

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

PRINTED: 09/21/2006
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 012529	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 04/27/2006
NAME OF PROVIDER OR SUPPLIER FLORENCE DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 216 MARENCO STREET SUITE 1 FLORENCE, AL 35630		
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V 144	<p>405.2136(d)(1) PERSONNEL P/P: STAFF QUALIFIED</p> <p>The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedures that ensure that all members of the facility's staff are qualified to perform the duties and responsibilities assigned to them and meet such Federal, State, and local professional requirements as may apply.</p> <p>This STANDARD is not met as evidenced by:</p> <p>Based on observation of staff, review of the personnel records, and interview with the agency staff it was determined the facility failed to have a policy, orientation check list and competency checklist to ensure the facility's staff were qualified to add the correct Acid Concentrate Additives for the 15 different baths the facility was using.</p> <p>Findings include:</p> <p>An observation was made on 4/26/06 at 2:30 PM of the RN mixing a bath of 4K-2 Ca++.</p> <p>An observation was made on 4/27/06 at 11:00 AM of the RN mixing a bath of 2K- 0.5 Ca++.</p> <p>An interview with the Nurse Manager on 4/27/06 at 11:30 AM verified there was no policy, orientation check list or competency checklist to ensure the facility's staff were qualified to add the correct Acid Concentrate Additives for the 15 different baths the facility was using.</p>	V 144		6/9/06	
V 146	<p>405.2136(d)(2) PERSONNEL P/P: INCIDENTS REVIEWED</p>	V 146		6/9/06	

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 146	<p>Continued From page 1</p> <p>The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedures that ensure that reports of incidents and accidents to patients and personnel are reviewed to identify health and safety hazards.</p> <p>This STANDARD is not met as evidenced by:</p> <p>Based on interview and observations of the facility medications in house, the facility failed to ensure that outdated medications were removed from availability for patient care.</p> <p>Findings Include:</p> <p>A tour of the medication room was conducted on 4/25/06 at 3:00 PM. The following medications were found to be expired as follows: 1 vial of Enalaprilat 2.5 mg in 2 ml expired 3-1-06 3 vials of Calcium Gluconate 10% in 10 ml expired 3-1-06</p> <p>An interview with the Registered Nurse on 4/25/06 at 3:15 PM verified that the above drugs were expired and should not have been available for patient care.</p> <p>On 4/26/06 at 1:45 PM the Crash Cart contained 6 vials of Penytoin Na+ 250 mg in 5 ml which expired 4/1/06.</p> <p>An interview with the Nurse Manager on 4/26/06 at 21:00 PM verified the above drug was expired and should not have been available for patient care.</p> <p>A tour of the lab room was conducted on 4/26/06</p>	V 146			

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V 146	Continued From page 2 at 2:15 PM. The following blood culture bottles were expired: 2 Aerobic bottles expired 12/31/05 2 Anaerobic bottles expired 1/31/06 An interview with the Nurse Manager on 4/26/05 at 2:30 PM verified the above blood culture bottles were expired and should not have been available for patient care.	V 146			
V 147	405.2136(d)(2) PERSONNEL P/P: HEALTH EXAMS The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedures that ensure that health supervision of personnel is provided, and they are referred for periodic health examinations and treatments as necessary or as required by Federal, State, and local laws. This STANDARD is not met as evidenced by: Based on review of personnel records, facility policies and interview the facility failed to ensure annual health examinations had been completed for eight of eight employees. Findings include: A review of eight personnel records, for staff employed over a year, revealed a Employee Annual Health Physical had not been completed annually. An interview with the facility manager on 4/27/06 at 10:40 AM confirmed the physicals had not been completed annually and no policy was	V 147		6/9/06	

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V 147	Continued From page 3 available for review.	V 147			
V 157	405.2136(f) PATIENT CARE POLICIES: WRITTEN The ESRD facility has written policies approved by the governing body concerning the provision of dialysis and other ESRD services to patients. This STANDARD is not met as evidenced by: Based on observation of staff, review of the policy and procedure manuals, and interview with the agency staff it was determined the facility failed to ensure that a policy was written for the correct Acid Concentrate Additives for the 15 different baths the facility was using. Findings include: An observation was made on 4/26/06 at 2:30 PM of the RN mixing a bath of 4K-2 Ca++. An observation was made on 4/27/06 at 11:00 AM of the RN mixing a bath of 2K- 0.5 Ca++. An interview with the Nurse Manager on 4/27/06 at 11:30 AM verified there was no written policy for additives to be used for the different baths the facility was using.	V 157		6/9/06	
V 258	405.2140(a)(2) PE: EQUIPMENT MAINTENANCE PROGRAM All electrical and other equipment used in the facility is maintained free of defects which could be a potential hazard to patients and personnel. There is established a planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility.	V 258		6/9/06	

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V 258	Continued From page 4 This STANDARD is not met as evidenced by: Based on observations, review of facility policies and interview with management staff, the facility failed to ensure that the conductivity was checked before each treatment for two of two patients. Findings include: The policy titled "Prescription Verification and Safety Checks" included, "Procedure: Trained teammates will verify the dialysis prescription and perform safety checks prior to each treatment initiation...Safety checks: ... Manual conductivity appropriate to sodium and bicarbonate level prescribed. pH between 6.0-8.0 by test strip. Rationale: Conductivity should not be less than 13.5 or greater then 15.0 to prevent cell destruction." Observations during the survey on 4/26/06 at 11:00 AM revealed two patients dialysis treatments were initiated without the conductivity or pH manually checked using a meter or test strips. An interview with the facility manager on 4/26/06 at 2:00 PM confirmed the machine conductivity is manually checked on the machines once a day and is not manually checked for conductivity or pH prior to each patient's treatment initiation as required in the facility policy.	V 258			
V 264	405.2140(a)(5)(ii) AAMI - CHEMICAL CONTAMINANTS (AAMI 3.2.2) Maximum Level of Chemical Contaminants. The water used to prepare dialysate shall not	V 264		6/9/06	

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V 264	<p>Continued From page 5</p> <p>contain chemical contaminants at concentrations in excess of those in AAMI's Table 2. The manufacturer or supplier of the water treatment device shall recommend a system capable of meeting the requirements of this section. The physician in charge of dialysis has the ultimate responsibility for selecting the water treatment system and is also responsible for monitoring the water.</p> <p>Table 2 - Hemodialysis Water Quality: Maximum Allowable Chemical Contaminant Levels:</p> <table border="0"> <tr> <td>Contaminant</td> <td>Suggested Max Level</td> </tr> <tr> <td>Calcium</td> <td>2 (0.1 mEq/l)</td> </tr> <tr> <td>Magnesium</td> <td>4 (0.3 mEq/l)</td> </tr> <tr> <td>Sodium**</td> <td>70 (3.0 mEq/l)</td> </tr> <tr> <td>Potassium</td> <td>8 (0.2 mEq/l)</td> </tr> <tr> <td>Fluoride</td> <td>0.2</td> </tr> <tr> <td>Chlorine (free)</td> <td>0.5</td> </tr> <tr> <td>Chloramine</td> <td>0.1</td> </tr> <tr> <td>Nitrate (N)</td> <td>2.0</td> </tr> <tr> <td>Sulfate</td> <td>100.0</td> </tr> <tr> <td>Copper, Barium, Zinc</td> <td>each 0.1</td> </tr> <tr> <td>Aluminum</td> <td>0.01</td> </tr> <tr> <td>Arsenic, Lead, Silver</td> <td>each 0.005</td> </tr> <tr> <td>Cadmium</td> <td>0.001</td> </tr> <tr> <td>Chromium</td> <td>0.014</td> </tr> <tr> <td>Selenium</td> <td>0.09</td> </tr> <tr> <td>Mercury</td> <td>0.0002</td> </tr> </table> <p>**230 mg/l (10mEq/l) where sodium concentration has been reduced to compensate for the excess sodium in the water, as long as conductivity of the water is being continually monitored.</p>	Contaminant	Suggested Max Level	Calcium	2 (0.1 mEq/l)	Magnesium	4 (0.3 mEq/l)	Sodium**	70 (3.0 mEq/l)	Potassium	8 (0.2 mEq/l)	Fluoride	0.2	Chlorine (free)	0.5	Chloramine	0.1	Nitrate (N)	2.0	Sulfate	100.0	Copper, Barium, Zinc	each 0.1	Aluminum	0.01	Arsenic, Lead, Silver	each 0.005	Cadmium	0.001	Chromium	0.014	Selenium	0.09	Mercury	0.0002	V 264		
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V 264	Continued From page 6 This STANDARD is not met as evidenced by: Based on review of daily water logs, policies and procedures and interviews it was determined the facility failed to ensure the water used for hemodialysis was safe for patient treatment. Findings include: The policy titled "Hardness Testing: Water" included, "Hardness testing of water is done each treatment day: prior to the first patient run and after the RO (reverse osmosis) has been operating for no less than 15 min. and at the end of the day after the last patient shift and reuse is completed (if applicable)." On 4/25/06 at 1:30 PM during the initial tour of the facility the daily water logs were reviewed. The hardness testing for 4/25/06 had been documented as completed for the end of the day. The facility ran three dialysis shifts and were currently dialyzing the second shift. An interview with the facility manager on 4/25/06 at 3:00 PM confirmed the hardness testing had been completed prior to the end of the day and before the last patient shift.	V 264			
V 266	405.2140(b)(1) PE: INFECTION CONTROL There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to, appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and contaminants, and sterilization and disinfection, including the sterilization and	V 266		6/9/06	

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V 266	<p>Continued From page 7</p> <p>maintenance of equipment. Where dialysis supplies are reused, there are written policies and procedures covering the rinsing, cleaning, disinfection, preparation, and storage of reused items which conform to requirements for reuse in 405.2150.</p> <p>This STANDARD is not met as evidenced by:</p> <p>Based on observations and interviews the facility staff failed to follow their infection control policies for environmental cleaning.</p> <p>Findings include:</p> <p>Agency Policy Bleach Policy</p> <p>5. A 1:10 bleach solution is used to clean and decontaminate any environmental surface or non-disposable supplies which are visibly contaminated with blood or body fluids.</p> <p>6. A 1:100 bleach solution is used for routine disinfection procedures of environmental surface or non-disposable supplies which are not visibly contaminated with blood or body fluids.</p> <p>Agency Policy: Preparation of 1:10 Bleach Solution</p> <p>Calculations are 1000 ml (milliliters)= 100 ml of bleach to 900 ml water and 500 ml = 50 ml of bleach to 450 ml water.</p> <p>Agency Policy: Preparation of 1:100 Bleach Solution</p> <p>Calculations are 1000 ml (milliliters)= 10 ml of bleach to 990 ml water and 500 ml = 5 ml of</p>	V 266			

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V 266	Continued From page 8 bleach to 495 ml water. Observations in the treatment area on 4/25/06 revealed a pan of water labeled 1:100 bleach. A PCT (Patient Care Tech) was asked to describe the preparation of the bleach solution. The PCT replied, "I get a medication cup (30cc) of bleach and pour water up to here" and pointed to a level on the pan that was not the same as the amount in the pan. The surveyor asked what the facility used to clean blood spills and the PCT replied, "We use this 1:100 bleach for blood spills." An interview with the Nurse Manager on 4/26/06 at 11:00 AM verified the PCT did not follow the correct procedure for the preparation of the bleach solution and for blood spills.	V 266		
V 280	405.2140(d)(2) EMERGENCY PREP: PERIODIC DRILLS All personnel are trained, as part of their employment orientation, in all aspects of preparedness for any emergency or disaster. The emergency preparedness plan provides for orientation and regular training and periodic drills for all personnel in all procedures so that each person promptly and correctly carries out a specific role in case of an emergency. This STANDARD is not met as evidenced by: Based on review of fire drill reports, policies and procedures and interviews it was determined the facility failed to follow their policy for emergency preparedness. Findings include:	V 280		6/9/06

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V 280	Continued From page 9 The policy titled, "Fire/Disaster Drills" included, "Fire drills are to be conducted quarterly in order that all teammates are familiar with the appropriate steps which are to be followed during a fire." A review of the Fire Drill reports revealed no documentation of fire drills being conducted in 2004 and 2005. Interview with the facility manager on 4/26/06 at 8:30 AM confirmed no documentation of fire drills for staff for 2004 and 2005.	V 280			
V 431	405.2162(a) REGISTERED NURSE The dialysis facility employs at least one full time qualified nurse responsible for nursing service. (See 405.2102.) This STANDARD is not met as evidenced by: Based on record review and interview with the staff, it was determined the facility failed to ensure the RNs followed physician's orders in 2 of 2 records reviewed of patients with blood pressures above a diastolic of 110. Findings include: 1. Review of medical record # 377291 revealed standing orders dated 1-25-06 included: Hypertension: May give Clonidine 0.1mg (milligrams) PO (by mouth) for systolic >190 or diastolic >110..... Review of the flowsheet dated 4/10/06 revealed the patient's blood pressure was as follows: 7:36 AM - 205/135 8:17 AM - 190/112 9:17 AM - 183/114	V 431		6/9/06	

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V 431	<p>Continued From page 10</p> <p>9:49 AM - 176/117 10:47 AM - 188/115 11:17 AM - 174/112 11:47 AM - 178/121</p> <p>There was no documentation on the flowsheet of the patient receiving Clonidine.</p> <p>An interview with the Nurse Manager on 4/26/06 at 2:30 PM verified the nurse should have given the patient the Clonidine.</p> <p>2. Review of medical record # 1 revealed standing orders dated 1/25/06 to include: "Hypertension: May give Clonidine 0.1mg (milligrams) PO (by mouth) for systolic >190 or diastolic >110.....".</p> <p>Review of the flowsheet dated 3/27/06 at 0800 revealed the blood pressure was 155/113 and on 3/29/06 at 0821 the blood pressure was 154/111.</p> <p>There was no documentation on the flowsheet of the patient receiving Clonidine.</p>	V 431			