

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

PRINTED: 12/30/2013
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152522	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED R 05/15/2013
NAME OF PROVIDER OR SUPPLIER COMPREHENSIVE RENAL CARE - HAMMOND			STREET ADDRESS, CITY, STATE, ZIP CODE 222 DOUGLAS ST HAMMOND, IN 46320		
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{V 000}	<p>INITIAL COMMENTS</p> <p>This visit was a revisit for an ESRD Recertification Survey completed on 5/3/13 that resulted in an Immediate Jeopardy that was not removed at exit. This visit was to determine whether the Immediate Jeopardy had been removed.</p> <p>Survey date: 5-15-13</p> <p>Facility: 005981</p> <p>Medicaid Vendor: 100147640B</p> <p>Surveyor: Bridget Boston, RN, PHNS</p> <p>An Immediate Jeopardy was identified on 5/3/13. The facility was informed of the immediate Jeopardy on 5/3/13 at 2:45 PM. The Immediate Jeopardy remained uncorrected at survey exit.</p> <p>This survey identified that the Immediate Jeopardy had been removed on 5/15/13 through interview, observation, in-service attendance, record review, and administrative audit reviews.</p> <p>Upon arrival to the in-center treatment floor at 11:30 AM, observation noted two patients, #28 and 29, in the first pod, dialyzing on a 2.0 K - 2.0 Ca++ dialysate bath, supplied by gallon jugs that were on the front lip of their dialysis machine. Employee N indicated she was assigned to provide care to patient 29. The employee was interviewed to determine her knowledge of the new processes and procedures to ensure the prescribed dialysis treatment was delivered. She demonstrated the process in place to set up the dialysis machine prior to the dialysis treatment</p>	{V 000}			

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 000}	<p>Continued From page 1</p> <p>using the document titled "Pre - treatment." She indicated the document was used to prepare the machine and she was to verify the prescription on the Pre-treatment document with the dialysis machine settings. She was to document on "Line one" of the treatment record the dialysate bath that was in place for delivery of the dialysis treatment which included the delivery of a specialized or non - standard dialysate bath. She evidenced, within the electronic medical record, the location of her documentation from earlier in the shift, prior to the observation, when the machine was prepared for dialysis treatment. This documentation, time stamped, evidenced the dialysate bath observed was documented on "Line one" of the Treatment Record at the time the machine was set up and was completed prior to the observation.</p> <p>Employees E, J, L, and O were interviewed, and they verbalized the same processes and procedures in place and the safeguards to ensure the delivery of the dialysis prescription.</p> <p>Employee M was interviewed to determine his knowledge of the new processes and procedures in place. Through interview and review of the daily audit logs, it was determined he was aware of the new processes and procedures in place for the PCT and for the registered nurses.</p> <p>The facility's in-service records identified that all staff received education regarding the facility policy for the documentation of physician orders, the discipline responsible and the process in place to ensure treatment was provided according to the physician order, and the location in the record physician orders would be located for the purpose of communication to the</p>	{V 000}			

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{V 000}	<p>Continued From page 2</p> <p>employee initiating and delivering the dialysis treatments. In addition, the registered nurses were provided education regarding additional new processes and their daily audits and responsibilities. Education included the process in place to ensure critical labs were processed timely and physician orders were acted upon.</p> <p>DaVita policy for the use of a low potassium dialysate - policy 1-03-18 - revision August 2012 addressed, related to low potassium dialysate, rounding with physicians and expectations and follow through. The rounding report addresses critical lab values and expected documentation and follow through to be completed by the licensed staff with the physician. The policy for the delivery of a potassium <2.0 dialysate the facility may obtain an order for the dialysate for a minimum of 30 days.</p> <p>The facility's audit records evidenced 100% of the treatment records were audited by the administrator for the first 2 days to determine if the treatment delivered met the physician order. After that, audit records evidenced 25% of the post treatment records were reviewed daily for the same purpose. Appropriate documentation and follow through was evident. The audit tools identified areas of facility concern and these were addressed with appropriate education and re-training.</p> <p>The audit tools utilized by the in-center registered nurses evidenced up to date daily logs and appropriate documentation.</p> <p>Comprehensive Renal Care Hammond continues to be out of compliance with the Conditions for Coverage 42 CFR 494.30 Infection Control, 42 CFR 494.40 Water and Dialysate Quality, 42 CFR</p>	{V 000}			

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{V 000}	Continued From page 3 494.90 Patient Plan of Care, 42 CFR 494.110 Quality Assessment and Performance Improvement, and 42 CFR 494.150 Responsibilities of the Medical Director. Quality Review: Joyce Elder, MSN, BSN, RN May 17, 2013	{V 000}			
{V 110}	494.30 CFC-INFECTON CONTROL This CONDITION is not met as evidenced by:	{V 110}			
{V 111}	494.30 IC-SANITARY ENVIRONMENT The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas. This STANDARD is not met as evidenced by:	{V 111}			
{V 130}	494.30(a)(1)(i) IC-HBV-ISOLATION-MACHINES/EQUIP/SUPPLIES Isolation of HBV+ Patients To isolate HBsAg positive patients, ... dedicate machines, equipment, instruments, supplies, and medications that will not be used by HBV susceptible patients. This STANDARD is not met as evidenced by:	{V 130}			
{V 131}	494.30(a)(1)(i) IC-HBV-ISOLATION-STAFFING	{V 131}			

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{V 131}	Continued From page 4 Isolation of HBV+ Patients Staff members caring for HBsAg positive patients should not care for HBV susceptible patients at the same time, including during the period when dialysis is terminated on one patient and initiated on another. This STANDARD is not met as evidenced by:	{V 131}			
{V 175}	494.40 CFC-WATER & DIALYSATE QUALITY This CONDITION is not met as evidenced by:	{V 175}			
{V 195}	494.40(a) CARBON ADSORPTION-10 MINUTES EBCT 5.2.5 Carbon adsorption: 10 min EBCT Refer to RD62:2001, 4.3.9 Carbon adsorption media: When granulated activated carbon is used as the adsorption medium ... each adsorption bed shall have an [empty bed contact time] EBCT of at least 5 minutes at the maximum product water flow rate (a total EBCT of at least 10 minutes). This STANDARD is not met as evidenced by:	{V 195}			
{V 196}	494.40(a) CARBON ADSORP-MONITOR, TEST FREQUENCY	{V 196}			

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{V 196}	Continued From page 5 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, or total chlorine should be recorded in a log sheet. 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]. 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.	{V 196}			
{V 213}	494.40(a) DIST SYS-CULTURE/LAL/SITES/FREQ(NEW)/LOG 6.3.3 Water distribution systems: culture/LAL sample sites/frequency (new)/log Water distribution piping systems should be monitored for bacteria and endotoxin levels.	{V 213}			

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{V 213}	Continued From page 6 Bacteria and endotoxins shall not exceed the levels specified in [AAMI] 4.1.2. [(i.e., bacteria <200 CFU/mL and endotoxin <2 EU/mL] Bacteria and endotoxin testing should be conducted at least monthly. For a newly-installed water distribution piping system, or when a change has been made to an existing system, it is recommended that weekly testing be conducted for 1 month to verify that bacteria or endotoxin levels are consistently within the allowed limits. Monitoring should be accomplished by taking samples from the first and last outlets of the water distribution loop and the outlets supplying reuse equipment and bicarbonate concentrate mixing tanks. If the results of this testing are unsatisfactory, additional testing (e.g., ultrafilter inlet and outlet, RO product water, and storage tank outlet) should be undertaken as a troubleshooting strategy to identify the source of contamination, after which appropriate corrective actions can be taken. Bacteria and endotoxin levels shall be measured as specified in ANSI/AAMI RD62:2001 (see 2.3). All bacteria and endotoxin results should be recorded on a log sheet to identify trends that may indicate the need for corrective action. This STANDARD is not met as evidenced by:	{V 213}			
{V 253}	494.40(a) MICROB MONITOR-MO DIALYS SAMPLE/COLLECT/FREQ 7.2 Microbial monitoring methods: 7.2.1 General: Dialysate: monthly dialysate sample/collection/freq	{V 253}			

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{V 253}	Continued From page 7 Culture ...dialysate fluid weekly for new systems until a pattern has been established. For established systems, culture monthly unless a greater frequency is dictated by historical data at a given institution. Dialysate samples should be collected from at least two machines monthly and from enough machines so that each machine is tested at least once per year. If testing of any dialysis machine reveals a level of contamination above the action level, an investigation should be conducted that includes retesting the offending machine, reviewing compliance with disinfection and sampling procedures, and evaluating microbiological data for the previous 3 months to look for trends. The medical director also should be notified. An example of a decision tree for this process is given in Figure 1. 7.2.2 Sample collection Dialysate samples should be collected from a dialysate port of the dialyzer ... [or] dialysate sampling ports that can be accessed using a syringe. At least 25 mL of fluid, or the volume specified by the laboratory performing the test, should be collected in sterile endotoxin-free specimen containers. This STANDARD is not met as evidenced by:	{V 253}			
{V 403}	494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU 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	{V 403}			

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{V 403}	Continued From page 8 maintained and operated in accordance with the manufacturer's recommendations.	{V 403}			
{V 463}	This STANDARD is not met as evidenced by: 494.70(a)(12) PR-RECEIVE SERVICES OUTLINED IN POC The patient has the right to- (12) Receive the necessary services outlined in the patient plan of care described in §494.90;	{V 463}			
{V 520}	This STANDARD is not met as evidenced by: 494.80(d)(2) PA-FREQUENCY REASSESSMENT-UNSTABLE Q MO 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- At least monthly for unstable patients including, but not limited to, patients with the following: (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.	{V 520}			

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{V 520}	Continued From page 9	{V 520}			
	This STANDARD is not met as evidenced by:				
{V 540}	494.90 CFC-PATIENT PLAN OF CARE	{V 540}			
	This CONDITION is not met as evidenced by:				
{V 541}	494.90 POC-GOALS=COMMUNITY-BASED STANDARDS	{V 541}			
	The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.				
	This STANDARD is not met as evidenced by:				
{V 542}	494.90(a) POC-IDT DEVELOPS PLAN OF CARE	{V 542}			
	The interdisciplinary team must develop a plan of care for each patient.				
	This STANDARD is not met as evidenced by:				
{V 544}	494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE	{V 544}			

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{V 544}	Continued From page 10 Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. This STANDARD is not met as evidenced by:	{V 544}			
{V 545}	494.90(a)(2) POC-EFFECTIVE NUTRITIONAL STATUS The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate. This STANDARD is not met as evidenced by:	{V 545}			
{V 559}	494.90(b)(3) POC-OUTCOME NOT ACHIEVED-ADJUST POC If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must- (i) Adjust the plan of care to reflect the patient's current condition; (ii) Document in the record the reasons why the patient was unable to achieve the goals; and (iii) Implement plan of care changes to address	{V 559}			

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{V 559}	Continued From page 11 the issues identified in paragraph (b)(3)(ii) of this section.	{V 559}			
{V 625}	This STANDARD is not met as evidenced by: 494.110 CFC-QAPI	{V 625}			
{V 627}	This CONDITION is not met as evidenced by: 494.110(a)(1) QAPI-ONGOING;USES INDICATORS=IMPROVEMENT	{V 627}			
{V 628}	The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors. This STANDARD is not met as evidenced by: 494.110(a)(2) QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS	{V 628}			
	The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves.				

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{V 628}	Continued From page 12 This STANDARD is not met as evidenced by:	{V 628}			
{V 629}	494.110(a)(2)(i) QAPI-INDICATOR-ADEQUACY OF DIALYSIS The program must include, but not be limited to, the following: (i) Adequacy of dialysis. This STANDARD is not met as evidenced by:	{V 629}			
{V 693}	494.140(e)(3) PQ-PCT-COMPLETE TRAINING PROGRAM Patient care dialysis technicians must- (3) Have completed a training program that is approved by the medical director and governing body, under the direction of a registered nurse, focused on the operation of kidney dialysis equipment and machines, providing direct patient care, and communication and interpersonal skills, including patient sensitivity training and care of difficult patients. This STANDARD is not met as evidenced by:	{V 693}			
{V 710}	494.150 CFC-RESPONSIBILITIES OF THE MEDICAL DIRECTOR This CONDITION is not met as evidenced by:	{V 710}			
{V 711}	494.150 MD RESP-MED DIR QUAL/ACCOUNTABLE TO GOV BODY	{V 711}			

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{V 711}	Continued From page 13 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:	{V 711}			
{V 712}	494.150(a) MD RESP-QAPI PROGRAM Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program. This STANDARD is not met as evidenced by:	{V 712}			
{V 713}	494.150(b) MD RESP-STAFF ED, TRAINING & PERFORM Medical director responsibilities include, but are not limited to, the following: (b) Staff education, training, and performance. This STANDARD is not met as evidenced by:	{V 713}			
{V 715}	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P 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}			

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

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FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152522	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED R 05/15/2013
NAME OF PROVIDER OR SUPPLIER COMPREHENSIVE RENAL CARE - HAMMOND		STREET ADDRESS, CITY, STATE, ZIP CODE 222 DOUGLAS ST HAMMOND, IN 46320		
(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}	Continued From page 14 patients in the facility, including attending physicians and nonphysician providers; This STANDARD is not met as evidenced by:	{V 715}		