

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152652	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 06/26/2015
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NAME OF PROVIDER OR SUPPLIER PAOLI DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP CODE 555 WEST LONGEST STREET PAOLI, IN 47454
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V 0000 Bldg. 00	<p>This was a Federal ESRD [CORE] recertification survey.</p> <p>Survey Dates: 6-24-15, 6-25-15, and 6-26-15</p> <p>Facility #: 012749</p> <p>Medicaid Vendor #: 201083600</p> <p>QR: JE 6/29/15</p>	V 0000		
V 0113 Bldg. 00	<p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE 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.</p> <p>Based on observation, interview, and review of facility policy, the facility failed to ensure staff had changed gloves and cleansed hands in accordance with facility policy in 2 (#s 7 and 14) of 14 infection control observations completed. (Employees E and M)</p> <p>The findings include:</p> <p>1. Employee E, a patient care technician</p>	V 0113	V113 Facility Administrator (FA) held in-service for clinical teammates (TMs) on 07/03/2015 reviewing Policy #1-05-01: Infection Control for Dialysis Facilities. 1) TMs instructed to remove gloves and perform hand hygiene after palpating and listening to access; 2) Perform hand hygiene before and after contact with the data entry keyboard; 3) Perform hand hygiene before gloves donned and after removal of gloves.	08/10/2015

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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	<p>(PCT), was observed to initiate the dialysis treatment on patient number 5 on 6-26-15 at 9:30 AM using an arteriovenous fistula (AVF). The PCT palpated the fistula and listened with the stethoscope . The PCT failed to change her gloves and cleanse her hands after assessing the fistula and applying the antiseptic to the needle insertion sites.</p> <p>After applying antiseptic to the needle insertion sites, the PCT removed her gloves and cleansed her hands. The PCT then touched the data entry keyboard and then donned clean gloves without cleansing her hands. The PCT retrieved the thermometer and took the patient's temperature, replaced the thermometer after cleaning it, and removed her gloves and cleansed her hands. The PCT touched the data entry keyboard and again donned clean gloves without cleansing her hands.</p> <p>2. Employee M, a registered nurse (RN), was observed to administer intravenous Epogen to patient number 6 on 6-26-15 at 11:35 AM. The RN was observed to draw up the medications into the syringe and take it to the dialysis station. The RN touched the data entry keyboard and then donned clean gloves without cleansing her hands. The RN administered 1500 units of Epogen to the</p>		<p>Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet. FA or designee will conduct documented observational audits to monitor compliance daily x 4 weeks, then with monthly infection control audits. Results of audits will be discussed with Medical Director during Facility Health Meeting (FHM) monthly, creating/monitoring improvement plan as needed, minutes will reflect. FA is responsible for compliance with this plan of correction</p>				

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V 0122 Bldg. 00	<p>patient.</p> <p>3. The facility administrator, employee B, indicated, on 6-26-15 at 12:25 PM, employees E and M should have cleansed their hands prior to donning clean gloves.</p> <p>4. The facility's September 2014 "Infection Control For Dialysis Facilities" policy number 1-05-01 states, "Hand hygiene is to be performed upon entering the patient treatment area, prior to gloving, after removal of gloves . . . Gloves are to be removed and hands washed or alcohol based hand rubs used before and after touching the keyboard."</p> <p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing-</p> <p>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]</p> <p>(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.</p> <p>Based on observation, interview, and review of facility policy, the facility failed to ensure dialysis stations had been appropriately cleaned and disinfected in 2 (#s 1 and 2) of 2 cleaning and</p>	V 0122	V122 FA held in-service for clinical TMs on 07/03/2015 reviewing Policy #1-05-01: Infection Control for Dialysis Facilities emphasizing proper procedure for disinfection with	08/10/2015			

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	<p>disinfection of the dialysis station observations completed. (Employees C and D)</p> <p>The findings include:</p> <p>1. Employee D, a patient care technician (PCT), was observed to clean the dialysis machine and chair at station number 8 on 6-24-15 at 1:10 PM. The PCT was not observed to clean the Hansen connectors or the dialysate hoses.</p> <p>A. The PCT was not observed to clean the fronts of the arms of the chair where patients place their hands or the sides of the chair under the attached chair-side tables. After cleaning the foot rest of the chair, the PCT was observed to remove the bag from the trash can and place the trash can on the foot rest. The PCT was not observed to clean the bottom of the trash can prior to placing it upon the foot rest.</p> <p>B. The PCT was not observed to clean the television or the data entry keyboard.</p> <p>2. Employee C, a PCT, was observed to clean the dialysis machine and the chair at station number 1 on 6-24-15 at 1:20 PM. The PCT was not observed to clean the sides of the chair under the attached</p>		<p>bleach solution between patient treatments of machine, chair and surrounding equipment. 1) TMs instructed to recline and open sides of chairs to better access all surfaces to wipe down including the front of the arms and under the chair side table; 2) TMs instructed to open door on side of dialysis machine to wipe down Hansen connectors and dialysate hoses attached; 3) TMs instructed to wipe down all surfaces of trash can, including the bottom; 4) TMs instructed to wipe down all equipment between patients, to include BP cuffs, TV controls, TV arms, dialysis machine, dialysis chair, snappy carts and keyboards. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet. FA or designee will conduct documented observational audits to monitor compliance daily x 4 weeks, then with monthly infection control audits. Results of audits will be discussed with Medical Director during FHM monthly, creating/monitoring improvement plan as needed, minutes will reflect. FA is responsible for compliance with this plan of correction</p>		

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V 0408 Bldg. 00	<p>chair-side tables. The PCT was not observed to clean the fronts of the arms of the chair where patients place their hands.</p> <p>The PCT was not observed to clean the television or the data entry keyboard.</p> <p>3. The facility administrator, employee B, indicated, on 6-26-15 at 12:25 PM, the employees had not cleaned and disinfected the dialysis stations in accordance with facility policy.</p> <p>4. The facility's September 2014 "Infection Control For Dialysis Facilities" policy number 1-05-01 states, "Equipment including the dialysis delivery system, . . . the dialysis chair and side tables including opening the chair to reach crevices, . . . television arms and control knobs . . . as well as all work surfaces will be wiped clean with a bleach solution of the appropriate strength after completion of procedures, before being used on another patient, after spills of blood, throughout the work day, and after each treatment."</p> <p>494.60(d) PE-EMERGENCY PREPAREDNESS-PROCEDURES The dialysis facility must implement processes and procedures to manage</p>			

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	<p>medical and non medical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.</p> <p>Based on observation, interview, and administrative record and facility policy review, the facility failed to maintain current medications in the emergency evacuation kit in 1 of 1 emergency evacuation kit observation completed.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. On 6-24-15 at 12:10 PM, observation noted 2 thirty (30) milliliter vials of heparin in the emergency evacuation kit. The heparin was observed to be expired with one (1) vial having an expiration date of 12-1-14 and the other an expiration date of 1-1-15. 2. The facility administrator, employee B, indicated, on 6-24-15 at 12:10 PM, the heparin was expired. 3. The facility's administrative records included an "Emergency Evacuation Kit Checklist" dated 1-2-15, 2-20-15, 3-20-15, 4-30-15, 5-1-15, and 6-11-15. The checklists identified there were 4 heparin vials that were "not expired" in 	V 0408	<p>V408 All expired Heparin was removed from Emergency Evacuation Kit, discarded and replaced on 06/24/2015. FA held in-service for TMs on 7/03/2015 reviewing Policy #4-07-02: Evacuation Kit emphasizing TMs must conduct and document monthly checks on evacuation kits to ensure kits is complete and supplies have not expired. TMs educated that using expired items could have the potential to affect 100% of facility patient census.</p> <p>1) FA instructed designated Patient Care Technician (PCT) to establish list to place on outside of evacuation kit with items and expiration dates; 2) Designated PCT will be assigned to review all items in evacuation kit and replace missing or expired supplies at a minimum of monthly, write expiration date on audit list, date and initial of TM checking contents documented on outside of kit. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet. FA will audit and complete Emergency Evacuation Checklist monthly x 3 months, and then review designated PCTs audit monthly at</p>	08/10/2015

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V 0503 Bldg. 00	<p>the emergency evacuation kit.</p> <p>4. The facility's September 2014 "Evacuation Kit" policy number 4-07-02 states, "The Facility Administrator or designee will review the contents of the kit(s) and replace missing or expired supplies at least monthly."</p> <p>The facility's March 2010 "Emergency Evacuation Kit Checklist" procedure number 4-07-02A identifies a total of 4 thirty (30) milliliter vials of heparin should be maintained in the kit.</p> <p>494.80(a)(2) PA-APPROPRIATENESS OF DIALYSIS RX The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>(2) Evaluation of the appropriateness of the dialysis prescription, Based on clinical record and facility policy review and interview, the facility failed to ensure the comprehensive assessment had been updated to include an evaluation of the patient's blood flow rate in 1 (# 1) of 3 incenter records reviewed.</p> <p>The findings include:</p> <p>1. Clinical record number included physician orders dated 4-28-15 that</p>	V 0503	<p>FHM with Medical Director creating/monitoring improvement plan as needed, minutes will reflect. FA is responsible for compliance with this plan of correction</p> <p>V503 FA will hold in-service for clinical TMs to review Policy #1-14-02: Patient Assessment and Plan of Care When Utilizing Falcon Dialysis, Policy #01-03-09: Intradialytic Treatment Monitoring emphasizing TMs must verify patient prescriptions and set all treatments as prescribed. 1) TMs instructed to follow prescribed Blood Flow Rate (BFR) as ordered; 2) TMs instructed to alert RN if unable to achieve ordered BFR; 3) RN instructed to complete note in Falcon</p>	08/10/2015	

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	<p>identified the prescribed BFR was 350 milliliters (mL) per minutes. Hemodialysis treatment flow sheets evidenced the BFR was greater than or less than the prescribed rate. The record failed to evidence the comprehensive assessment had been updated to reflect the current status of the patient's BFR.</p> <p>A. Hemodialysis treatment flow sheets, dated 6-3-15, 6-5-15, 6-10-15, and 6-15-15, evidenced a BFR of 450 mL.</p> <p>B. A hemodialysis treatment flow sheet dated 6-17-15 evidenced a BFR of 270 mL.</p> <p>C. A hemodialysis treatment flow sheet dated 6-19-15 evidenced a BFR of 300 mL.</p> <p>2. The facility administrator, employee B, was unable to provide any additional documentation and/or information when asked on 6-26-15 at 1:00 PM.</p> <p>3. The facility's March 2013 "Patient Assessment and Plan of Care When Utilizing Falcon Dialysis" policy number 1-14-02 states, "Assessment criteria will include, but not be limited to, evaluation of: . . . dialysis prescription."</p>		<p>regarding problems achieving BFR as ordered, patient assessment, any interventions taken, and patient's response; 4) RN to review all BFRs and document on daily audit tool. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA will review RN audits daily x 1 week, then weekly x 3 weeks, then monthly. FA or designee will conduct Medical Records Audits for 10% of patient census monthly to ensure prescribed physician orders are followed for patient treatments, significant changes reported to nurse and assessment, interventions are documented. Audit will also review patient's individualized comprehensive assessment and plan of care to verify evaluation, and physician orders for patient access is up-to-date, and documentation appropriate. Results of audits will be discussed with Medical Director during FHM monthly, creating/monitoring improvement plan as needed, minutes will reflect.</p> <p>FA is responsible for compliance with this plan of correction</p>		

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V 0544 Bldg. 00	<p>494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE 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. Based on clinical record and facility policy review and interview, the facility failed to ensure the prescribed blood flow rate (BFR) had been maintained in 1 (# 1) of 3 incenter records reviewed.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Clinical record number included physician orders dated 4-28-15 that identified the prescribed BFR was 350 milliliters (mL) per minutes. <ul style="list-style-type: none"> A. Hemodialysis treatment flow sheets, dated 6-3-15, 6-5-15, 6-10-15, and 6-15-15, evidenced a BFR of 450 mL. B. A hemodialysis treatment flow sheet dated 6-17-15 evidenced a BFR of 270 mL. C. A hemodialysis treatment flow sheet dated 6-19-15 evidenced a BFR of 300 mL. The facility administrator, employee 	V 0544	<p>V544 FA will hold in-service for clinical TMs to review Policy #1-14-02: Patient Assessment and Plan of Care When Utilizing Falcon Dialysis, Policy #01-03-09: Intradialytic Treatment Monitoring emphasizing TMs must verify patient prescriptions and set all treatments as prescribed. 1) TMs instructed to follow prescribed Blood Flow Rate (BFR) as ordered; 2) TMs instructed to alert RN if unable to achieve ordered BFR; 3) RN instructed to complete note in Falcon regarding problems achieving BFR as ordered, patient assessment, any interventions taken, and patient's response; 4) RN to review all BFRs and document on daily audit tool. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet. FA will review RN audits daily x 1 week, then weekly x 3 weeks, then monthly. FA or designee will conduct Medical Records Audits for 10% of patient census monthly to ensure prescribed physician orders are followed for patient treatments, significant changes reported to nurse and</p>	08/10/2015			

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V 0550 Bldg. 00	<p>B, was unable to provide any additional documentation and/or information when asked on 6-26-15 at 1:00 PM.</p> <p>3. The facility's March 2013 "Patient Assessment and Plan of Care When Utilizing Falcon Dialysis" policy number 1-14-02 states, "The plan of care will address, but not be limited to, the following: Dose of dialysis which addresses care and services to manage the patient's volume status and achieve and sustain the prescribed dose of dialysis."</p> <p>494.90(a)(5) POC-VASCULAR ACCESS-MONITOR/REFERRALS The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement.</p> <p>Based on observation, interview, and review of facility policy, the facility failed to ensure pre-treatment access care had been completed per the facility's own policy in 2 (#s 1 and 2) of 2 accesses of arteriovenous fistula or graft for initiation of dialysis observations completed.</p> <p>The findings include:</p>	V 0550	<p>assessment, interventions are documented. Audit will also review patient's individualized comprehensive assessment and plan of care to verify evaluation, and physician orders for patient access is up-to-date, and documentation appropriate. Results of audits will be discussed with Medical Director during FHM monthly, creating/monitoring improvement plan as needed, minutes will reflect. FA is responsible for compliance with this plan of correction</p> <p>V550 FA held in-service for clinical TMs on 07/03/2015 reviewing Policy# 1-04-01D: AV Fistula or Graft Cannulation with JMS Sysloc Mini Safety Fistula Needles (SFN) and Administration of Heparin and Policy #1-05-01: Infection Control for Dialysis Facilities. 1) TMs instructed to give handout to patients "How to Wash Your</p>	08/10/2015			

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	<p>1. Employee E, a patient care technician (PCT), was observed to access an arteriovenous fistula (AVF) on patient number 5 on 6-26-15 at 9:30 AM. The PCT was not observed to wash the skin over the access with soap and water or antibacterial scrub or to ask the patient if the patient had washed the access upon arrival to the treatment floor. The patient stated, "I did it at home."</p> <p>2. Employee C, a PCT, was observed to access an AVF on patient number 7 on 6-26-15 at 9:45 AM. The PCT was not observed to wash the skin over the access with soap and water or antibacterial scrub or to ask the patient if the patient had washed the access upon arrival to the treatment floor.</p> <p>3. The facility administrator, employee B, indicated, on 6-26-15 at 12:25 PM, employees C and E had not provided care in accordance with facility policy.</p> <p>4. The facility's March 2015 "AV Fistula or Graft Cannulation With JMS Sysloc Mini Safety Fistula Needles (SFN) and Administration of Heparin" procedure number 1-04-01D states, "Have patient wash access site with appropriate antibacterial soap, if able. If patient unable to wash access site, patient care</p>		<p>Hands and Vascular Access" and educate patients on cleaning of access must be completed upon entering treatment floor; documentation of education to be placed in patient medical record; 2) TMs instruct and encourage patients to wash hands and access upon entering treatment floor. If patient unable to complete then TMs are to complete with soap and water or antibacterial scrub. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet. FA or designee will conduct documented observational audits to monitor compliance daily x 4 weeks, then with monthly infection control audits. Results of audits will be discussed with Medical Director during FHM monthly, creating/monitoring improvement plan as needed, minutes will reflect. FA is responsible for compliance with this plan of correction</p>		

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V 0638 Bldg. 00	<p>teammate will clean access extremity with skin cleansing agent and pat dry."</p> <p>The facility's September 2014 "Infection Control for Dialysis Facilities" policy number 1-05-01 states, "Patients are encouraged to wash their hands and access extremity upon entering the treatment area prior to the initiation of dialysis."</p> <p>494.110(b) QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time. Based on quality assessment and performance improvement (QAPI) documentation and facility policy review and interview, the facility failed to ensure it had implemented a performance improvement plan for anemia management in 3 (April, May, and June 2015) of 3 months reviewed.</p> <p>The findings include:</p> <p>1. The facility's QAPI documentation for February 2015 identified 0% of the facility's patients had a hemoglobin of less than 10 grams per deciliter (g/dL). The March 2015 documentation</p>	V 0638	<p>V638 FA will hold in service for Facility Health Team to review Policy #1-14-06: Continuous Quality Improvement Program with emphasis that team must set measurable goals, timelines, conduct ongoing monitoring/evaluation, and initiate interventions for quality indicators including anemia management which includes Hemoglobin goals. Any identified underperformance including patients with hemoglobin levels not meeting goal must be reviewed to identify root causes and will have action plan identified that will result in performance improvement, and must track change in</p>	08/10/2015			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152652		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 06/26/2015	
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	<p>identified 15% of the facility's patients had a hemoglobin level of less than 10 g/dL. The April 2015 documentation identified 18% of the patients had a hemoglobin of less than 10 g/dL. The May 2015 documentation identified 24% of the facility's patients had a hemoglobin of less than 10 g/dL.</p> <p>The facility's QAPI meeting minutes, dated 4-8-15, 5-22-15, and 6-3-15, failed to evidence the facility had implemented a performance improvement plan to address the increasing percentage of patients with a hemoglobin level of less than 10 g/dL.</p> <p>2. The facility administrator, employee B, stated, on 6-26-15 at 3:30 PM, "We have not implemented a performance improvement plan for hemoglobin levels of less than 10."</p> <p>3. The facility's September 2013 "Continuous Quality Improvement Program" policy number 12-16-06 states, "Any area identified as underperforming will be reviewed to identify root causes for underperformance, will have an action plan identified that will result in performance improvement, and will track this change in performance over time to ensure improvements are sustained."</p>		<p>performance over time to ensure improvements are sustained. Action plans must be re-evaluated for effectiveness with new interventions initiated as needed. FHM minutes must reflect discussion, actions and evaluation by team. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>Clinical Service Specialist (CSS) will attend FHM or review meeting minutes for the next 3 months to ensure team remains in compliance, minutes are comprehensive, and reflective of actions taken. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA is responsible for compliance with this plan of correction</p>				

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

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