

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: 552561	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 07/08/2009
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE OF LA JOLLA			STREET ADDRESS, CITY, STATE, ZIP CODE 4765 CARMEL MOUNTAIN ROAD, SUITE 100 SAN DIEGO, CA 92130	
(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 Surveyor: 14724 The following represents the findings of the Department of Public Health during a recertification visit. The facility census at the time of the visit was 47 patients and the patient sample size was 5 patients.	V 000		
V 116	Representing the Department of Public Health was Teri Spencer, HFEN. 494.30(a)(1)(i) CDC RR-5 AS ADOPTED BY REFERENCE 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: Surveyor: 14724 Based on observation and staff interview, the facility failed to ensure 8 of 8 electronic record data entry stations were kept at a sufficient distance from the hemodialysis stations to prevent contamination with blood borne pathogens, resulting in the potential for cross-contamination between patients, via the	V 116		8/5/09
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 116	Continued From page 1 data entry touch screens. Findings: On 7/06/09, direct care staff were continuously observed between 10:27 A.M. and 12:35 P.M., delivering care to the hemodialysis patients during the turnover between the first and second patient shifts. The staff recorded data on the dialysis treatment records at moveable chairside electronic entry stations, equipped with touch screens. A data entry station was located between every 2 dialysis stations. During the observation period, the data entry stations were located within 12-24 inches of the dialysis machines. The proximity of the data entry stations to the dialysis stations created the potential for contamination of the touch screens with blood borne pathogens. Staff repeatedly touched the data entry touch screens with bare hands, and did not sanitize their hands before proceeding to other tasks such as caring for another patient, obtaining clean supplies, and touching other data entry touch screens. Staff did not wipe or disinfect the data entry touch screens during the observation period. These actions increased the potential for cross contamination and the spread of infections between the patients, via the data entry touch screens. On 7/06/09 at 12:42 P.M., the Clinical Manager stated that the data entry stations should be kept within sufficient distance from the dialysis stations to prevent contamination and that staff were to touch the screens only with their clean bare hands.	V 116			
V 412	494.60(d)(2) EMERGENCY PREPAREDNESS	V 412		8/5/09	

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V 412	<p>Continued From page 2</p> <p>The facility must provide appropriate orientation and training to patients, including the areas specified in paragraphs (d)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 14724 Based on patient interview, staff interview and medical record review, the facility failed to ensure 4 of 5 sampled patients (1,2,4,5) received education and information about emergency evacuation and disaster preparedness.</p> <p>Findings:</p> <p>1. Patient 1 was admitted to the facility on 4/27/09 and received nocturnal hemodialysis 3 times per week for a period of 8 hours. When interviewed on 7/8/09 at 12:36 P.M., Patient 1 stated that no one at the facility had reviewed emergency disconnect and building evacuation procedures with him. The patient stated he had not received disaster preparedness information from the facility staff, nor instructions about whom to contact for information on how to obtain his dialysis treatments, in the case of a disaster.</p> <p>When reviewed on 7/8/09, the medical record for Patient 1 did not contain evidence that the patient was informed about emergency evacuation procedures or disaster preparedness. There was no "Patient Education" document in the record.</p> <p>2. Patient 4 was admitted to the facility on 4/20/09, and received hemodialysis 3 times a week. During an interview on 7/6/09 at 3:44 P.M., Patient 4 stated he was not given any education or information about emergency evacuation of the facility or disaster preparedness. Patient 4 was</p>	V 412			

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V 412	<p>Continued From page 3</p> <p>not aware of whom to contact about his dialysis treatments, in the case of a disaster.</p> <p>A 7/8/09 review of the medical record for Patient 4 showed no documented evidence that staff informed the patient of emergency procedures and disaster preparedness. There was no "Patient Education" document in the record.</p> <p>3. Patient 5 was admitted to the facility on 3/9/09. He stated during interview on 7/6/09 at 12:31 P.M. that no one had reviewed emergency disconnect and evacuation procedures with him since admission. The patient stated he was not aware of specific disaster procedures he should follow, or how to obtain information about getting his dialysis treatments in the case of a disaster.</p> <p>When reviewed on 7/8/09, Patient 5's medical record supported the information from the interview, showing no evidence that Patient 5 was given information about emergency evacuation procedures or disaster preparedness. There was a "Patient Education" document in the record, but the page titled "Medical Emergencies and Natural Disasters" was blank.</p> <p>4. During a 7/8/09 review of the medical record for Patient 2, there was no "Patient Education" document in the record. There was no indication that Patient 2 was instructed about emergency and disaster procedures.</p> <p>When interviewed on 7/8/09 at 9:39 A.M., the Charge Nurse explained that the previous Clinical Manager was responsible for educating all new patients in emergency and disaster procedures. The emergency disconnect and evacuation procedures were reviewed with all of the patients</p>	V 412			

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V 412	Continued From page 4 on a quarterly basis thereafter. The Charge Nurse stated she did not know who was responsible for new patient education since the previous Clinical Manager left. The Charge Nurse stated that all patient education was to be documented on the "Patient Education" form in the patients' medical records. When interviewed on 7/8/09 at 9:45 A.M., the current Clinical Manager stated she was unaware that no one at the facility was providing the new patients with emergency and disaster education. The Clinical Manager explained that the patients were to be provided with a centralized phone number to call for instructions on how to obtain their dialysis treatments, in the case of a disaster.	V 412			
V 506	494.80(a)(3) ASSESSMENT CRITERIA [The patient's comprehensive assessment must include, but is not limited to, the following:] Immunization history, and medication history. This STANDARD is not met as evidenced by: Surveyor: 14724 Based on staff interview and medical record review, the facility failed to ensure 5 of 5 sampled patients (1,2,3,4,5) were assessed for their immunization history and status, resulting in failure to offer vaccinations as indicated. Findings: 1. Patient 1 was transferred to the facility on 4/27/09. The medical record was reviewed on 7/8/09. The record did not contain evidence that the facility interdisciplinary team assessed the	V 506		8/5/09	

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V 506	<p>Continued From page 5</p> <p>patient's immunization status for hepatitis B, pneumococcal pneumonia, and influenza . There were no lab reports for hepatitis B immunity status (no antibody titer), and the section on the May, 2009 "Comprehensive Interdisciplinary Assessment" for "Immunization Status" was blank.</p> <p>2. Patient 2 was admitted to the facility on 2/9/09. The medical record was reviewed on 7/8/09. The record did not indicate that the facility interdisciplinary team assessed the patient's status regarding the pneumococcal vaccine. The "Immunization Status" section on the March, 2009 "Comprehensive Interdisciplinary Assessment" had the words "Pt. didn't get any of these vaccines" across it.</p> <p>3. Patient 3 was admitted to the facility on 2/9/07. The medical record was reviewed on 7/7/09. The most current "Comprehensive Interdisciplinary Assessment" of Patient 3 was dated March, 2009. There was no indication that the patient's immunization history was considered. That section was blank. Patient 3's record had no evidence that staff assessed assessed the patient's status related to the pneumococcal vaccine since admission, or assessed the patient's status related to the influenza vaccine since October, 2007.</p> <p>4. Patient 4 was admitted to the facility on 4/20/09. The medical record was reviewed on 7/8/09. There was no indication that the facility interdisciplinary team assessed Patient 4's status regarding the pneumococcal or influenza vaccines. The laboratory results since admission showed that Patient 4 was susceptible to hepatitis B; but there was no indication that the patient had</p>	V 506			

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V 506	Continued From page 6 been informed about or offered the hepatitis B vaccine. The immunization history section on the May, 2009 comprehensive assessment of the patient was blank. 5. Patient 5 was admitted to the facility on 3/9/09. The medical record was reviewed on 7/8/09. The record did not contain evidence that staff assessed Patient 5 for the presence of tuberculosis, or checked his immunization status for pneumococcal pneumonia or influenza. The immunization status section on the March, 2009 comprehensive assessment of Patient 5 was blank. During an interview on 7/6/09 at 10:00 A.M., the Clinical Manager explained that all new patients were to be assessed for the presence of tuberculosis, either by a recent chest x-ray or a skin test, on admission. During an interview on 7/8/09 at 3:20 P.M., the Charge Nurse explained that all new patients were to be interviewed about their immunization status for hepatitis B, pneumococcal pneumonia and influenza. If indicated, all patients were to be offered the vaccines. The influenza vaccine was to be offered to the existing patients every fall season. The Charge Nurse stated that it had been difficult to keep up with the vaccination program at the facility in recent months, and confirmed that the immunization histories for Patients 1,2,3,4, and 5 were not current.	V 506			
V 511	494.80(a)(8) ASSESSMENT CRITERIA [The patient's comprehensive assessment must include, but is not limited to, the following:] (8) Evaluation of dialysis access type and maintenance (for example, arteriovenous fistulas,	V 511		8/5/09	

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V 511	Continued From page 7 arteriovenous grafts and peritoneal catheters). This STANDARD is not met as evidenced by: Surveyor: 14724 Based on interview and record review, the facility interdisciplinary team failed to ensure assessment of the developing arteriovenous fistulas of 2 of 5 sampled patients (4,5). Findings: 1. Patient 4 was admitted to the facility on 4/20/09. He stated during interview on 7/6/09 at 3:44 P.M. that he was was being dialyzed via a central venous catheter. Patient 4 stated that he had an arteriovenous fistula placed in his forearm, but did not recall the date of his surgery. Patient 4 stated he did not know anything about his fistula, and had not had any instruction in how to exercise his arm to help it develop. When the medical record for Patient 4 was reviewed on 7/8/09, there was minimal documentation about the fistula. The dialysis treatment records listed the "AVFist/standard/Wrist-Radial/Cephalic-Rt...Matur ing" . The medical record did not indicate when the fistula was created or subsequent assessments of it to determine it's progress towards viability for use in hemodialysis except for the June, 2009 "Patient Plan of Care" under "Dialysis Access", that Patient 4 was dialyzed with a "cuffed catheter with maturing fistula" and that the patient "Met goal, continue with current plan". 2. Patient 5 was admitted to the facility on 3/9/09.	V 511			

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V 511	Continued From page 8 Patient 5 stated on 7/6/09 at 12:31 P.M. that he was dialyzed with a central venous catheter. Patient 5 stated he had an arteriovenous fistula placed a few months before, which had not yet been used for dialysis. When the medical record for Patient 5 was reviewed on 7/8/09, there was minimal documentation about the fistula. The dialysis treatment records listed the "AVFist\standard/Wrist-Radial/Cephalic-Rt...Matur ing", but there was no evidence staff assessed the fistula for its progress towards viability for use in hemodialysis. The March, 2009 Patient Plan of Care listed the catheter, without mention of the fistula. During an interview on 7/8/09 at 3:20 P.M., the Charge Nurse clarified that the goal for all patients being dialyzed via catheters while awaiting fistulas to develop was to encourage the patient to do exercises for fistula development and expedite removal of the catheter. The Charge Nurse stated that staff were expected to assess the fistula periodically while it was developing.	V 511			
V 516	494.80(b)(1) FREQUENCY OF ASSESSMENT An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session. This STANDARD is not met as evidenced by: Surveyor: 14724 Based on record review and interview, the facility interdisciplinary team failed to provide a comprehensive interdisciplinary assessment	V 516		8/5/09	

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V 516	Continued From page 9 within 30 days or 13 treatments after admission for 1 of 5 sampled patients (1). Findings: Patient 1 was admitted to the facility on 4/27/09. The medical record was reviewed on 7/8/09. Patient 1 received nocturnal hemodialysis 3 times per week. The initial "Comprehensive Interdisciplinary Patient Assessment" for Patient 1 was incomplete as was the corresponding Patient Plan of Care. There was no evidence of the involvement of the physician treating the patient. The documentation from the dietitian was incomplete and lacked the dietitian's signature. When interviewed on 7/8/09 at 3:30 P.M., the Clinical Manager stated that the initial comprehensive patient assessment was to be completed within the patient's first 30 days or 13 treatments.	V 516			
V 543	494.90(a)(1) DEVELOPMENT OF PATIENT PLAN OF CARE (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; This STANDARD is not met as evidenced by: Surveyor: 14724 Based on interview and record review, the facility failed to ensure the implementation of the plan of care for fluid and blood pressure management and intradialytic monitoring for 4 of 5 sampled patients (2,3,4,5) and 1 randomly observed patient (10).	V 543		8/5/09	

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V 543	<p>Continued From page 10</p> <p>Findings:</p> <p>1a. Patient 5 was admitted to the facility on 3/20/09. The medical record was reviewed on 7/8/09. A written physician's order, dated 5/29/09, increased Patient 5's dry weight (the target weight identified as the goal for fluid removal during dialysis) by 2 kilograms (4.4 pounds), to 83 kilograms. The dialysis treatment records between 6/1/09 and 6/22/09 did not reflect the increase in dry weight. Eight-one kilograms was still listed as the dry weight to be achieved. During the 3 week period, Patient 5 had occasional symptoms of fluid depletion, such as drops in blood pressure on 6/3/09 and 6/5/09, and muscle cramping on 6/18/09 and 6/22/09.</p> <p>During an interview on 7/8/09 at 3:20 P.M., the Charge Nurse confirmed that the 5/29/09 dry weight change for Patient 5 was missed.</p> <p>1b. On 7/6/09 at 9:15 A.M., during initial tour of the hemodialysis patient treatment area, the Clinical Manager stated that staff were to monitor the patients' vital signs and machine parameters at least every 30 minutes during dialysis. The 6/3/09 treatment record for Patient 5 showed that the patient was monitored by staff at 1:02 P.M., then not until 2:27 P.M., when his treatment was terminated</p> <p>2. On 7/6/09 at 9:15 A.M., during initial tour of the hemodialysis patient treatment area, the Clinical Manager stated that staff were to monitor the patients' vital signs and machine parameters at least every 30 minutes during dialysis.</p> <p>a. At 9:20 A.M. on 7/6/09, Patient 10 received dialysis at station 2, and the electronic dialysis</p>	V 543			

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V 543	Continued From page 11 treatment record for Patient 10 was reviewed with the Clinical Manager. The treatment record showed that the last time Patient 10 was monitored by staff was at 8:30 A.M., 50 minutes earlier. b. At 9:26 A.M. on 7/6/09, Patient 3 received dialysis at station 13. The electronic treatment record showed that the last time staff monitored Patient 3 was at 8:41 A.M., 45 minutes earlier. Subsequent review of the treatment records identified that on 6/22/09 Patient 3' s treatment was initiated at 6:28 A.M. The patient was not monitored again for one hour, at 7:29 A.M. c. The 6/24/09 treatment record showed that Patient 4 was monitored by staff at 5:01 P.M., then not again until his treatment was terminated at 7:03 P.M. d. .The 6/19/09 treatment record for Patient 2 showed that he was monitored by staff at 2:04 P.M., then not again until 3:05 P.M.	V 543		
V 715	494.150(c)(2)(i) POLICIES AND PROCEDURES The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; This STANDARD is not met as evidenced by: Surveyor: 14724 Based on observation, patient interview, staff interview and review of policies and procedures, the facility failed to ensure staff assessed the pulses of 3 of 5 sampled patients (2,4,5), and 5 randomly observed patients (6,7,8,9, 11) before	V 715		8/5/09

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552561	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 07/08/2009
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE OF LA JOLLA			STREET ADDRESS, CITY, STATE, ZIP CODE 4765 CARMEL MOUNTAIN ROAD, SUITE 100 SAN DIEGO, CA 92130		
(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 715	<p>Continued From page 12 and/or after their hemodialysis treatments, in accordance with facility policy.</p> <p>Findings:</p> <p>On 7/6/09, direct care staff were continuously observed between 10:27 A.M. and 12:35 P.M. while delivering care to the hemodialysis patients during the turnover between the first and second patient shifts. During the observation period, staff terminated the hemodialysis treatments and discharged Patient 6 (station 4), Patient 8 (station 3), and Patient 7 (station 5), and subsequently admitted and initiated the hemodialysis treatments for Patient 2 (station 2), Patient 9 (station 3) and Patient 11 (station 4). The staff members caring for the 6 patients did not auscultate (listen to and measure) the patient's apical pulses nor palpate (feel) their radial pulses at any time during the observation period. In each case, the patient's blood pressure and heart rate were taken by an automated blood pressure module on the hemodialysis machine. The automated blood pressure modules did not have the capability to determine the patient's heart rhythm as regular or irregular.</p> <p>On 7/6/09 at 12:23 P.M., Registered Nurse 1 (RN 1) stated that the staff were expected to either auscultate the apical pulse or palpate the radial pulse of all patients before and after their dialysis treatments. RN 1 confirmed that he had "forgotten" to do so when admitting Patient 2 on 7/6/09; but stated that he had palpated Patient 9's pulse before dialysis. When the documentation entered into the electronic dialysis treatment records for Patients 2,6,7,8,9, and 11 was reviewed with RN 1 at 12:30 P.M., the patients' pulse rhythms were documented as "R" in each</p>	V 715			

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

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V 715	<p>Continued From page 13</p> <p>case. RN 1 clarified that the "R" meant that the patient's heart rhythm was regular. RN 1 confirmed that without auscultating or palpating the patient's pulse, the staff could not determine whether the patient's heart rhythm was regular or irregular.</p> <p>During separate interviews on 7/6/09 with Patient 4 @ 3:44 P.M. and Patient 5 @12:31 P.M., both patients stated that the staff did not routinely palpate their pulses nor listen to their hearts before or after their dialysis treatments.</p> <p>The facility procedures for "Evaluating the Patient Pre-Dialysis" and "Evaluating the Patient Post-Dialysis" both included "determination of pulse" as a required component of the patient evaluations. The rationale listed for taking the patient's pulse before dialysis was to provide "baseline information should the patient develop chest pain, arrhythmias [irregular heart rhythms] or other symptoms during treatment". The rationale for taking the patient's pulse after dialysis was listed as "To determine...if rate is irregular. Can serve as an indicator of arrhythmias, patient's volume status or infection".</p> <p>The failure to assess patients' pulse rhythms before and after hemodialysis created the potential for undetected cardiovascular abnormalities, such as arrhythmias, which could result in adverse patient symptoms and cardiac arrest.</p>	V 715			