

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: 552513	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 04/17/2009
NAME OF PROVIDER OR SUPPLIER COLLEGE DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 6535 UNIVERSITY AVENUE SAN DIEGO, CA 92115	
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V 000	INITIAL COMMENTS Surveyor: 14724 The following represents the findings of the Department of Public Health during a recertification visit. The patient census of the facility at the time of the visit was 73, and the patient sample consisted of 5 hemodialysis patients and 2 home peritoneal dialysis patients. Representing the Department of Public Health was Teri Spencer, HFEN. Abbreviations used in this document: CC Clinical Coordinator FA Facility Administrator PCT Patient Care Technician RN Registered Nurse TB tuberculosis	V 000		
V 113	494.30(a)(1)(i) CDC RR-5 AS ADOPTED BY REFERENCE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station. This STANDARD is not met as evidenced by: Surveyor: 14724 Based on observation and interview, the facility failed to ensure 1 of 3 staff members (PCT 1) changed gloves when indicated between performing dirty and clean tasks, resulting in the potential for cross contamination with blood borne pathogens.	V 113		5/15/09

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 113	Continued From page 1 Findings: On 4/15/09, between 8:15 A.M. and 9:50 A.M. three direct care staff were continuously observed working at hemodialysis stations 13, 14, 17 and 18 during the turnover between the first and second shifts of hemodialysis patients. Episodes when PCT 1 did not change gloves and sanitize hands when indicated were as follows: 1. At 8:30 A.M., PCT 1 terminated the dialysis treatment for the first shift patient at station 13. PCT 1 donned gloves, disconnected the arterial blood line, flushed the patient's arterial needle, and initiated the blood return process. Without changing the contaminated gloves, PCT 1 proceeded to type on the keyboard between stations 13 and 14, contaminating the keyboard. 2. At 8:56 A.M., PCT 1 terminated the dialysis for the first shift patient at station 14. PCT 1 did not change gloves between disconnecting the patient's arterial needle, and typed on the keyboard between stations 14 and 13 with the contaminated gloves. On 4/15/09 at 9:10 A.M., RN 4 stated that the keyboards between every 2 dialysis stations were considered to be clean, and staff were to only type on them with sanitized bare hands or clean gloves, to prevent contamination of the keyboards.	V 113			
V 116	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	V 116		5/15/09	

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V 116	<p>Continued From page 2</p> <p>another patient.</p> <p>-- 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.</p> <p>-- 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.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 14724 Based on observation and staff interview, the facility failed to ensure staff disinfected 2 of 4 blood pressure cuffs between use on different patients.</p> <p>Findings:</p> <p>On 4/15/09, between 8:15 A.M. and 9:50 A.M., direct care staff were continuously observed working at hemodialysis stations 13, 14, 17 and 18 during the turnover between the first and second shifts of hemodialysis patients. The blood pressure cuffs, attached to each dialysis machine, were not changed out between patients, and were used for all of the patients dialyzed on that machine. During the observations, staff terminated the dialysis treatments for the first shift patients and prepared the dialysis stations for the second shift patients at the 4 stations. The staff did not wipe or sanitize the blood pressure cuffs at stations 13 and 14 when cleaning the station after the first shift patients and prior to using them on the second shift patients .</p>	V 116			

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V 116	Continued From page 3 When interviewed on 4/15/09 at 11:25 A.M., PCT 3 stated that the blood pressure cuffs were to be wiped with a disinfectant cloth between use on different patients.	V 116			
V 122	494.30(a)(4)(ii) PROCEDURES FOR INFECTION CONTROL [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. This STANDARD is not met as evidenced by: Surveyor: 14724 Based on observation and staff interview, the facility failed to ensure 5 of 7 dialysis chairs were sufficiently cleaned and disinfected between patients, resulting in residual blood and trash on the chairs. The facility also failed to keep dialysate concentrate jugs capped and periodically clean the outside surfaces of the same jugs on 2 of 2 storage carts. Findings: 1. On 4/14/09 at 8:59 A.M. the cleaned dialysis chairs at stations 1, 3, 7, 10, 15, 16, and 18 were inspected while in the reclining position. Five of the 7 chairs had dried brownish red liquid dripping along the inside surfaces of the seat cushion and chair back. The chairs at stations 3 and 15 had pieces of trash and soiled gauze along the sides of the chair cushions.	V 122		5/15/09	

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V 122	Continued From page 4 When interviewed on 9:15 A.M. on 4/14/09, the FA stated that the brownish-red liquid on the chairs was dried blood. The FA stated that the blood on the chairs indicated that staff did not thoroughly wipe down the chairs after a patient had bleeding from their vascular access sites. On 4/15/09, between 8:15 A.M. and 9:50 A.M., direct care staff cleaned and wiped down the dialysis chairs at stations 13, 14, 17, and 18 between the first and second shifts of hemodialysis patients. The staff did not recline the chairs while wiping them down, and wiped only the chair surfaces that were visible while the chairs were in the upright position. 2. On 4/14/09 at 11:50 A.M., two carts were located in the hemodialysis patient treatment area. The carts had numerous 5 gallon jugs on them. Some of the jugs were labeled as containing acid dialysate concentrate solution, while other jugs, which were identical to the acid dialysate concentrate jugs, had a small label of "citric acid" on them. The acid dialysate concentrate jugs did not have caps on them, leaving them open to air. The outside surfaces of the acid dialysate concentrate jugs were dirty with crusted dialysate on the outsides. When interviewed at the time, the Technical Supervisor stated that the acid jugs should have caps on them, and the outside surfaces should be cleaned periodically. The Technical Supervisor stated that, because they appeared so much alike, the acid dialysate concentrate jugs should not be stored with the citric acid jugs, to prevent accidental mix ups.	V 122			
V 142	494.30(b)(1) OVERSIGHT	V 142		5/15/09	

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V 142	<p>Continued From page 5</p> <p>The facility must-</p> <p>(1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit;</p> <p>This STANDARD is not met as evidenced by: Surveyor: 14724 Based on interview and record review, the facility failed to ensure the implementation of policies for screening staff for TB for 2 of 7 staff members whose personnel files were reviewed (RN 2 and PCT 4).</p> <p>Findings:</p> <p>On 4/17/09, the personnel files for 7 staff members who had direct contact with patients were reviewed. Two of the files did not have evidence of current screening for TB:</p> <p>1. The file for RN 2 showed a hire date of 8/28/08, and a TB symptom questionnaire, dated 8/18/08. There was no other screening for TB in the file.</p> <p>2. The most current screening for TB in PCT 4's file was a symptom questionnaire, dated in March, 2006.</p> <p>When interviewed on 4/17/09 at 3:35 P.M., the FA stated that the facility policy required all staff to have a PPD test upon hire and annually thereafter. Those staff who had a previous positive PPD test were required to have a chest x-ray upon hire and an annual symptom questionnaire thereafter. The FA confirmed that RN 2 should have had a chest x-ray upon hire, and that the TB screening for PCT 4 was not</p>	V 142			

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V 142	Continued From page 6	V 142			
V 228	<p>current.</p> <p>494.40(a) ANSI/AAMI RD52:2004 AS ADOPTED BY REFERENCE</p> <p>5.4.4.1 Mixing systems: labeling Labeling strategies should permit positive identification by anyone using the contents of mixing tanks, bulk storage/dispensing tanks, and small containers intended for use with a single hemodialysis machine.</p> <p>Mixing tanks: Prior to batch preparation, a label should be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. This labeling should remain on the mixing tank until the tank has been emptied.</p> <p>Bulk storage/dispensing tanks: These tanks should be permanently labeled to identify the chemical composition or formulation of their contents.</p> <p>Concentrate jugs: At a minimum, concentrate jugs should be labeled with sufficient information to differentiate the contents from other concentrate formulations used at the facility.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 14724 Based on observation and staff interview, the facility failed to ensure that 3 of 3 acid dialysate concentrate holding tanks were sufficiently labeled as to the chemical composition or formulation of their contents.</p> <p>Findings: On 4/14/09 at 8:23 A.M., the 3 acid dialysate</p>	V 228		5/15/09	

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V 228	Continued From page 7 concentrate holding tanks that supplied the centralized dialysate distribution system were not fully labeled, as to their contents. Each tank had a small label affixed to it, that identified the potassium and calcium concentrations, with no indication of the other dialysate components or the proportioning ratio of the acid dialysate concentrate. When interviewed at that time, the Technical Supervisor stated that the holding tanks should have a copy of the entire label from the acid dialysate concentrate powder on them, to fully identify the contents.	V 228			
V 402	494.60(a) PHYSICAL ENVIRONMENT: BUILDING 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: Surveyor: 14724 Based on observation and staff interview, the facility failed to ensure 1 of 2 acid dialysate concentrate pumps were adequately maintained and free of potential electrical hazards. Findings: On 4/14/09 at 8:26 A.M., the dialysate pump connected to the 1.0 potassium acid dialysate holding tank was corroded, rusted and had a buildup of crystallized, crusted dialysate on the outside surfaces. The transfer tubings from the acid concentrate mixing system were suspended over the pump, and dripping acid dialysate	V 402		5/15/09	

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V 402	Continued From page 8 concentrate on it. The pump was not covered or protected. This created an electrical hazard for anyone touching the pump. On 4/14/09 at 11:00 A.M., the Technical Supervisor confirmed that the dialysate concentrate dripping on the dialysate pump created an electrical hazard.	V 402			
V 502	494.80(a)(1) ASSESSMENT CRITERIA The patient's comprehensive assessment must include, but is not limited to, the following: (1) Evaluation of current health status and medical condition, including co-morbid conditions. 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 current health status of 1 of 7 sampled patients (6). Findings: Patient 6 was a home peritoneal dialysis patient of the facility. A 4/17/09 review of the medical record for Patient 6 showed that she was previously on hemodialysis, and transferred to the facility to be trained to do peritoneal dialysis in November, 2008. The most current history and physical in the record, used for the comprehensive patient assessment of Patient 6, was dated 2/06/06. During a 4/17/09, 1:53 P.M. interview, the Home Training Supervisor stated that all of the patients'	V 502		5/15/09	

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V 502	Continued From page 9	V 502			
V 520	<p>records were to have at least annual history and physical reports.</p> <p>494.80(d)(2) PATIENT REASSESSMENT</p> <p>[In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted-]</p> <p>(2) At least monthly for unstable patients including, but not limited to, patients with the following:</p> <ul style="list-style-type: none"> (i) Extended or frequent hospitalizations; (ii) Marked deterioration in health status; (iii) Significant change in psychosocial needs; or (iv) Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis. <p>This STANDARD is not met as evidenced by: Surveyor: 14724 Based on interview and record review, the facility failed to ensure there was a comprehensive interdisciplinary assessment of 1 of 7 sampled patients (2) when the patient became unstable.</p> <p>Patient 2 was admitted to the facility on 8/09/06, and was interviewed on 4/15/09. Patient 2 stated that his health had deteriorated significantly within the past year. The patient stated he had been in the hospital a few times, had one leg amputated, and had a serious blood infection.</p> <p>A 4/16/09 review of the medical record for Patient 2 showed that he met the regulatory criteria</p>	V 520		5/15/09	

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V 520	Continued From page 10 for "unstable" in 2009. The laboratory results and dietary progress notes showed that Patient 2 had poor nutritional status (albumin levels below 2.8), and the laboratory results showed that the patient had anemia (hemoglobin below 10) and poor adequacy values (Kt/V below 1.2) during February and March, 2009. The most recent comprehensive interdisciplinary assessment of Patient 2 in the record was completed in October, 2008. The most recent patient care plan document, in the record, was dated May, 2008. During an interview on 4/17/09 at 2:00 P.M., the CC stated that Patient 2 was well-known to the facility interdisciplinary team, and had not changed much since October, 2008. The CC confirmed that Patient 2 met the criteria for "unstable", and should have been on the list for monthly comprehensive assessments.	V 520			
V 587	494.100(b)(2),(3) HOME DIALYSIS MONITORING [The dialysis facility must -] (2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and (3) Maintain this information in the patient's medical record. This STANDARD is not met as evidenced by: Surveyor: 14724 Based on interview and record review, the facility failed to ensure self-monitoring data was retrieved and reviewed for 1 of 2 home peritoneal dialysis patients (7).	V 587		5/15/09	

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V 587	Continued From page 11 Findings: Patient 7 was a home peritoneal dialysis patient whose medical record was reviewed on 4/17/09. The medical record lacked any documentation of Patient 7's dialysis treatments. There were no peritoneal dialysis "flow sheets" in the record. During a 4/17/09, 1:50 P.M. interview, the Home Training Nurse stated that all home dialysis patients were instructed to record their dialysis treatment data daily onto "flow sheets", and bring the "flow sheets" into the facility every month for staff review. The Home Training Nurse stated that Patient 7 was readmitted to the facility in 2008, and was resistant to bringing in his flow sheets, despite being reminded about the requirement to do so. The Home Training Nurse stated that the facility interdisciplinary team had not discussed Patient 7's resistance to comply with this and she had not documented it in the medical record.	V 587			
V 589	494.100(c)(1)(i) SUPPORT SERVICES Services include, but are not limited to, the following: (i) Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care. This STANDARD is not met as evidenced by: Surveyor: 14724 Based on interview, record review and policy and procedure review, the facility failed to monitor the home adaptation of 1 of 2 home peritoneal dialysis patients (6).	V 589		5/15/09	

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V 589	Continued From page 12 Findings: Patient 6 was admitted to the facility on 9/11/08 and was trained to do home peritoneal dialysis in November, 2008. When the medical record for Patient 6 was reviewed on 4/17/09, there was no evidence of physical surveillance of the patient's home dialysis environment. There was no "home visit" documented in the record. When interviewed on 4/17/09 at 1:55 P.M., the Home Training Nurse stated that home training staff were required to go to every home dialysis patient's home at the completion of the patient's training, to assess their home dialysis environment. The Home Training Nurse acknowledged that no home visit was conducted for Patient 6, due to scheduling problems. The facility policy #5-01-23, originated in September, 2006, required staff to conduct an initial home visit "to assess the patient's home adaptation" during their training period or within 30 days thereafter.	V 589			
V 711	494.150 RESPONSIBILITIES OF THE MEDICAL DIRECTOR The dialysis facility must have a medical director who meets the qualifications of §494.140(a) to be responsible for the delivery of patient care and outcomes in the facility. The medical director is accountable to the governing body for the quality of medical care provided to patients. This STANDARD is not met as evidenced by: Surveyor: 14724	V 711		5/15/09	

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NAME OF PROVIDER OR SUPPLIER COLLEGE DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 6535 UNIVERSITY AVENUE SAN DIEGO, CA 92115		
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V 711	Continued From page 13 Based on staff interview and facility record review, the facility failed to ensure there was one individual medical director of the facility as required. Findings: On 4/17/09 at 11:08 A.M., the Facility Administrator (FA) explained there were 2 medical directors at the facility, who shared the medical director responsibilities. The FA stated that the medical directors covered different shifts of the hemodialysis patients and both attended the QAPI meetings and patient care conferences. The FA confirmed awareness of the new requirement for one individual medical director at the facility. The FA stated that both medical directors were under contracts which extended over a ten year period. When the medical director contracts were reviewed on 4/17/09, both were initiated in 2001, and extended over a 10 year period. Both contracts included provisions for renewal of the contracts for 2 additional 5 year periods. During an interview on 4/17/09 at 3:45 P.M., Medical Director A confirmed that he shared the responsibilities of medical director with Medical Director B. Medical Director A stated he was not aware of the requirement for one medical director of a facility at a time.	V 711			
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	V 715		5/15/09	

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V 715	<p>Continued From page 14</p> <p>patients in the facility, including attending physicians and nonphysician providers;</p> <p>This STANDARD is not met as evidenced by: Surveyor: 14724 Based on observation, staff interview, medical record review and review of policies and procedures, the facility medical director failed to ensure staff monitored 3 of 5 sampled patients (1,3,5) and 1 non-sampled hemodialysis patients every 30 minutes, during dialysis, as required by facility policy.</p> <p>Findings:</p> <p>1. On 4/15/09 between 8:15 A.M., and 10:10 A.M., Patient 8 was continuously observed receiving hemodialysis at station 5. During the observation period, no staff approached Patient 8 or the dialysis machine.</p> <p>At 10:10 A.M. on 4/15/09, the Clinical Coordinator (CC) was asked how often staff were to monitor patients during dialysis. The CC explained that the dialysis treatment records were electronic, and were interactive with the dialysis machines. Staff programmed the dialysis machines to take the patients' blood pressure and pulse, and the machine parameters every 30 minutes, which were automatically recorded on the electronic treatment records. Staff were to monitor the patients at least every 30 minutes, by verifying the patient's vital signs and machine parameters recorded by the interactive system, and observing the condition of the patient and their vascular access.</p> <p>At 10:10 A.M. on 4/15/09, the CC checked Patient</p>	V 715			

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V 715	<p>Continued From page 15</p> <p>8's electronic treatment record. The treatment record showed that the last time staff made an entry, signifying monitoring the patient, his vascular access and the machine parameters, was at 7:41 A.M., 2 hours and 29 minutes earlier.</p> <p>On 4/15/09 at 2:49 P.M. the CC presented a printed copy of the "Post Treatment" record for Patient 8's 4/15/09 dialysis. The record had no documentation of staff entries for monitoring the patient between 7:41 A.M. and 10:24 A.M., with only the automatic interactive electronic entries of vital signs and machine settings recorded during the 2 hour, 43 minute period. The CC confirmed that the treatment record indicated staff had not monitored Patient 8 during dialysis, every 30 minutes, as required.</p> <p>2. A 4/16/09 review of the medical record for Patient 1 showed a gap in excess of 3 hours between documentation of staff monitoring the patient during the dialysis treatment on 3/23/09. The 3/23/09 dialysis treatment record had a staff entry at 10:25 A.M., with the next staff entry at 2:41 P.M., when the treatment was terminated. There were no automatic interactive entries, recorded from the dialysis machine during the 3 hour and 16 minute gap.</p> <p>3. A 4/16/09 review of the medical record for Patient 3 showed a 70 minute gap between documentation of staff monitoring the patient, during dialysis, on 3/13/09. The 3/13/09 dialysis treatment record had an entry by staff at 3:10 P.M., with the next staff entry at 4:20 P.M., when the treatment was terminated.</p> <p>4. A 4/17/09 review of the medical record for Patient 5 showed gaps exceeding 45 minutes</p>	V 715			

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V 715	<p>Continued From page 16</p> <p>between staff monitoring the patient during the dialysis treatments on 3/27/09 (between 4:33 P.M. and 5:24 P.M.), 3/30/09 (between 1:45 P.M. and 2:41 P.M.), and 4/6/09, when there was a 90 minute gap between 3:57 P.M. and 5:27 P.M.</p> <p>During a 4/17/09, 2:00 P.M. interview, the CC confirmed that the above-mentioned treatment records indicated that staff did not document monitoring the patients every 30 minutes, per policy.</p> <p>The facility policy #1-03-09, revised in September, 2008, required staff to perform "treatment checks", including blood pressure, heart rate, machine parameters, vascular access status, and "Patient status and subjective well-being" at least every 30 minutes during dialysis.</p>	V 715			