

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: 552542 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 09/30/2010 |
|---|--|---|---|---|
| NAME OF PROVIDER OR SUPPLIER RAI - ELK GROVE BLVD - ELK GROVE | | | STREET ADDRESS, CITY, STATE, ZIP CODE 8139 ELK GROVE BLVD SUITE 200 ELK GROVE, CA 95758 | |
| (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 by the California Department of Public Health during a recertification survey. Representing the Department: Carol Erickson, HFES Census: 132 hemodialysis patients 35 peritoneal dialysis patients 6 home hemodialysis patients | V 000 | | |
| V 116 | 494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient. -- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient. -- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to disinfect or discard used acid concentrate (a solution used by hemodialysis machines) containers at hemodialysis stations which had the potential to expose the subsequent | V 116 | | 1/17/11 |

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 116 | <p>Continued From page 1</p> <p>patients to transmission of infection and cross contamination.</p> <p>Findings:</p> <p>During an observation on September 27, 2010 at 9:40 AM, a gallon container of acid concentrate was on the floor next to the right side of the patient's chair at station 13. The container was open and a connection wand was extending out of the mouth of the container. The current patient was not using this concentrate; however, the patient's dialysis tubing containing blood was draped over the top of the container.</p> <p>During an observation on September 28, 2010 at 7:50 AM, an opened container of acid concentrate was on the floor in front of the dialysis machine at station 8. The patient was ending the dialysis treatment. At 8:07 AM, PCT 1 cleaned the hemodialysis machine and placed new tubing on the machine while the opened acid container remained in front of the machine.</p> <p>During an observation on September 29, 2010 at 7:24 AM, an open container of acid concentrate was on the floor in front of the hemodialysis machine where Patient 7 was applying pressure to control bleeding of the access site of her right arm. Patient 7 had just completed a hemodialysis treatment and was waiting for her needle site to stop bleeding. At 7:35 AM, a clean set of tubing was placed on the machine and the acid container remained in front of the machine.</p> <p>During an interview on September 30, 2010 at 8:12 AM, PCT 2 stated (after a treatment is done), "the acid jug is put back on the cart and one person is assigned to refill them. We don't</p> | V 116 | | | |

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| V 116 | Continued From page 2 clean them until the end of the day." PCT 2 motioned to a cart several feet away which held several filled containers. During an interview on September 30, 2010 at 1:20 PM, the Center Director stated the acid containers should be capped and removed after treatment. | V 116 | | | |
| V 117 | 494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled. When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station. Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to prevent handling of contaminated items in clean areas which exposed visitors and staff to infectious waste. | V 117 | | 1/17/11 | |

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| V 117 | Continued From page 3 Findings: During an observation on September 27, 2010 at 9:17 AM, PCT 5 was removing the used bloody dialyzer and tubing from the hemodialysis machine at station 15 and carried the tubing through a clean area to the biohazard waste container approximately 20 feet away. The biohazard container was positioned at the end of a counter which held a clean sink on one side. The biohazard container was positioned in such a way that the opened lid would extend back towards the clean sink. This proximity would allow a contaminated biohazard lid to splash onto the clean sink area. During an interview with the Center Director on September 30, 2010 at 1:20 PM, she acknowledged the biohazard container was next to the clean sink. She acknowledged staff was transporting used tubing from one side of the unit to the other and stated they had discussed getting wheeled biohazard carts but felt it was a hazard for visitors. | V 117 | | | |
| V 132 | 494.30(a)(1)(i) IC-TRAINING & EDUCATION Infection Control Training and Education Infection control practices for hemodialysis units: intensive efforts must be made to educate new staff members and reeducate existing staff members regarding these practices. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to provide infection control training to one new staff member as required per facility policy. | V 132 | | 1/17/11 | |

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| V 132 | Continued From page 4 Findings: During a record review on September 30, 2010 at 9 AM, PCT 6's personnel record contained no documentation of infection control training. PCT 6 had been hired on June 16, 2010 and was scheduled to work on September 1, 8, 24, 29 of 2010. During a review on September 30, 2010 of the facility policy titled "Mandatory Inservices" dated October 2007, page 2 indicated the facility will "ensure employees received inservice training and education on critical safety and compliance programs affecting the employees' and patients' health and well-being. This will be done at the time of hire, annually, and whenever changes within the center required additional training. Annual mandatory inservices includeInfection Control " During an interview on September 30, 2010 at 10:30 AM, the Center Director stated "(PCT 6) is per diem and has had problems completing the training " | V 132 | | | |
| V 196 | 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, | V 196 | | 1/17/11 | |

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| V 196 | <p>Continued From page 5</p> <p>or total chlorine should be recorded in a log sheet.</p> <p>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].</p> <p>Samples should be drawn when the system has 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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to develop a procedure for chloramine testing which had the potential for staff to incorrectly perform the chloramine test which would expose hemodialysis patients to chloramines (chlorine and ammonia found in tap water and may cause death if hemodialysis patients are exposed to large amounts).</p> <p>Findings:</p> <p>During an observation on September 27, 2010 at 7:40 AM, PCT 3 performed a chloramine check using the Stericheck Comparator (a handheld device which measures chloramine levels by comparing color changes in fluid). PCT 3 rinsed vials with water from a valve labeled SP3 and then filled the vials with this water. She then put powder into the right vial, swirled the liquid, and</p> | V 196 | | | |

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| V 196 | Continued From page 6 placed the vials into the comparator. She compared the colors and located the appropriate chloramine level on the dial. She took the comparator to RN1 to verify results. During a review on September 27, 2010 at 1500 of the facility policy titled "Chlorine/Chloramine Monitoring: Water " dated April 2007 and revised July 2010, it indicated "The approved procedure for Total Chlorine testing is the manufacturer's instructions for use." The instructions were requested at this time and were not available. During an interview on September 28, 2010 at 9 AM, Staff 7 was unable to provide manufacturer's instructions or procedure for the test. Manufacturer's instructions were provided by the Center Director on September 28, 2010 at 11:40 AM. | V 196 | | | |
| V 245 | 494.40(a) ACID CONC DIST-CONC LABELED & COLOR-CODED RED 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). All joints should be sealed to prevent leakage of concentrate. If the acid system remains intact, no rinsing or disinfection is necessary. More than one type of acid concentrate may be delivered, and each line should clearly indicate the type of acid concentrate it contains. This STANDARD is not met as evidenced by: Based on observation and interview, the facility | V 245 | | 1/17/11 | |

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| V 245 | <p>Continued From page 7</p> <p>failed to maintain a closed system for acid concentrate (a solution used in hemodialysis treatment) which had the potential to expose patients to infectious items.</p> <p>Findings:</p> <p>During an observation on September 27, 2010 at 9:40 AM, a gallon container of acid concentrate was on the floor next to the right side of the patient's chair at station 13. The container was open and a connection wand was extending out of the mouth of the container. The current patient was not using this concentrate; however, the patient's dialysis tubing containing blood was draped over the top of the container.</p> <p>During an observation on September 28, 2010 at 7:50 AM, an opened container of acid concentrate was on the floor in front of the dialysis machine at station 8. The patient was ending the dialysis treatment. At 8:07 AM, PCT 1 cleaned the machine and placed new tubing on the machine while the opened acid container remained.</p> <p>During an observation on September 29, 2010 at 7:24 AM, an open container of acid concentrate was on the floor in front of the hemodialysis machine where Patient 7 was applying pressure to the access site of her right arm. At 7:35 AM, a clean set of tubing was placed on the machine and the acid container remained.</p> <p>During an interview on September 30, 2010 at 8:12 AM, PCT 2 stated (after a treatment is done), "the acid jug is put back on the cart and one person is assigned to refill them. We don't clean them until the end of the day."</p> | V 245 | | | |

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| V 245 | Continued From page 8 During an interview on September 30, 2010 at 1:20 PM, the Center Director stated the acid containers should be capped and removed after treatment. | V 245 | | | |
| V 402 | 494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to restrict entrance by outsiders into the treatment area which left hemodialysis patients vulnerable while sleeping and connected to the hemodialysis machines. Findings: During an observation on September 27, 2010 at 6 AM, the door leading into the treatment area from the waiting room was propped open with a chair. No staff was present in the front office and staff in the treatment area were occupied with patient treatments. The surveyor was able to walk directly into the patient treatment area. After several seconds, RN1 approached the surveyor and asked for identification. At 6:25 AM, the door was closed. During an interview on September 30, 2010 at 1:20 PM, the Centor Director stated the front door should have been locked. | V 402 | | 1/17/11 | |
| V 403 | 494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU | V 403 | | 1/17/11 | |

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| V 403 | Continued From page 9 The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to maintain the upholstery on staff chairs to avoid contamination by infectious materials. Findings: During an observation on September 27, 2010 at 9:31 AM, one staff upholstered chair in the hemodialysis unit had torn areas on the end of the left armrest. During an interview on September 30, 2010 at 1:25 PM, the Center Director stated "We didn't know our staff chairs were torn." | V 403 | | |
| V 412 | 494.60(d)(2) PE-ER PREP-PTS ORIENTED/TRAINED The facility must provide appropriate orientation and training to patients, including the areas specified in paragraphs (d)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to provide sufficient training to 3 of 18 sampled patients (1,2,18) for emergency preparedness which had the potential to cause serious injury or death in case of emergency. Findings: | V 412 | | 1/17/11 |

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| V 412 | Continued From page 10 During an interview on September 27, 2010 at 7:30 AM, Patient 1 was unable to demonstrate or describe what to do in case of emergency. Patient 1 stated "It's arranged for us. There are ways." During an interview on September 27, 2010 at 7:40 AM, Patient 2 was unable to demonstrate or describe what to do in case of emergency. During a record review on September 28, 2010 at 2:35 PM, the fire drill evaluation dated March 26, 2010 at 10 AM, indicated "No " for the question: " Patients have knowledge of emergency take-off? " During an interview on September 29, 2010 at 7 AM, Patient 18 was unable to demonstrate or describe what to do in case of emergency. She stated "I don't know." | V 412 | | | |