

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152676	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 03/29/2023
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NAME OF PROVIDER OR SUPPLIER  THREE RIVERS DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP COD 6721 OLD TRAIL RD FORT WAYNE, IN 46809
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V 0000  Bldg. 00	<p>This visit was for a Federal complaint survey of an End Stage Renal Dialysis (ESRD) Provider.</p> <p>Survey Date: March 29, 2023</p> <p>Facility Census: 66 In-Center Hemodialysis: 57 Home Peritoneal Dialysis: 9</p> <p>Complaint #IN00354599 was investigated and related Federal deficiencies were cited.</p> <p>Complaint #IN00250683 was investigated and related Federal deficiencies were cited.</p> <p>QR on 4/11/23 Area 2</p>	V 0000		
V 0112  Bldg. 00	<p>494.30(a) IC-CDC MMWR 2001</p> <p>The facility must demonstrate that it follows standard infection control precautions by implementing-</p> <p>(1)(i) The recommendations (with the exception of screening for hepatitis C), found in "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS</p>			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Alex Lachat	RN; Facility Administrator	04/19/2023

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 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 disclosed 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>Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: <a href="http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html">http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html</a>.</p> <p>The recommendation found under section header "HBV-Infected Patients", found on pages 27 and 28 of RR05 ("Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients"), concerning isolation rooms, must be complied with by February 9, 2009.</p> <p>Based on observation, record review, and interview, the End Stage Renal Disease (ESRD) facility failed to ensure all staff followed facility policies and procedures specific to fistula and graft access disinfection prior to cannulation for 1 of 1 observations of staff performing cannulation of a fistula or graft (Patient Care Technician #1).</p> <p>Findings include:</p> <p>Review of facility policy #1-04-01D titled "AV [arteriovenous] Fistula or Graft Cannulation ...", revised 10/2022, indicated when disinfecting the cannulation sites prior to cannulation, the staff member should scrub the site for a minimum of 30 seconds when using povidone iodine and 60 seconds when using 70% isopropyl alcohol.</p> <p>During an observation at Station #8 conducted on 03/29/2023 beginning at 10:49 AM with Patient #7,</p>	V 0112	The Facility Administrator or designee will in-service all clinical teammates on Policy #1-04-01D "AV Fistula or Graft Cannulation" starting on 4/14/2023. Verification of attendance will be evidenced by a signature sheet. Teammates will be instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) Skin Antiseptic: Povidone Iodine - Effective Contact Time: 30 seconds...2) Skin Antiseptic: Isopropyl Alcohol 70% - Effective Contact Time: 60 seconds...The Facility Administrator or designee will conduct observational infection control audits daily for two (2) weeks then weekly for two (2) weeks to verify compliance with	04/27/2023

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V 0113 Bldg. 00	<p>Patient Care Technician #1 was observed initiating dialysis through the patient's arteriovenous dialysis site. The technician scrubbed the first cannulation site with one 70% isopropyl alcohol wipe for 20 seconds and the second cannulation site with one 70% isopropyl alcohol wipe for 23 seconds. The technician then scrubbed the first cannulation site with povidone iodine (length of scrubbing time not obtained) and the second cannulation site with povidone iodine for 26 seconds. The technician failed to clean the cannulation sites according to facility policy.</p> <p>During an interview conducted on 03/29/2023 beginning at 5:03 PM, Administrative Staff #1 relayed staff should disinfect the AV dialysis site by scrubbing each site for 30 seconds each with the disinfectant.</p> <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, record review, and interview, the End Stage Renal Disease (ESRD) facility failed to ensure all staff performed hand hygiene prior to donning gloves for 3 of 3 staff members observed (Patient Care Technician (PCT) #1, #2, Registered Nurse (RN) #1, failed to ensure all staff performed hand washing for at least 20 seconds for 1 of 1 hand washing observations (PCT #1), and failed to ensure all staff wore gloves when preparing medications for 1 of 1 medication preparation observations (RN #1).</p>	V 0113	<p>facility policy for prepping the vascular access site. Ongoing compliance will be verified monthly during internal infection control audits. Instances of non-compliance will be addressed immediately. The Facility Administrator or designee will review the results of the audits with teammates during homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement meetings, known as Facility Health Meetings, with supporting documentation included in the meeting minutes. The Facility Administrator is responsible for compliance with this plan of correction.</p> <p>The Facility Administrator or designee will in-service all clinical teammates on Policy 1-05-01B "Handwashing", Policy 1-05-01 "Infection Control For Dialysis Facilities", and 1-06-01 "Medication Policy" starting on 4/14/2023. Verification of attendance will be evidenced by a signature sheet. Teammates will be instructed using surveyor observations as examples with</p>	04/27/2023
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	<p>Findings include:</p> <ol style="list-style-type: none"> <li>1. Review of facility procedure #1-05-01b titled "Handwashing," revised 10/2020, indicated washing hands with soap and water, staff should scrub their hands for a minimum of 20 seconds.</li> <li>2. During an observation on 03/29/2023 beginning 10:49 AM, conducted at Station #8 with Patient #7, PCT #1 was observed entering the station. The technician failed to perform hand hygiene prior to donning gloves. At 10:53 PM during the same observation, RN #1 was observed entering Station #8. The nurse failed to perform hand hygiene prior to donning gloves.</li> <li>3. During an observation on 03/29/2023 beginning at 11:07 AM, conducted in the medication preparation area, RN #1 was observed preparing a liquid protein supplement for Patient #7. The nurse failed to perform hand hygiene and don gloves prior to preparing the medication.</li> <li>4. During an observation on 03/29/2023 beginning at 1:13 PM, conducted at Station #12 with Patient #8, PCT #2 was observed failing to perform hand hygiene prior to donning gloves upon entering the room. At 1:16 PM during the same observation, RN #1 was observed failing to perform hand hygiene prior to donning gloves upon entering the room.</li> <li>5. During an observation on 03/29/2023 beginning at 1:43 PM conducted at a hand washing station, PCT #1 was observed washing their hands for only 15 seconds.</li> <li>6. During an observation on 03/29/2023 beginning at 1:50 PM conducted at Station #9 with Patient #9, RN #1 was observed entering the station. The</li> </ol>		<p>emphasis on, but not limited to the following: 1) Cover hands (palms, back of hands, between fingers) and wrists with lather and wash vigorously for a minimum of 20 seconds. 2) All teammates, Physicians and Non-Physician (NPP) will perform hand hygiene: ... prior to gloving and immediately after removal of gloves...3) An aseptic environment and aseptic technique are used when preparing medications. The Facility Administrator or designee will conduct observational infection control audits daily for two (2) weeks and then weekly for two (2) weeks to verify compliance with facility policy for hand hygiene. Ongoing compliance will be verified monthly during internal infection control audits. Instances of non-compliance will be addressed immediately. The Facility Administrator or designee will review the results of the audits with teammates during homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement meetings, known as Facility Health Meetings, with supporting documentation included in the meeting minutes. The Facility Administrator is responsible for compliance with this plan of correction.</p>	

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V 0147  Bldg. 00	<p>nurse failing to perform hand hygiene prior to donning gloves.</p> <p>7. During an interview conducted on 03/29/2023 beginning at 2:39 PM, PCT #1 confirmed hand hygiene should be done prior to donning gloves.</p> <p>8. During an interview conducted on 03/29/2023 beginning at 2:54 PM, RN #1 confirmed a staff member's hands should be clean prior to donning gloves. The nurse denied the need to wear gloves when preparing patient medications.</p> <p>9. During an interview conducted on 03/29/2023 beginning at 5:03 PM, Administrative Staff #1 confirmed staff should wear gloves during medication preparation.</p> <p>494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE Recommendations for Placement of Intravascular Catheters in Adults and Children</p> <p>I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters.</p> <p>II. Surveillance A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream</p>			

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	<p>infection], the dressing should be removed to allow thorough examination of the site.</p> <p>Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.</p> <p>VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].</p> <p>Based on observation, record review, and interview, the End Stage Renal Dialysis (ESRD) facility failed to ensure all staff followed facility procedure specific to disinfection of a central venous catheter (CVC) prior to use for 1 of 1 observations of initiation of dialysis using a CVC (Patient Care Technician (PCT) #2).</p> <p>Findings include:</p> <p>Review of facility procedure #1-04-02B titled "Central Venous Catheter (CVC) ...," revised 10/2022, indicated staff should scrub the hub (end connector of the CVC) for 15 seconds "every time a CVC is connected or disconnected from the blood lines [tubing which moves blood to and from the dialysis machine].</p> <p>During an observation conducted on 03/29/2023 beginning at 1:57 PM at Station #12 with Patient #10, Patient Care Technician #2 was observed preparing the patient's left chest CVC for dialysis. The technician scrubbed the blue CVC hub for 10 seconds and the red CVC hub for 3 seconds with 70% alcohol wipes prior to connecting the dialysis blood lines. The technician failed to clean the hubs per agency policy.</p>	V 0147	<p>The Facility Administrator or designee will in-service all clinical teammates on Policy 1-04-02B "Central Venous Catheter (CVC) With CLEARGUARD HD Antimicrobial End Caps Procedure" starting on 4/14/2023. Verification of attendance will be evidenced by a signature sheet. Teammates will be instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) Perform a 15-second hub scrub of the CVC during the process of connecting or disconnecting from the bloodlines, including line reversal, or if the patient is disconnected during treatment for any reason. The Facility Administrator or designee will conduct observational infection control audits daily for two (2) weeks and then weekly for two (2) weeks to verify compliance with facility policy for CVC care. Ongoing compliance will be verified monthly during internal</p>	04/27/2023

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V 0543 Bldg. 00	<p>During an interview conducted on 03/29/2023 beginning at 2:45 PM, PCT #2 reported each CVC hub should be scrubbed with a disinfectant for 15-20 seconds.</p> <p>During an interview conducted on 03/29/2023 beginning at 5:03 PM, Administrative Staff #1 confirmed staff should scrub each hub of a CVC for 15 seconds prior to connecting dialysis blood lines.</p> <p>494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; Based on record review and interview, the agency failed to ensure the patient (Patient #2) received the correct dialyzer in 1 of 1 medication/ treatment error report for the last 6 months, with the potential to affect all patients.</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>Review of an agency procedure for preparing the dialysis machine for a specific patient included the verification of the dialysis prescription and inspection of the dialyzer (a device that filters the blood).</li> <li>Review of an agency event report for the</li> </ol>	V 0543	<p>infection control audits. Instances of non-compliance will be addressed immediately. The Facility Administrator or designee will review the results of the audits with teammates during homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement meetings, known as Facility Health Meetings, with supporting documentation included in the meeting minutes. The Facility Administrator is responsible for compliance with this plan of correction.</p> <p>The Facility Administrator or designee will in-service all clinical teammates on Policy 1-03-08 "Pre-Intra-Post Treatment Data Collection Monitoring and Nursing Assessment" starting on 4/14/2023. Verification of attendance will be evidenced by a signature sheet. Teammates will be instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) Patient identity, prescription, and machine settings are verified by teammate prior to</p>	04/27/2023

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	<p>months October 2022 to March 2023, evidenced one medication/ treatment event dated 12/3/2022 in which Patient #2 received treatment with the wrong size dialyzer.</p> <p>3. Review of the clinical record for Patient #2 evidenced a dialysis order dated 10/03/2022, which included the use of the Gambro Revaclear 300 dialyzer. The treatment sheet for 12/3/2022 indicated a prescription order for the Gambro Revaclear 300 dialyzer. The treatment record indicated registered nurse (RN) 1 verified the prescription and verified the machine setup, which included the dialyzer. The treatment record indicated the amount of treatment time of 4 hours was not met. RN 1 documented the reason treatment time was not met as "Setup issue (delayed getting pt [patient] on, machine set incorrectly)."</p> <p>4. During interviews on 3/29/2023, Administrative Staff 1 indicated the dialysis machine was set up for a Patient #4; Patient #4 canceled their treatment and Patient #2 was early. Administrative Staff 1 indicated Patient #2 was placed in the treatment station which was for Patient #4, who used a Revaclear 400 dialyzer. When asked, Administrative Staff 1 indicated the agency had procedures / practices in place to ensure patients received the correct treatment, including RN verification of the machine and prescription and a list of the 5 patients who used the Revaclear 400 dialyzer at the nurses' station. When asked, administrative staff #1 indicated the procedures and practices were in place prior to the incident on 12/3/2022 and confirmed the agency did not put any new safeguards in place after the 12/3/2022 event.</p> <p>5. During an interview on 3/29/2023 at 4:15 PM,</p>		<p>initiation of treatment...2) Prescription components include but are not necessarily limited to: Dialyzer make and model...3) The prescription components are confirmed by a licensed nurse within one (1) hour of treatment initiation 4) The licensed nurse notifies the physician (or NPP if applicable) as needed of changes in patient status. 5) All findings, interventions, and patient response will be documented in the patient's medical record. The Facility Administrator or designee will audit 100% of post treatment records daily x 2 weeks, then 25% of post-treatment records weekly x 2 weeks to verify compliance with facility policy for verification of the dialysis prescription, documentation of treatment findings, and physician notification. Ongoing compliance will be verified with 10% of post-treatment records audited monthly x 3 months during the internal medical record audit. Instances of noncompliance will be addressed immediately. The Facility Administrator or designee will review the results of the audits with teammates during homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement meetings, known as Facility Health Meetings, with supporting documentation included in the meeting minutes.</p>	

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

PRINTED: 04/20/2023  
FORM APPROVED  
OMB NO. 0938-039

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	RN 1 indicated they made the error, and the situation was as described by Administrative Staff 1. RN 1 indicated they should have verified the dialyzer and relayed he/ she shortened the treatment session to account for the larger dialyzer and relayed the physician was not notified and should have been called for new orders.		The Facility Administrator is responsible for compliance with this plan of correction.		