

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: 052694	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 04/02/2009
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE - LOS GATOS	STREET ADDRESS, CITY, STATE, ZIP CODE 14651 SOUTH BASCOM AVENUE #100 LOS GATOS, CA 95032
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V 000	<p>INITIAL COMMENTS</p> <p>Surveyor: 05189 The following represents the findings of the Department of Public Health during an investigation of Complaint Intake Number: CA00179912.</p> <p>Representing the Department of Public Health: Dorothy Rice, HFEN.</p> <p>The inspection was limited to the specific complaint being investigated and does not represent the findings of a full inspection of the facility.</p>	V 000		
V 126	<p>494.30(a)(1)(i) CDC RR-5 AS ADOPTED BY REFERENCE</p> <p>Hepatitis B Vaccination</p> <p>Vaccinate all susceptible patients and staff members against hepatitis B.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 05189 Based on staff interview and record review, the facility failed to implement its policy/procedure to offer the hepatitis vaccine to one (Patient 1) of one patients reviewed. This failure increased the risk of Patient 1 acquiring Hepatitis B (blood borne disease).</p> <p>Findings:</p> <p>A visit was made to the facility on 4/2/09. The review of the record showed that Patient 1 was admitted to the facility on 8/18/08. The</p>	V 126		5/6/09

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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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 126	Continued From page 1 pre-admission physician orders, dated 8/14/08 included an order for Hepatitis B antibody testing. Review of the test report dated 8/18/08 showed Patient 1 had a Hepatitis B antibody test result of <(less than) 10 mIU/ml . On 4/2/09 review of the facility policy for "Hepatitis B Vaccine: Guidelines" showed the following: 1. The Hepatitis B vaccine shall be offered to all ...patients including persons with positive immune status. 2. A protective antibody response is 10 or more milliinternational units (mIU) per milliliter (anti-HBs [at or above] 10 mIU/ml). There was no documentation in the record that showed Hepatitis B vaccine was offered to Patient 1. For example, the "Patient Consent Engerix-B Vaccination and Administration Record" for Patient 1 was blank (absent the patient's name). There was no documentation indicating that Patient 1 consented or declined the Hepatitis B vaccine. On 4/2/09, Staff B stated that the facility's practice was to include all relevant Hepatitis monitoring documentation (that included the Hepatitis vaccine offer) in the Infection Control Log. After intensive research, Staff B acknowledged that Patient 1's name was not in the Infection Control Log with any Hepatitis monitoring information. Staff B acknowledged the deficient practice and stated,"if it wasn't documented, it wasn't done".	V 126			
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	V 726		5/6/09	

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V 726	<p>Continued From page 2</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 05189 Based on staff interview and record review, the clinical record for one patient was not complete and accurate. (Patient 1) This failure placed Patient 1 at risk that medical and clinical decision might be made on inaccurate or incomplete information.</p> <p>Findings:</p> <p>1. On 4/2/09 during a visit to the facility, the record review showed that Patient 1 was admitted to the facility on 8/18/08. The pre-admission physician orders, dated 8/14/08 , included the following:</p> <ul style="list-style-type: none"> - Duration: 3 hours - Blood Flow (rate): 350-450 mL(milliliter)/min (minute) - Dialysate Flow (rate): 800 mL/min - Diphenhydramine (Benadryl), 25 mg, PRN (whenever necessary) severe Itching/severe Anxiety, IV (intravenously). - Acetaminophen, 1-2 tabs, PRN, Headache, Fever, Generalized pain, q (every) 4 hours. <p>a. On 4/2/09, review of the admission treatment record , dated 8/18/08, showed that Patient 1 had blood pressure readings from 119/68 mmHg (millimeter of mercury) to 138/68 mmHg during treatment . However, the treatment record showed an inaccurate computer-generated prescription for a 2.0 hour duration (instead of the ordered 3 hour duration), and a 300 mL/min</p>	V 726			

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V 726	<p>Continued From page 3</p> <p>Blood Flow Rate (instead of the ordered 350-450 mL/min Blood Flow Rate) without any justification/rationale. Moreover, the treatment record subsequently showed that Patient 1 inaccurately received the 2 hours of treatment from 1845 to 2045 , and only a 205 mL/min Blood Flow Rate delivery.</p> <p>During an interview on 4/2/09, Staff C stated that the possible justification for the lower blood flow rate was probably due to the needle gauge size which should have been documented. Staff C stated that the possible justification of the shorten treatment was that patients often received shorten treatments on their first day in the facility. Staff C acknowledged that the justification/rationale should have been documented in the medical record.</p> <p>b. Review on 4/2/09, showed that Patient 1's Nursing History and Assessment form, dated 8/20/08, was incomplete for Patient 1's vital sign assessment, i.e., no pulse, blood pressures and temperature readings were recorded.</p> <p>Additionally, the 8/20/08, dated treatment record continued to show an inaccurate computer-generated prescription. For example, the prescription continued to show a 2 hour duration (instead of the 3 hour ordered duration), a 300 mL/min Blood Flow Rate (instead of the 350-450 mL/min ordered Blood Flow Rate), and an additional inaccuracy of a 500 mL/min Dialysate Flow Rate (instead of the 800 mL/min ordered Dialysate Flow Rate) without any justification/rationale. The treatment record also showed that the inaccurate 250 mL/min Blood Flow Rate delivery (instead of the ordered 350-450 mL Blood Flow Rate) was delivered</p>	V 726			

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V 726	<p>Continued From page 4 during treatment.</p> <p>2. On 4/2/09, the review of the acute care hospital records showed that Patient 1 had a history of hypertension (high blood pressure) and had an abdominal aorta (large artery) aneurysm (blood vessel sac) repair done in 8/08.</p> <p>The 9/1/08 dated physician orders included the following: - Increase Dialysate Flow to 800 ml/min, per MD's (physician's) orders. - Increase tx (treatment) time to 3 hours, per MD's orders.</p> <p>a. Further review showed that on 10/25/08, Patient 1's treatment was initiated at 12:50 p.m. and was discontinued at 4:08 p.m. However, the treatment record showed an inaccurate 500 mL/min Dialysate Flow Rate delivery (instead of the ordered 800 mL/min Dialysate Flow Rate delivery) during treatment from 12:53 p.m. to 4:04 p.m..</p> <p>b. The 11/4/08 (Tuesday) dated treatment record showed that Patient 1's pre-treatment assessment included a 215/118 mmHg sitting blood pressure recording, and a 214/123 mmHg standing blood pressure recording. According to Staff B, the physician expected to be notified by staff when the systolic [top number] blood pressure reading was over 200 and the diastolic [lower number] reading was above 110. According to the treatment record, Patient 1 continued to have high blood pressure readings of 201/146 mmHg to 225/134 mmHg. Moreover, the post-treatment assessment included a sitting blood pressure reading of 223/143 mmHg.</p>	V 726			

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V 726	<p>Continued From page 5</p> <p>On 4/2/09 at approximately 1:40 p.m., Staff B stated that the physician stated (via telephone) that he expected staff to notify him when the systolic (top number) was over 200 mmHg and the diastolic (lower number) was above 110 mmHg.</p> <p>There was no documentation that the physician was notified on 11/4/08 of Patient 1's high blood pressure readings.</p> <p>c. The treatment record , dated 11/7/08 (Friday), showed a prescription for a 3.5 hour duration treatment. The pre-treatment assessment documentation on this date showed that Patient 1 had a 227/127 mmHg blood pressure reading, and "new complaints or new observations since last treatment". (According to the interview with Staff B and Staff C, and direct observation of the machine functioning mechanism on 4/2/09, the RN must evaluate/assess the patient's condition before the treatment could commence indicating that the RN was aware of the elevated blood pressure at that time.) The treatment record , dated 11/7/08, showed that Patient 1's treatment was started at 10:45 a.m. resulting in the completion at 14:15 (2:15 p.m.). During the treatment, Patient 1's blood pressure continued to be elevated. For example,</p> <ul style="list-style-type: none"> - At 10:48 (a.m.), the blood pressure reading was 217/129 mmHg. - At 11:32, the blood pressure reading was 211/119. - At 12:03 (p.m.) the blood pressure reading was 215/132. - At 12:33, the blood pressure reading was 215/119. <p>At 12:43 p.m., the "comment" section of the</p>	V 726			

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V 726	<p>Continued From page 6</p> <p>treatment record showed that Patient 1 "c/o [complained of pain] in back" and, in the medications section that Acetaminophen, 650 mg was administered at 12:39 (p.m.), and Diphenhydramine/Benadryl 25 mg was administered at 12:43 (p.m.). There was no severe Itching/severe Anxiety assessment documentation indicating the need for Benadryl administration at that time.</p> <p>- At 13:04 (1:04 p.m.), the blood pressure reading was 218/129 mmHg . The correlating "comment" section of the treatment record read, "Resting comfortably; bp [blood pressure] high; RN [registered nurse] aware."</p> <p>-At 13:27 (1:27 p.m.), the treatment record showed that staff administered Clonidine (medication indicated for high blood pressure), 0.10 mg., to Patient 1. The physician telephone orders instructed staff "To give 0.1 mg Clonidine, if diastolic [lower number] blood pressure > [above] 100 mmHg..." There was no time entry shown to designate when the staff initially attempted to call the physician (or refer the patient's condition to the physician), and subsequently received the medication order.</p> <p>- At 13:31 (1:31 p.m.), the blood pressure reading was 168/131 mmHg. with a correlating time interval "comment" section of the treatment record showed that Patient 1 "denies complaints".</p> <p>-At 14:02 (2:02 p.m.), the correlating "comment" section of the treatment record at this time interval showed: "Pt [patient] requested to go to the restroom."</p>	V 726			

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V 726	<p>Continued From page 7</p> <p>At 14:07 (2:07 p.m.), the correlating "comment" section of the treatment record showed the following: " [patient] vomiting; tx terminated. CN [charge nurse] notified of bp [blood pressure]".</p> <p>At 15:13 (3:13 p.m.), the post treatment "Note" section of the treatment record showed the following summary assessment: "High bp [blood pressure] pre, during and post hd [hemodialysis]; referred to [MD] with orders made; to give .1 mg. clonidine and rechecked after hd; - Tx ended 19 minutes early due to Agitation; bp still high, 230/121; referred to [MD] with orders made; to give .1 mg. clonidine and rechecked after 30-45 minutes. If still high, may send to [acute care hospital] er [emergency room]; -1515 [3:15]H [hour]; bp rechecked 210/118; may send to [acute care hospital] er [emergency room]as ordered."</p> <p>In summary, the documentation was not consistently clear. For example, the "medications" section of the treatment record documentation showed that staff administered a one time dose of Diphenhydramine/Benadryl, 25 mg, IV (ordered for severe anxiety) at 12:43 p.m.. The correlating "comment" section of the treatment record at this time entry showed no documentation indicating anxiety.</p> <p>Additionally, the medical record was not complete with pertinent clinical information. For example, staff started Patient 1's treatment at 10:45. Prior to and throughout the treatment, Patient 1 had high blood pressure readings. Although the documentation, staff interview and machine operation observation (as indicated above) showed that the RN was knowledgeable about the high blood pressure condition even</p>	V 726			

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V 726	<p>Continued From page 8</p> <p>prior to the start of treatment at 10:45, there was no documentation that showed when the physician was initially notified of the ongoing high blood pressure condition until staff administered the first dose of Clonidine medication at 1:27 p.m..</p> <p>d. The review of the facility's Guidelines For Emergency Transfer Of Patient To Hospital" showed the following instructions:</p> <p>a. Emergency Rescue must be called to transport the patient to the hospital.</p> <p>b. The nurse in charge will call the hospital emergency unit, inform them of the planned transfer of the patient and relate pertinent information about the patient's condition.</p> <p>c. The family should be notified of the event by the Nurse in charge, ...</p> <p>d. Refer to the Clinical Variance & Medical Device Reporting Manual for the list of events that must be documented in a clinical variance report. Any clinical variance resulting in ...hospitalization...of patients...must be reported immediately to Clinical Services...</p> <p>The review of the Clinical Variance & Medical Device Reporting Manual showed a clinical variance is "a serious or unexpected patient...occurring in the facility which include: Event that occur in conjunction with ...the dialysis treatment..."</p> <p>There was no documented evidence that Patient 1's family was notified of the transfer that paramedics were called for transport, and there was no documented variance report filed.</p>	V 726			