated 7/02/08 indicated, "Experienced RN & PCT is defined as having current or past experience in dialysis. The CM (Clinical Manager) is responsible to follow-up the progress of the training and the Medical Director will oversee the program....Note: Per Diem RN and PCT will be given one week orientation. A Preceptor will be assigned to the new employee. The new employee is required to follow the work schedule of his/her Preceptor during the training period..."</p>	V 760			