

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

PRINTED: 06/15/2023

FORM APPROVED

OMB NO. 0938-039

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152625 | | X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING | | X3) DATE SURVEY COMPLETED 05/19/2023 | |
| NAME OF PROVIDER OR SUPPLIER KENDALLVILLE RENAL CENTER | | | | STREET ADDRESS, CITY, STATE, ZIP COD 602 SAWYER RD KENDALLVILLE, IN 46755 | | | |
| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIE (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 |
| E 0000 Bldg. 00 | <p>An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62</p> <p>Survey Dates: May 17, 18, and 19, 2023</p> <p>Total Census: 60 In-Center Hemodialysis: 60</p> <p>At this Emergency Preparedness survey, Kendallville Renal Center was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62</p> <p>QR Area 2 on 5/30/23</p> | | | E 0000 | | | |
| V 0000 Bldg. 00 | <p>This visit was for a CORE Federal recertification survey of an ESRD provider.</p> <p>Survey dates: May 17, 18, and 19, 2023</p> <p>Census by Service Type: In Center Hemodialysis: 60 Home Hemodialysis: 0 Home Peritoneal dialysis: 0 Total Census: 60</p> <p>Isolation Room: 1</p> <p>Kendallville Renal Center was found to be out of</p> | | | V 0000 | <p>The Governing Body of Kendallville Renal Center, IN, has reviewed the statement of deficiency resulting from a recertification survey completed on 5/19/2023. The Governing Body has approved and respectfully submits this plan of correction.</p> | | |

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Trina Gross Pfafman

RN, FA

06/12/2023

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 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 30 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 0113 Bldg. 00 | <p>compliance with the Conditions of Coverage 42 CFR 494.60 - Physical Environment.</p> <p>QR be Area 2 on 5/31/23</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) provider failed to ensure all staff followed hand hygiene policies while discontinuing a patient's dialysis for 1 of 4 observations of staff discontinuing dialysis on a patient with an AV fistula or graft (Patient Care Technician (PCT) #5.</p> <p>Findings include:</p> <p>Review of facility policy #1-05-01 titled "Infection Control for Dialysis Facilities," last revised 04/2023, indicated staff should perform hand hygiene prior to gloving, immediately after removal of gloves, and between patient contact.</p> <p>During an observation on 05/17/2023 beginning at 3:10 PM at Station #15, Patient #12's dialysis treatment completed and PCT #5 discontinued the treatment. With gloved hands, the technician picked up a piece of trash off the floor then removed the patient's dialysis cannulation needles. The technician failed to change their gloves and perform hand hygiene prior to removing the patient's dialysis needles.</p> <p>During an interview on 05/19/2023 beginning at 4:45 PM, Corporate Employee #3, an administrator</p> | | | V 0113 | <p>The Facility Administrator or designee held mandatory in-service(s) for all Clinical Teammates starting on 6/12/23. Surveyor observations were reviewed. Education included but was not limited to a review of Policy # 1-05-01 Infection Control for Dialysis Facilities with the emphasis on but not limited to: 1) All teammates, Physicians and Non-Physician (NPP) will perform hand hygiene: prior to gloving and immediately after removal of gloves, between patients even if the contact is casual. 2. Gloves should be changed when: going from a "dirty" area or task to a "clean" area or task. Verification of attendance at in-service will be evidenced by teammates signature on in-service sheet. The Facility Administrator or designee will conduct infection control audits for wearing Gloves/Hand Hygiene daily for two (2) weeks then weekly for four (4) weeks then monthly during internal</p> | | 06/19/2023 |

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| V 0114 Bldg. 00 | <p>of a sister dialysis facility, confirmed PCT #5 should have removed their gloves and performed hand hygiene prior to removing Patient #12's dialysis needles.</p> <p>494.30(a)(1)(i) IC-SINKS AVAILABLE A sufficient number of sinks with warm water and soap should be available to facilitate hand washing.</p> <p>Based on observation and interview, the End Stage Renal Dialysis (ESRD) provider failed to ensure handwashing sinks, soap, and paper towels were available in 5 of 7 handwashing sinks observed, with the potential to affect all patients and employees.</p> <p>Findings include:</p> <p>1. During a facility tour on 5/17/2023 at 11 AM, the handwashing station located at the facility's laboratory station (not on the treatment floor) failed to have soap or paper towels available.</p> <p>2. During a treatment floor observation on 5/17/2023 at 11:13 AM, six handwashing sinks were observed. One of the three sinks available</p> | | | V 0114 | <p>infection control audits to verify compliance. Instances of non-compliance will be addressed immediately. The Facility Administrator or designee will review the results of the gloves/hand hygiene audits with teammates during homeroom meetings and with Medical Director during monthly 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 held mandatory in-service(s) for all Clinical Teammates starting on 6/12/23. Surveyor observations were reviewed. Education was included but not limited to a review of policy #1-05-01 Infection Control for Dialysis Facilities with emphasis on but not limited to: Sinks should be easily accessible and readily available in the treatment area and in other appropriate areas such as the medication area, home training room, and isolation area/room. Clean supplies or equipment will not be placed adjacent to a sink unless a splash guard is in place.</p> | | 06/19/2023 |

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| V 0117 Bldg. 00 | <p>for staff and patients failed to have soap or paper towels available. Two of the three clean sink stations in the staff work area failed to have soap present. The paper towel dispensers in the staff work area were either empty, not present, or had a trash can and / or a biohazard bin touching the dispenser, causing contamination.</p> <p>3. During an interview conducted during the treatment floor observation, Patient Care Technician (PCT) #2 identified the 6 handwashing sinks on the treatment floor and confirmed there were 2 handwashing sinks currently stocked for use, with soap and uncontaminated paper towels. Corporate Employee #3, an administrator of a sister ESRD facility, confirmed the observation.</p> <p>4. Review of facility policy #1-05-01 titled "Infection Control for Dialysis Facilities," last revised 04/2023, indicated the facility would have sinks "easily accessible and readily available in the treatment area" and indicated each clean sink should have soap and a "supply of paper towels protected from contamination."</p> <p>494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples</p> | | | | <p>Soap and a supply of paper towels protected from contamination must be available at each clean sink. The Facility Administrator or designee will conduct Infection Control audits to ensure sinks with warm water are available with soap and supply of paper towels protected from contamination daily for two (2) weeks then weekly for four (4) weeks then monthly during infection control audits to verify compliance. Instances of non-compliance will be addressed immediately. The Facility Administrator or designee will review the results of the sink/supply audits with teammates during homeroom meetings and with Medical Director during Monthly 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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| | <p>are handled.</p> <p>When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.</p> <p>Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.</p> <p>Based on observation, record review, and interview, the End Stage Renal Dialysis (ESRD) provider failed to ensure supplies were stored and maintained in a way to prevent contamination at 3 of 3 staff work stations observed, which had the potential to affect all facility patients and employees.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Review of an article from the Centers for Disease Control and Prevention (CDC) titled "Reduce Risk from Water" available at https://www.cdc.gov, indicated patient supplies should not be placed on counters next to sinks. 2. During a treatment floor observation on 5/17/2023 at 11:13 AM, new supplies were observed immediately next to a sink, in 3 of the 3 staff workstations. The first workstation had patient supply bundles (containing syringes, clamps, dialysis needles, and gauze pads) adjacent to the sink. The second workstation had supplies of syringes and gauze pads directly across from a sink used for contaminated items. | | | V 0117 | <p>The Facility Administrator or designee held mandatory in-service(s) for all Clinical Teammates starting on 6/12/23. Surveyor observations were reviewed. Education included but was not limited to a review of Policy # 1-05-01 Infection Control for Dialysis Facilities with the emphasis on but not limited to: 1) Clean supplies or equipment will not be placed adjacent to a sink unless a splash guard is in place. Verification of attendance at in-service will be evidenced by teammates signature on in-service sheet. The Facility Administrator or designee will conduct observational audits for clean supplies or equipment being placed adjacent to a sink without a splash guard and administration daily for two (2) weeks then weekly for four (4) weeks then monthly during internal infection</p> | | 06/19/2023 |

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| V 0122 Bldg. 00 | <p>The third workstation had a case of supplies placed over part of the sink.</p> <p>3. During an interview at the time of the treatment floor observation, Corporate Employee #3, an administrator of a sister dialysis facility, confirmed clean supplies should not be near a sink. The Administrator reported the facility had limited space and needed to put supplies on the counter.</p> <p>4. Review of facility policy #1-05-01 titled "Infection Control for Dialysis Facilities," last revised 04/2023, indicated all equipment and work surfaces would be cleaned and/or disinfected "as soon as possible following exposure to blood or other potentially infectious material." The policy also indicated staff should avoid placing clean supplies or equipment adjacent to a sink without a splash guard.</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, document review, and interview, the End Stage Renal Dialysis (ESRD) provider failed to ensure all staff cleaned the dialysis station after treatment according to facility policy for 2 of 3 observations of staff cleaning dialysis stations (Patient Care Technician (PCT) #4 and #6), which had the potential to affect all patients.</p> | | | V 0122 | <p>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 Medical Director during monthly Quality Assurance and 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 held mandatory in-service(s) for all Clinical Teammates starting on 6/12/23. Surveyor observations were reviewed. Education included but was not limited to a review of Policy # 1-05-01 Infection Control for Dialysis Facilities with the</p> | | 06/19/2023 |

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| | <p>Findings include:</p> <ol style="list-style-type: none"> 1. Review of facility policy #1-05-01 titled "Infection Control for Dialysis Facilities," last revised 04/2023, indicated each dialysis station would be cleaned and disinfected after each treatment. Cleaning and disinfection of the station included the dialysis chair. 2. During an observation at Station #16 on 05/19/2023 beginning at 3:12 PM, PCT #6 was observed cleaning the station after it was vacated. The technician failed to fully recline the treatment chair when cleaning the station. 3. During an observation at Station #18 on 5/19/2023 at 8:57 AM, PCT #4 cleaned the station after it was vacated. PCT #4 failed to clean the blood pressure cuff and failed to recline the dialysis chair and clean all surfaces. 4. During an interview on 5/19/2023 at 3 PM, Corporate Employee #2, an administrator of a sister dialysis facility, confirmed the dialysis chair must be reclined to clean all the crevices. | | <p>emphasis on but not limited to: 1) At the end of each treatment, the dialysis station will be cleaned and disinfected. a. Surfaces to disinfect include but are not necessarily limited to: all surfaces in contact with the patient or their belongings (e.g., dialysis chair, tray tables, blood pressure cuffs) and frequently contacted by healthcare personnel (e.g., control panel; top, front and sides of dialysis machine; touchscreens; countertops). Verification of attendance at in-service will be evidenced by teammates signature on in-service sheet. The Facility Administrator or designee will conduct infection control audits for station disinfection daily for two (2) weeks then weekly for four (4) weeks then monthly during internal infection control audits to verify compliance. 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 Medical Director during monthly Quality Assurance and 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>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 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, document review, and interview, the agency failed to ensure central venous lines (CVC, a tube that goes in a vein near the heart as part of the dialysis process) were cleaned appropriately to reduce the chance of</p> | | | V 0147 | The Facility Administrator or designee held mandatory in-service(s) for all Clinical Teammates starting on 6/12/23. Surveyor observations were reviewed. Education included but | | 06/19/2023 |

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| | <p>infection in 3 of 3 CVC dialysis initiation and discontinuation observations (Patients #1, 4, 21), with the potential to affect all patients with a CVC.</p> <p>Findings include:</p> <p>1. Review of facility policy #1-04-02B titled "Central Venous Catheter (CVC) with Clearguard HD Antimicrobial End Caps Procedure," last revised 04/2023, indicated the "effective contact time" for a CVC hub (end connection) with a 70% alcohol pad was a "15 second scrub" and the hub was to be allowed to air dry. When accessing a CVC prior to initiating dialysis, the policy indicated staff were to "scrub each CVC hub for 15 seconds including the sides, threads, and end of hub thoroughly with friction ... Hold the limbs until the antiseptic has dried."</p> <p>2. During an observation on 5/17/2023 at 1:06 PM, patient care technician (PCT) 5 initiated dialysis for Patient #1. During the disinfection process, PCT 5 used an alcohol pad to scrub the CVC arterial hub for 10 seconds. Prior to flushing the line with saline, the scrub was 6 seconds. The initial scrub for the venous line was 12 seconds.</p> <p>3. During an observation on 5/17/2023 at 1:25 PM, PCT 3 initiated dialysis for Patient #4. During the disinfection process, PCT 3 used an alcohol pad to scrub the CVC arterial hub for 6 seconds. Prior to flushing the line with saline, the scrub was 7 seconds. The initial scrub for the venous line was 8 seconds and the scrub before flushing the line was 6 seconds.</p> <p>4. During an interview on 5/17/2023 at 11:55 AM, the Administrator indicated the scrub should be 30 seconds at each step of the process (prior to use and before the flush).</p> | | | | <p>was not limited to a review of Procedure 1-04-02B: Central Venous Catheter (CVC) with Clearguard HD Antimicrobial End Caps Procedure emphasizing: 1) Set-up clean field with supplies on a clean moisture proof barrier. 2) Place a second moisture proof barrier under catheter limbs. With clean gloved hands remove old dressing and discard without reaching over patient and contaminating clean field, assess CVC exit site for infection. Remove and discard gloves, conduct hand hygiene, don new gloves. Teammates must hold catheter with the non-dominant hand using aseptic technique, clean exit site with 2% Chlorhexidine Gluconate/70% Isopropyl Alcohol swab for a minimum of 30 seconds, and apply to CVC exit site in a "back and forth" pattern, using gentle friction progressing from insertion site to periphery using both sides of the swab. Then wait 60 seconds for air dry time. 3) Clean each CVC limb with new alcohol prep pad; starting close to exit site and down to the end cap removing accumulated biological matter. 4) Remove and discard gloves, conduct hand hygiene, don new gloves. Place sterile gauze over catheter and exit site leaving catheter limbs accessible. 5) Using aseptic technique, remove each cap. One at a time, disinfect</p> | | |

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| | <p>5. During an interview on 5/19/2023 at 3 PM, Corporate Staff 4 indicated the scrub should be 15 seconds if using an alcohol pad.6. Review of facility policy #1-04-02B titled "Central Venous Catheter (CVC) with Clearguard HD Antimicrobial End Caps Procedure," last revised 04/2023, indicated the "effective contact time" for a CVC hub (end connection) with a 70% alcohol pad was a "15 second scrub" and the hub was to be allowed to air dry. When accessing a CVC prior to initiating dialysis, the policy indicated staff were to "scrub each CVC hub for 15 seconds including the sides, threads, and end of hub thoroughly with friction ... Hold the limbs until the antiseptic has dried." When discontinuing access to a CVC at the end of the dialysis treatment, the policy indicated staff were to "set-up [a] new clean field ... on a new clean, moisture proof barrier."</p> <p>7. During an observation at Station #14 on 05/17/2023 beginning at 3:35 PM, PCT #5 initiated dialysis for Patient #14. Using a 70% alcohol pad for each hub, the technician scrubbed the two hubs of the patient's CVC for 4 seconds each prior to continuing on in the initiation process.</p> <p>8. During an observation at Station #23 on 05/17/2023 beginning at 2:52 PM, Registered Nurse (RN) #2 initiated dialysis for Patient #15. Using a 70% alcohol pad for each hub, the nurse scrubbed the two hubs of the patient's CVC for 2 seconds each prior to continuing on in the dialysis initiation process.</p> <p>9. During an observation at Station #9 on 05/19/2023 beginning at 3:30 PM, PCT #2 performed site care to Patient #14's CVC line then initiating dialysis. The technician failed to change their gloves and perform hand hygiene in between</p> | | | | <p>each CVC hub with a new alcohol prep pad. Scrub each CVC hub for 15 seconds including the sides, threads and end of hub thoroughly with friction making sure to remove any residue, for example blood. Hold the limbs until the antiseptic has dried then attach sterile 10ml syringes to the arterial and venous limbs to aspirate 5 ml from each limb. Verification of attendance at in-service will be evidenced by teammates signature on in-service sheet. The Facility Administrator or designee will conduct observational audits for CVC care daily for two (2) weeks then weekly for four (4) weeks then ongoing monthly during internal infection control audits to verify compliance. 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 and 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 0400 Bldg. 00 | <p>removing the old CVC dressing and cleaning the site.</p> <p>494.60 CFC-PHYSICAL ENVIRONMENT</p> <p>Based on observation, document review, and interview, the End Stage Renal Dialysis (ESRD) provider failed to ensure all supplies were dated when opened per policy and not expired (See V401), failed to maintain a safe and functional environment specific to water pipe maintenance and prevention of builup, replacement of broken and/or water-stained ceiling tiles, and thorough cleaning of all surfaces (See V402), and failed to ensure the patient's access site was visible at all times (see V407).</p> <p>The cumulative effect of these systemic problems resulted in the ESRD provider failed to provide a safe environment for all patients and staff, which resulted in the provider being found out of compliance with Condition of Coverage 42 CFR 494.60 Physical Environment.</p> | | V 0400 | <p>Kendallville Renal Dialysis takes the Conditions for Coverage very seriously. Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the Plan of Correction (POC). Immediate steps were taken to ensure facility has a safe, functional and maintained Physical Environment. These actions are outlined in depth in the plan of correction under V401, V402, and V407 that are not met, as well as other standards and contain specifics of corrective action plans. The Governing Body will meet weekly to ensure compliance with the POC. Further compliance to the POC will be reviewed during monthly QAPI/Facility Health Meeting (FHM) and reported to the Governing Body. Once compliance is reached the GB will review and provide oversight no less than semi- annually. The Facility administrator (FA) representing the GB will be responsible for implementation and ongoing compliance with this POC.</p> | | 06/19/2023 | |
| V 0401 | <p>494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE</p> | | | | | | |

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| Bldg. 00 | <p>ENVIRONMENT</p> <p>The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.</p> <p>Based on observation, document review, and interview, the End Stage Renal Dialysis (ESRD) provider failed to ensure all supplies were dated when opened per policy and not expired, which had the potential to affect all patients.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Review of facility policy #1-05-01 titled "Infection Control for Dialysis Facilities," last revised 04/2023, indicated supply expiration dates would be verified prior to use. 2. Review of facility procedure #1-06-02A titled "Utilizing Acid Concentrate in Containers," last revised 04/2023, indicated staff should label containers of acid concentrate with the date of opening and their initials. 3. During a treatment floor observation on 05/17/2023 at 11:26 AM, one container of 1 K+ (potassium) acid concentrate was observed to be previously opened. The container failed to have a date the container was opened nor the initials of the staff member who opened the containers. 4. During a second treatment floor observation on 05/17/2023 at 3:57 PM, 1 of 2 supply carts, used by the facility for storage of emergency supplies and equipment, contained one bag of 2 inch by 2 inch gauze with an expiration date of 05/02/2023. 5. During an interview conducted on 05/17/2023 at 4:24 PM, the Administrator confirmed the opened | | | V 0401 | <p>The Facility Administrator or designee held mandatory in-service(s) for all Clinical Teammates starting on 6/16/23. Surveyor observations were reviewed. Education included but was not limited to a review of Policy # 1-06-02A Utilizing Acid Concentrate in Containers. Emphasis was placed on: 1) Upon opening an acid concentrate container, label container with date opened, and initials of teammate. Education also included a review of Policy 1-05-01 Infection Control for Dialysis Facilities. Emphasis was placed on: Expiration date and package integrity will be verified prior to use. Verification of attendance at in-service will be evidenced by teammates signature on in-service sheet. The Facility Administrator or designee will conduct observational audits of acid concentrate daily for two (2) weeks then weekly for four (4) weeks then monthly during internal infection control audits to verify compliance. Instances of non-compliance will be addressed immediately. The Facility Administrator or designee will review the results of the audits</p> | | 06/19/2023 |

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| V 0402 Bldg. 00 | <p>container of 1 K+ acid concentrate should be marked with the date the container was opened. The Administrator also confirmed the bag of 2 inch by 2 inch gauze contained in the emergency supply cart was expired.</p> <p>494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY</p> <p>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.</p> <p>Based on observation and interview, the facility failed to maintain a safe and functional environment specific to water pipe maintenance and prevention of buildup, replacement of broken and/or water-stained ceiling tiles, and thorough cleaning of all surfaces, which had the potential to affect all facility patients and staff.</p> <p>Findings include:</p> <p>1. During treatment floor observation on 5/17/2023 at 11:13 AM, one water - stained ceiling tile was observed over the treatment floor, which created an environment for the growth of mold or other potential contaminates. One ceiling tile was missing a portion in the corner of the tile, and in one location there was a missing ceiling tile. This created a potential for debris to contaminate the treatment floor.</p> | V 0402 | <p>with teammates during homeroom meetings and with the Medical Director during monthly Quality Assurance and 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 held mandatory in-service(s) for all Clinical Teammates starting on 6/12/23. Surveyor observations were reviewed. Education included but was not limited to a review of Policy # 8-04-01 Physical Environment. Education included but not limited to: The dialysis facility will implement and maintain a program to verify that all equipment, including emergency equipment, dialysis delivery systems and the water treatment systems are maintained and operated in accordance with the manufacturer's recommendations. Refer to biomed policies for further instructions regarding dialysis</p> | 06/19/2023 | |

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| | <p>2. During the same observation period, the emergency cart was observed to have dried, white splatter on the front and side.</p> <p>During an interview during the observation period, the Administrator and BioMed Tech confirmed this was likely due to residual water spraying from a dialysis machine that had been disconnected (for maintenance).</p> <p>3. During an observation on 05/18/2023 beginning at 9:45 AM the water access components (for the intake and drainage of the treated water used for dialysis, located directly behind each treatment station), revealed active water leaks in stations 7 and 18.</p> <p>4. Observation of the water access compartments evidenced mineral buildup on the water tubing, drainage tube, and / or floor in 16 of 20 compartments. Mineral buildup measured up to approximately 6.5 inches by 6.5 inches (top to bottom and side to side of the water tubing). Mineral buildup was evident on compartment floors, measuring up to approximately 1 foot high.</p> <p>5. During an interview on 5/18/2023 at 9:45 AM, the BioMedical Technician (BioMed Tech) confirmed the mineral buildup was the result of a slow water leak. The BioMed tech indicated there was no program or schedule to periodically inspect the water access compartments for leaks.</p> <p>6. During a phone interview on 5/18/2023 at 11:41 AM, the regional biomed director confirmed there was no routine monitoring for water leaks in the water access compartments. The regional biomed director reported the water access compartments were only opened if there was a problem which required opening of the compartment, such as a</p> | | | | <p>delivery systems and the water treatment systems. Verification of attendance at in-service will be evidenced by teammate signature on in-service sheet. The Facility Administrator or designee will conduct physical plant observational audits daily for two (2) weeks then weekly for four (4) weeks then monthly during OSHA Safety audits. Issues requiring physical plant repair will be escalated to the Regional Operations Director and a timeline developed for completion of repairs. 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 and Performance Improvement meetings known as Facility Health Meetings with supporting documentation included in the meeting minutes. The Governing Body will review physical plant audits and will oversee the timeline for physical plant repairs until all repairs have been completed. The Facility Administrator is responsible for compliance with this plan of correction.</p> | | |

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| V 0407 Bldg. 00 | <p>leak that had spread past the compartment or an issue with the dialysis machine. The regional biomed director confirmed the buildup indicated a longstanding slow leak.</p> <p>494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS</p> <p>Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement).</p> <p>Based on observation and interview, the End Stage Renal Dialysis (ESRD) provider failed to ensure the patient's access site was visible at all times for 4 of 20 patients observed during 2 days of treatment floor observations (Patients #4, 5, 7, 8).</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. During an observation at Station #20 on 05/17/2023 at 11:19 AM, Patient #7 was observed with their access site covered. 2. During an observation at Station #1 on 05/17/2023 at 11:20 AM, Patient #8 was observed with their access site covered. 3. During an observation at Station #8 on 05/19/2023 at 2:35 PM, Patient #5 was observed with their access site covered. 4. During an observation at Station #10 on 05/19/2023 at 2:36 PM, Patient #4 was observed with their access site covered. 5. During an interview conducted on 05/19/2023 beginning at 4:45 PM, Corporate Employee #3, an administrator of a sister dialysis facility, confirmed | | | V 0407 | <p>The Facility Administrator or designee held mandatory in-service(s) for all Clinical Teammates starting on 6/16/23. Surveyor observations were reviewed. Education included but was not limited to a review of Policy 1-03-08 Pre-Intra-Post Data Collection, Monitoring and Nursing Assessment with emphasis on: 1) The vascular access site, blood line connections and the patient's face should be visible throughout the dialysis treatment. Education also included a review of Policy 8-04-01 Physical Environment emphasizing that teammates will be able to visualize patients at all times during hemodialysis treatments for patient safety. Verification of attendance at in-service will be evidenced by teammates signature on in-service sheet. The Facility Administrator (FA) or designee has provided written education to all patients on the importance of having vascular access uncovered and in view</p> | | 06/19/2023 |

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| | the patient's access site should be visible at all times. | | during treatment. A signed copy of this patient education was also placed in each patient's medical record. Teammates were also instructed to re-educate any patient that has his/her vascular access covered and uncover the access. Teammate will also document in patient's medical record that re-education was given to patient. Patients refusing to keep access, bloodline connection or faces visible will be re-educated by the physician. Care conferences will be scheduled with the Interdisciplinary team and the patient to develop individual plans of correction. The Facility Administrator or designee will conduct daily observational audits for access site, Facility face and bloodline connection visibility daily for two (2) weeks then weekly for four (4) weeks then 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 and 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. | | |

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| V 0543 Bldg. 00 | <p>494.90(a)(1) POC-MANAGE VOLUME STATUS</p> <p>The plan of care must address, but not be limited to, the following:</p> <p>(1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status;</p> <p>Based on record review and interview, the End Stage Renal Dialysis (ESRD) provider failed to ensure patients were assessed by the registered nurse (RN) within 60 minutes of the start of dialysis and every 30 minutes thereafter by the RN or patient care technician (PCT), in 3 of 7 patient records reviewed (Patients #3, 4, 6, 14, 16), with the potential to affect all patients.</p> <p>Findings include:</p> <p>1. Review of the clinical record for Patient #3 included a treatment flowsheet for the treatment provided on 05/08/2023. The flowsheet indicated PCT #3 initiated dialysis at 9:40 AM and the patient's initial nurse assessment was completed by RN #1 at 11:32 AM.</p> <p>The record included a treatment flowsheet for the treatment provided on 5/10/2023. The flowsheet indicated PCT #2 initiated dialysis at 9:45 AM and the patient's initial nurse assessment was completed by RN #1 completed the nursing assessment at 11:13 AM, which was 1 hour and 28 minutes after the start of dialysis.</p> <p>The record included a treatment flowsheet for the treatment provided on 5/12/2023. The flowsheet indicated during treatment, staff obtained vital signs at 11:00 AM and then 11:59 AM, which was 59 minutes in between vital signs being obtained.</p> | | | V 0543 | <p>The Facility Administrator or designee held mandatory in-service(s) for all Clinical Teammates starting on 6/12/23. Surveyor observations were reviewed. Education included but was not limited to a review of Policy 1-03-08 Pre-Intra-Post Treatment Data Collection Monitoring and Nursing Assessment emphasizing but not limited to: 1) Patient identity, prescription and machine settings are verified by teammates prior to initiation of treatment with the exception of blood flow rate (BFR) which is verified and documented when the ordered rate is obtained after onset of treatment. The prescription component are confirmed by a licensed nurse by 1 hour of treatment initiation along with the nursing assessment. 2) Intra dialytic treatment monitoring and data collection which may be performed by the PCT or licensed nurse includes vital signs and treatment monitoring at least every 30 minutes. Verification of attendance at in-service will be evidenced by teammates signature on in-service sheet.</p> | | 06/19/2023 |

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| | <p>The record included a treatment flowsheet for the treatment provided on 5/17/2023. The flowsheet indicated PCT #6 initiated dialysis at 9:23 AM and the patient's initial nurse assessment was completed at 11:38 AM, which was 2 hours and 15 minutes after the start of dialysis. Subsequent monitoring indicated staff failed to obtain a set of vital signs due at 10:29 AM.</p> <p>2. Review of the clinical record for Patient #4 included a treatment flowsheet for the treatment provided on 05/12/2023. The flowsheet indicated dialysis was initiated at 1:49 PM ad the nurse assessment was completed at 3:54 PM by RN #1, which was 2 hours and 5 minutes after the start of dialysis.</p> <p>The record included a treatment flowsheet for the treatment provided on 05/15/2023. The flowsheet indicated dialysis was initiated at 10:00 AM and the nurse assessment was completed at 11:34 AM by the Administrator, which was 1 hour and 34 minutes after the start of dialysis.</p> <p>The record included a treatment flowsheet for the treatment provided on 5/17/2023. The flowsheet indicated dialysis was initiated at 1:25 PM and the nurse assessment was completed at 4:12 PM by the Administrator, which was 2 hours and 47 minutes after the start of dialysis.</p> <p>3. Review of the clinical record for Patient #6 included a treatment flowsheet for the treatment provided on [date]. The flowsheet indicated dialysis was initiated at 12:55 PM and the nurse assessment was completed at 3:49 PM by RN #1, which was 2 hours and 54 minutes after the start of dialysis.</p> | | | | | | |

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| | <p>4. During an interview on 05/19/2023 at 5:15 AM, RN #2 reported the nurse assessment should be completed within 60 minutes from the initiation of dialysis.</p> <p>5. During an interview on 05/19/2023 at 3:00 PM, Corporate Employee #2, an administrator of a sister dialysis facility, confirmed the assessments for Patients #3, 4, and 6 were completed late.6. Review of the clinical record for Patient #14 included a treatment flowsheet for the treatment on 05/15/2023. The flowsheet indicated dialysis was initiated at 3:31 PM by and the nurse assessment was completed at 5:18 PM, which was 1 hour and 47 minutes after the start of dialysis.</p> <p>The record included a treatment flowsheet for the treatment provided on 05/17/2023. The flowsheet indicated treatment was initiated at 3:44 PM by PCT #6. During the treatment, staff obtained the patient's vital signs at 4:00 PM then the next set of vital signs at 4:55 PM, which was 55 minutes between vital signs being obtained. The staff also obtained Patient #14's vital signs at 5:10 PM then the next set of vitals at 6:00 PM (the end of treatment), which was 50 minutes between vital signs been obtained.</p> <p>7. During an interview on 05/19/2023 at 6:15 PM, Corporate Employee #3, an administrator of a sister dialysis facility, confirmed the nurse failed to perform an assessment of Patient #14 within 1 hour of start of treatment on 05/15/2023 and staff failed to obtain the patient's vital signs were every 30 minutes on 05/17/2023.</p> <p>8. Review of the clinical record for Patient #16 included a treatment flowsheet for the treatment performed on 04/05/2023. The flowsheet indicated treatment was initiated at 9:53 AM by PCT #2 and</p> | | | | | | |

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

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152625 | | X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING | | X3) DATE SURVEY COMPLETED 05/19/2023 | |
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| | <p>the initial nurse assessment was completed at 11:57 AM by RN #1, which was 2 hours and 4 minutes after the start of dialysis.</p> <p>The record included a treatment flowsheet for the treatment performed on 04/07/2023. The flowsheet indicated treatment was initiated at 9:45 AM by PCT #6 and the initial nurse assessment was completed on 11:13 AM by the Administrator, which was 1 hour and 28 minutes after the start of treatment.</p> <p>9. During an interview on 05/19/2023 at 6:35 PM, Corporate Employee #3, an administrator of a sister dialysis facility, confirmed the nurse failed to perform an assessment of Patient #16 within 1 hour of start of treatment on 04/05/2023 and 04/07/2023. Corporate Employee #4, an administrator of a sister dialysis facility, reported Patient #16 was admitted to a hospital after their treatment on 04/07/2023 and did not resume dialysis treatment at the facility until 05/19/2023.</p> | | | | | | |