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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:<br><br>152615 | X2) MULTIPLE CONSTRUCTION<br>A. BUILDING 00<br>B. WING _____ | X3) DATE SURVEY COMPLETED<br><br>03/17/2014 |
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| NAME OF PROVIDER OR SUPPLIER<br><br>GREENSBURG DIALYSIS | STREET ADDRESS, CITY, STATE, ZIP CODE<br>1531 N COMMERCE E DR STE 6<br>GREENSBURG, IN 47240 |
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| (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 |
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| V000000            | <p>This visit was an ESRD recertification survey.</p> <p>Facility: #006654</p> <p>Dates: March 12, 13, 14, and 17, 2014</p> <p>Medicaid: # 200884520</p> <p>Surveyors: Janet Brandt, RN, PHNS, Team Leader<br/>Bridget Boston, RN, PHNS, Team Member</p> <p>Greensburg Dialysis was found to be out of compliance with the Condition for Coverage 42 CFR 494.40: Water and dialysate quality.</p> <p>Census: 15<br/>5 In-center Hemodialysis<br/>5 Peritoneal Dialysis<br/>5 Home Hemodialysis</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN<br/>March 28, 2014<br/>494.30(c)(2)<br/>IC-CATHETERS:GENERAL<br/>(2) The "Guidelines for the Prevention of Intravascular Catheter-Related Infections" entitled "Recommendations for Placement of Intravascular Catheters in Adults and Children" parts I - IV; and "Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients," Morbidity and Mortality Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in</p> | V000000       |                                                                                                                 |                      |
| V000146            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |               |                                                                                                                 |                      |

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>accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection as the CMS 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:<br/><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>Based on policy review, observation, and staff interview, the facility failed to ensure 1 of 1 Patient Care Technician (PCT) (employee F) observed providing care to 2 of 2 patients with a central venous catheter (CVC) access (patients 3 and 6) during 1 of 2 observations were in compliance with central venous catheter policy creating the potential to spread infectious and communicable disease which could affect both patients with a CVC and any future CVC patient.</p> <p>The findings include:</p> <p>1. Facility policy titled "CENTRAL VENOUS CATHETER (CVC) CLEANING AND DRESSING CHANGE" policy number 1-04-02C with a revision date of March 2013 states, "Materials required: ... Germicidal solution / disinfectant appropriate for type of catheter ... Exit site cleansing procedure are required each treatment for all catheters. ... Hypochlorite (ExSept Plus Plus) If using sterile 4 X 4 gauze, saturate with 8 - 12 milliliters ... contact time 60 seconds air drying time 2 minutes. ... Holding catheter with the non dominant hand, and using</p> | V000146       | <p><b>V 146</b></p> <p>100% of clinical teammates were in-serviced on 3/28/14 on <i>Policy 01-04-02 "Central Venous Catheter (CVC) Care" and Procedure 1-04-02A "Central Venous Catheter (CVC) Procedure"</i>. Verification of attendance is evidenced by a signature sheet. Teammates were instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) scrub CVC limbs and caps with large alcohol prep pad, one per limb for 60 seconds, and 2) remove each CVC lumen end cap and disinfect the hub with a new alcohol prep pad for each hub. Scrub the sides, threads, and end of hub thoroughly with friction to remove any residue. Physician orders were obtained on the patient identified in the survey to complete the dressing change for both catheters each treatment. Facility Administrator (FA) or designee will complete CVC Care Process Procedural Skills</p> | 04/16/2014           |

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|                    | <p>aseptic technique, clean exit site with germicidal moistened gauze, per [ area blank] manufacturers recommendations. ... Using fresh germicidal moistened gauze, clean catheter limbs, starting at exit site and cleaning entire length of catheter limbs. ... Place sterile gauze over catheter and exit site leaving connected or sealed catheter limbs accessible."</p> <p>2. Observation on 3/14/14:</p> <p>A. At 7:10 AM, observed patient 3 with two catheters in the patients right chest. The right catheter was covered with a dressing, the catheter on the left was not. Employee F indicated the patient returned to the facility on 3/7/14 after being hospitalized. The employee indicated the patient returned with the second catheter and she was not aware why a second was placed, the purpose, or what care she was to provide if any to the access. The patient indicated staff of the extended care facility used the catheter daily to administer intravenous medications and no one had provided a dressing to the second access. The patient indicated the second access was placed while in the hospital.</p> <p>Observed employee F to provide to cleanse the area surrounding the far right catheter. The employee identified the catheter on the right as the dialysis catheter. The employee wiped the limbs of the CVC. She did not perform any catheter or access care to the catheter on the left of the dialysis catheter. Employee F, while wearing clean gloves, held a sterile 4 X 4 piece of gauze and began applying pre torn tape to the edges of the gauze, turning the gauze as she applied to each side. As she held the gauze, her gloved fingers were in contact with the center of the</p> |               | <p>Checklist for each teammate working each treatment day for 4 weeks, and then weekly for 1 month. FA will review findings with the Medical Director in the monthly QAPI meeting, known as the Facility Health Meeting (FHM). The FA is responsible for ongoing compliance with this Plan of Correction (POC).<br/>Completion date: 4/16/14</p> |                      |

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| V000147                                                 | <p>gauze and then she placed the gauze ovetop of the dialysis catheter and overlapping the second catheter. The limbs of the dialysis catheter were not soaked or scrubbed, nor were the hubs soaked or scrubbed prior to initiation of hemodialysis.</p> <p>B. At 7:55 AM, observed employee F in station 5 with patient 6. Patient 6 arrived with a standard size Band-Aid over the CVC access. Employee F indicated the patient historically declined a dressing over the access and had accepted a Band-Aid. The patient was interviewed during the observation and indicated no experience with an infection and had not covered the access for years.</p> <p>Observed employee F to initiate dialysis with patient 6. The employee wiped the limbs of the CVC with 2 X 2 gauze which was soaked with cleanser. The limbs and the hub were not soaked or scrubbed prior to initiation of the dialysis treatment.</p> <p>3. On 3/14/14 at 8:15 AM, employee D indicated the observation described was not per policy and that the policy was to soak the limbs for one minute. She indicated it was not the facility policy to scrub the limbs of the CVC.</p> <p>494.30(a)(2)<br/>IC-STAFF<br/>EDUCATION-CATHETERS/CATHETER CARE<br/>Recommendations for Placement of Intravascular Catheters in Adults and Children</p> <p>I. Health care worker education and training<br/>A. Educate health-care workers regarding the ... appropriate infection control</p> |                                                                 |                                                                                                                 |                      |                                             |

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|                    | <p>measures to prevent intravascular catheter-related infections.</p> <p>B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters.</p> <p>II. Surveillance<br/>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<br/>B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].</p> <p>Based on policy review, observation, and staff interview, the facility failed to ensure 1 of 1 Patient Care Technician (PCT) (employee F) observed providing care to 2 of 2 patients with a central venous catheter (CVC) access (patients 3 and 6) during 1 of 2 observations were in compliance with central venous catheter policy creating the potential to spread infectious and communicable disease which could affect both patients with a CVC and any future CVC patient.</p> <p>The findings include:</p> <p>1. Facility policy titled "CENTRAL VENOUS CATHETER (CVC) CLEANING AND</p> | V000147       | <b>V147</b> 100% of clinical teammates were in-serviced on 3/28/14 on <i>Policy 01-04-02 "Central Venous Catheter (CVC) Care"</i> and <i>Procedure 1-04-02A "Central Venous Catheter (CVC) Procedure"</i> . Verification of attendance is evidenced by a signature sheet. Teammates were instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) scrub CVC limbs and caps with large alcohol prep pad, one per limb for 60 seconds, and 2) remove each CVC lumen end cap and disinfect the hub with a new alcohol prep pad for | 04/16/2014           |

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|                    | <p>DRESSING CHANGE" policy number 1-04-02C with a revision date of March 2013 states, "Materials required: ... Germicidal solution / disinfectant appropriate for type of catheter ... Exit site cleansing procedure are required each treatment for all catheters. ... Hypochlorite (ExSept Plus Plus) If using sterile 4 X 4 gauze, saturate with 8 - 12 milliliters ... contact time 60 seconds air drying time 2 minutes. ... Holding catheter with the non dominant hand, and using aseptic technique, clean exit site with germicidal moistened gauze, per [ area blank] manufacturers recommendations. ... Using fresh germicidal moistened gauze, clean catheter limbs, starting at exit site and cleaning entire length of catheter limbs. ... Place sterile gauze over catheter and exit site leaving connected or sealed catheter limbs accessible."</p> <p>2. Observation on 3/14/14:</p> <p>A. At 7:10 AM, observed patient 3 with two catheters in the patients right chest. The right catheter was covered with a dressing, the catheter on the left was not. Employee F indicated the patient returned to the facility on 3/7/14 after being hospitalized. The employee indicated the patient returned with the second catheter and she was not aware why a second was placed, the purpose, or what care she was to provide if any to the access. The patient indicated staff of the extended care facility used the catheter daily to administer intravenous medications and no one had provided a dressing to the second access. The patient indicated the second access was placed while in the hospital.</p> <p>Observed employee F to provide to cleanse the area surrounding the far right catheter.</p> |               | <p>each hub. Scrub the sides, threads, and end of hub thoroughly with friction to remove any residue. Physician orders were obtained on the patient identified in the survey to complete the dressing change for both catheters each treatment. FA or designee will complete CVC Care Process Procedural Skills Checklist for each teammate working each treatment day for 4 weeks, and then weekly for 1 month. FA will review findings with the Medical Director in the monthly FHM. The FA is responsible for ongoing compliance with this POC.</p> <p>Completion date: 4/16/14</p> |                      |

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|                    | <p>The employee identified the catheter on the right as the dialysis catheter. The employee wiped the limbs of the CVC. She did not perform any catheter or access care to the catheter on the left of the dialysis catheter. Employee F, while wearing clean gloves, held a sterile 4 X 4 piece of gauze and began applying pre torn tape to the edges of the gauze, turning the gauze as she applied to each side. As she held the gauze, her gloved fingers were in contact with the center of the gauze and then she placed the gauze overtop of the dialysis catheter and overlapping the second catheter. The limbs of the dialysis catheter were not soaked or scrubbed, nor were the hubs soaked or scrubbed prior to initiation of hemodialysis.</p> <p>B. At 7:55 AM, observed employee F in station 5 with patient 6. Patient 6 arrived with a standard size Band-Aid over the CVC access. Employee F indicated the patient historically declined a dressing over the access and had accepted a Band-Aid. The patient was interviewed during the observation and indicated no experience with an infection and had not covered the access for years.</p> <p>Observed employee F to initiate dialysis with patient 6. The employee wiped the limbs of the CVC with 2 X 2 gauze which was soaked with cleanser. The limbs and the hub were not soaked or scrubbed prior to initiation of the dialysis treatment.</p> <p>3. On 3/14/14 at 8:15 AM, employee D indicated the observation described was not per policy and that the policy was to soak the limbs for one minute. She indicated it was not the facility policy to scrub the limbs of the CVC.</p> |               |                                                                                                                 |                      |

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| V000175            | <p>494.40<br/>CFC-WATER &amp; DIALYSATE QUALITY</p> <p>Based on observation and interview and review of administrative documents, it was determined the facility failed to ensure the empty bed contact time (EBCT) was monitored and documentation evidenced the minimum of 5 minutes of EBCT for each carbon tank for a total of a minimum of 10 minutes was met at the maximum product water flow rate for 1 of 1 facility with the potential to have affected all dialysis patients (See V 196); failed to ensure the configuration of the current water distribution loop was documented and known to the individuals responsible for the maintenance and the entire loop and all distal portions of the loop were maintained and disinfected at least monthly for 1 of 1 facility with the potential to affect all in-center patients and all future home hemodialysis patients whom may train on the same system (See V 211); failed to ensure samples of product water were collected at least monthly from the first and last outlets of the water distribution loop at the time in which the water would be in the worst condition, pre-disinfection, to monitor for bacteria and endotoxin levels for 3 of the last 6 months with the potential to effect all current 5 in-center hemodialysis patients (See V 213); and failed to ensure the minimum requirements for disinfection of the reverse osmosis product water loop was met by means of documentation on that the minimum temperature was reached for the heat disinfection of the loop for 1 of 3 months reviewed (See V 217).</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to</p> | V000175       | <p><b>V175</b></p> <p>A Governing Body (GB) meeting was held to review the Statement of Deficiencies (SOD) and formulate the Plan of Correction (POC). The standards under Conditions of Water and Dialysate Quality (V175) that are not met have detailed POCs referenced to the specific V tags. Ongoing compliance to the POC includes promoting implementation of policies and procedures to ensure correct and effective practices in water and dialysate monitoring including but not limited to: ensuring the EBCT is documented, the schematic of the water system is posted, cultures and endotoxins are tested per policy, and documentation of disinfection of water distribution system is complete. Members of the GB including the Facility Administrator (FA), Regional Operations Director (ROD), and Medical Director (MD), have agreed to meet weekly to monitor the facility's progress toward compliance. Then ongoing compliance to the POC will be monitored during GB meetings at least semi-annually. This POC will also be reviewed at each monthly QAPI meeting known as the Facility Health Meeting (FHM) when the FA will report progress, as well as any barriers to maintaining compliance, to the committee.</p> | 04/16/2014           |

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| V000196            | <p>provide safe water as required by the Condition for Coverage 494.40: Water and dialysate quality.</p> <p>494.40(a)<br/>CARBON ADSORP-MONITOR, TEST FREQUENCY<br/>6.2.5 Carbon adsorption: monitoring, testing freq<br/>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.</p> <p>Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet.</p> <p>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].<br/>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.</p> <p>Based on observation, interview, and review of administrative documents, the facility failed to ensure the empty bed contact time (EBCT) was monitored and documentation evidenced</p> | V000196       | <p>Completion date: 4/16/14</p> <p><b>V 196</b><br/>Area Biomedical Manager (ABM) in-serviced the facility's Biomedical Technician (BMT) on 3/31/14 on Policy 2-03-01 "Water Treatment Systems Minimum Component</p> |                      |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:<br><br>152615 |  | X2) MULTIPLE CONSTRUCTION<br>A. BUILDING 00<br>B. WING _____                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | X3) DATE SURVEY COMPLETED<br><br>03/17/2014 |                      |
| NAME OF PROVIDER OR SUPPLIER<br><br>GREENSBURG DIALYSIS |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                 |  | STREET ADDRESS, CITY, STATE, ZIP CODE<br>1531 N COMMERCE E DR STE 6<br>GREENSBURG, IN 47240 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                             |                      |
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| V000211                                                 | <p>the minimum of 5 minutes of EBCT for each carbon tank for a total of a minimum of 10 minutes was met at the maximum product water flow rate for 1 of 1 facility with the potential to have affected all dialysis patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>Observed on 3/12/14 at 2 PM during a tour of the water room, two carbon tanks with an adhesive label attached which indicated each tank was bed with 8 cubic feet of activated carbon on 9/14/07.</li> <li>On 3/13/2014 at 12 PM, employee E indicated he had not determined the empty bed contact time (EBCT) and was not aware of this documentation need. He indicated the patient care technicians complete the chlorine checks and he would look into the EBCT if there was a problem with those results.</li> <li>Review of the facility maintenance logs failed to evidence the EBCT was evaluated and monitored since 9/14/07.</li> </ol> <p>494.40(a)<br/>H2O DIST SYS-CONSTANT FLOW/NO DEAD ENDS<br/>5.3.3 Water distribution systems: continuous flow rates/no dead ends<br/>Water distribution systems should be configured as a continuous loop and designed to minimize bacterial proliferation</p> |                                                                 |  |                                                                                             | <p><i>Requirements</i>". Verification of attendance at in- service is evidenced by a signature sheet. Teammate was instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) carbon filters are required that provide an empty bed contact time (EBCT) of at least 10 minutes for the total system with 5 minutes for the primary filter(s) and 5 minutes for the secondary filter(s) during peak demand operating conditions for municipal water supplies disinfected with free chlorine, chloramines (chlorine + ammonia), chlorine dioxide, ozone, or other germicide. ABM calculated the EBCT for the facility's carbon filters. This was posted on the carbon tanks on 3-31-14. Additional posting on the RO system states that the maximum flow must be <u>&lt;&lt;/u&gt; 45 liters to maintain the minimum EBCT. FA or designee will audit the water room weekly x 4 to ensure that the EBCT is posted. FA will review findings with the Medical Director in the monthly FHM. The FA is responsible for ongoing compliance with this POC.</u></p> <p>Completion date: 4/16/14</p> |                                             |                      |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:<br><br>152615 | X2) MULTIPLE CONSTRUCTION<br>A. BUILDING 00<br>B. WING _____ | X3) DATE SURVEY COMPLETED<br><br>03/17/2014 |
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| NAME OF PROVIDER OR SUPPLIER<br><br>GREENSBURG DIALYSIS | STREET ADDRESS, CITY, STATE, ZIP CODE<br>1531 N COMMERCE E DR STE 6<br>GREENSBURG, IN 47240 |
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|                    | <p>and biofilm formation. A centrifugal pump made of inert materials is necessary to distribute the purified water and aid in effective disinfection.</p> <p>7 Strategies for bacterial control<br/>7.1 General<br/>To minimize biofilm formation, there should always be flow in a piping system. A minimum velocity of 3 ft/sec in the distal portion of the loop of an indirect feed system and a minimum velocity of 1.5 ft/s in the distal portion of a direct feed system are recommended when the system is operating under conditions of peak demand.</p> <p>Dead-end pipes and unused branches and taps that can trap fluid must be eliminated because they act as reservoirs of bacteria and are capable of continuously inoculating the entire volume of the system. These measures also minimize the possibility that pockets of residual disinfectant could remain in the piping system after disinfection.</p> <p>Based on observation, policy review, and interview, the facility failed to ensure the configuration of the current water distribution loop was documented and known to the individuals responsible for the maintenance and the entire loop and all distal portions of the loop were maintained and disinfected at least monthly for 1 of 1 facility with the potential to affect all in-center patients and all future home hemodialysis patients who may train on the same system.</p> <p>The findings include:</p> <p>1. On 3/12/14 at 2 PM, observed the in-center with 12 stations plumbed for</p> | V000211       | <p><b>V211</b><br/>Area Biomedical Manager (ABM) in-serviced the facility's Biomedical Technician (BMT) on 3/31/14 on <i>Policy 2-03-01 "Water Treatment Systems Minimum Component Requirements"</i>. Verification of attendance at in- service is evidenced by a signature sheet. Teammate was instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) all water systems will include a posted schematic diagram which identifies components, valves, sample ports,</p> | 04/16/2014           |

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|                    | <p>hemodialysis. A Nxstage machine was in station 12; there was not a dialysis machine in station 2, 10, and 11.</p> <p>Employee F indicated the facility only has 5 in-center patients, they were all scheduled to be on dialysis on Mondays, Wednesdays, and Fridays and only stations 5, 6, 7, 8, and 9 were used for hemodialysis treatments. She indicated one day a week, for integrated heat disinfection of the R. O. loop, all nine hemodialysis machines are connected to the loop. She indicated a machine is connected to the outlet in the bio med maintenance room and one machine is connected in stations 1, 3, and 4. She indicated there was not sufficient machines nor adapters to connect all outlets, leaving the outlets in stations 2, 10, 11, and 12 disconnected during the loop disinfection process.</p> <p>2. On 3/12/14 at 2 PM, during a tour of the water room, no schematic of the reverse osmosis water loop was observed.</p> <p>3. On 3/13/14 at 12 PM, employee E, the biomedical technician, indicated the facility had only 9 hemodialysis machines and every Wednesday the reverse osmosis machine, the water loop, and the nine dialysis machines were placed into an integrated heat for end to end disinfection. He indicated he does not connect anything to stations 2, 10, 11, and 12; he indicated he has no adapter to connect these ports to the loop to complete the end to end disinfection, when asked. He indicated the portion of the loop which fed the previously used reuse room and stations 11 and 12 were not connected to the loop during disinfection. He indicated only the home program staff use stations 11 and 12 and he was not aware of a schematic available of the</p> |               | <p>and flow directions. The Group Facility Administrator (GFA) posted the flow direction during the survey. FA or designee will audit the water room weekly x 4 to ensure that the water schematic and flow direction is posted. We respectfully submit that we disagree with the citation regarding disinfection of the loop and that we are in full compliance with this regulation. The facility is following <i>Policy 2-03-01 "Water Treatment Systems Minimum Component Requirements"</i> (Attachment A) which states: "A continuous loop will be designed to minimize bacteria proliferation and biofilm formation." The two inch fittings are part of the continuous loop. The facility is following <i>Policy 2-03-03 "Water Treatment System Disinfection"</i> (Attachment B) which states: "Hot water- disinfected direct feed systems utilize chemicals for the RO and hot water for the distribution system. The distribution system is disinfected at least weekly." The hot water goes into the two inch fittings during disinfection and does not require that a machine be connected to complete disinfection. The water distribution system is disinfected daily with heat. Heating water to a high temperature naturally kills bacteria and these systems are therefore self-sanitizing. The facility is following the Hemodialysis Water Treatment System (CWP) operation</p> |                      |

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|                                                         | <p>water loop that identified the route of the R. O. loop throughout the facility.</p> <p>At 12 PM, all twelve stations were observed plumbed for hemodialysis. There was an approximately two inch extension, fitting, from the loop to feed and attach the connections for the dialysis machine to the loop. Employee E indicated, when asked, these connections in stations 2, 10, 11, and 12 were not part of the disinfection process and indicated it was insignificant.</p> <p>4. On 3/13/14 at 2 PM, employee G indicated she collected a dialysate sample once every 3 months form the Nxstage home dialysis machine in station 12 used for training on site. The Nxstage connects to tap water outlet. She indicated she does not connect to the loop in stations 11 and 12.</p> <p>5. On 3/13/14 at 4:30 PM, employee D indicated she was not aware of the loop configuration and was not aware if the portion which fed the previously used Reuse Room was still connected. Employee D was observed to connect to the RO loop in the previously used Reuse Room. Water flowed from the port and was, therefore, connected. The facility failed to evidence the outlet was part of the monthly disinfection process and the portion which fed the reuse room was not a dead leg in the system.</p> <p>6. The policy titled "Water Treatment System Disinfection" number 2-03-03 dated September 2013 stated, "6. Both chemically disinfected direct feed and indirect feed distribution systems will be disinfected in a end to end process, during which disinfectant solution will be introduced to the following via their water inlet lines: Dialysis Delivery</p> |                                                                 | <p>and maintenance manual (Attachment C) that states: "For best results, Gambro recommends that a heat disinfection of the loop be completed on a nightly basis. Hot water disinfection of the distribution loop is accomplished by circulating hot water throughout the piping system. The WRO H store the hot water at or between the high of 90-92¿ C. The periods of heating to 90-92¿ C should be long enough to allow the return water from the clinic, at least once every circulation period, to reach the preset acceptance temperature. This is normally set to 85¿ C. An alarm will notify the operator if the acceptance temperature was not reached." The facility is documenting the daily hot water disinfection of the loop on the Daily CWP Water Log (Attachment D). The absence of "Low Disinfection Temperature Alarms" indicates that the CWP reached the minimum temperature required for disinfection of the loop. This was provided to the surveyor at the time of the survey. We request removal of this citation.The FA will review results of all water cultures and endotoxins monthly with the Medical Director during FHM. The FA is responsible for ongoing compliance to this POC.<br/>Completion date: 4/16/14</p> |                      |                                             |

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| V000213            | <p>System, Dialyzer reprocessing equipment (if applicable), ... Any unused outlet. ... Written facility specific disinfection procedures are developed and written by the Biomed team, in conjunction with the facility administrator."</p> <p>494.40(a)<br/>DIST<br/>SYS-CULTURE/LAL/SITES/FREQ(NEW)/LOG</p> <p>6.3.3 Water distribution systems: culture/LAL sample sites/frequency (new)/log</p> <p>Water distribution piping systems should be monitored for bacteria and endotoxin levels. Bacteria and endotoxins shall not exceed the levels specified in [AAMI] 4.1.2. [(i.e., bacteria &lt;200 CFU/mL and endotoxin &lt;2 EU/mL]</p> <p>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.</p> <p>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</p> |               |                                                                                                                 |                      |

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|                    | <p>and endotoxin levels shall be measured as specified in ANSI/AAMI RD62:2001 (see 2.3).</p> <p>All bacteria and endotoxin results should be recorded on a log sheet to identify trends that may indicate the need for corrective action.</p> <p>Based on administrative document review and interview, the facility failed to ensure samples of product water were collected at least monthly from the first and last outlets of the water distribution loop, at the time in which the water would be in the worst condition, pre-disinfection, to monitor for bacteria and endotoxin levels for 3 of the last 6 months (December, February, and March) with the potential to effect all current 5 in-center hemodialysis patients.</p> <p>The findings include:</p> <p>1. The administrative documents titled "Monitored Process or Component" evidenced a chemical and hot water disinfection occurred on 12/9/13. Laboratory results evidenced culture and endotoxin water sample was collected on 12/10/13, one day following.</p> <p>A. Administrative documents evidenced a chemical and hot water disinfection occurred on 2/3/14. Laboratory results evidenced culture and endotoxin water sample was collected on 2/4/14, one day following.</p> <p>B. Administrative documents evidenced a chemical disinfection occurred on 3/3/14. Laboratory results evidenced culture and endotoxin water sample was collected on</p> | V000213       | <p><b>V 213</b></p> <p>We respectfully submit that we disagree with the citation and that we are in full compliance with this regulation. The facility completes monthly cultures of the product water from the first and last outlets of the water distribution loop as required by Vtag 213. These were provided to the surveyor at the time of the survey. The facility is following the Hemodialysis Water Treatment System (CWP) operation and maintenance manual (Attachment C) that states: "In the CWP WRO H and WRO S, the RO membranes are not designed to be disinfected with hot water. As a result, a chemical disinfectant will be used to disinfect the RO membranes. The disinfectant only circulates within the RO Machine. A series of closed valves and an air gap provide isolation between the RO Machine and the distribution loop during disinfection procedures." The facility is following <i>Policy 2-03-03 "Water Treatment System Disinfection"</i> (Attachment B) which states: "Hot water-disinfected direct feed systems utilize chemicals for the RO and hot water for the distribution system.</p> | 04/16/2014           |

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|                    | <p>3/4/14, one day following</p> <p>2. On 3/13/14 at 12 PM, Employee E indicated the loop which carried permeate throughout the facility was disinfected nightly with hot water. He indicated no documentation was available to evidence nightly disinfection and indicated there was no relationship to the collection of water samples for cultures and endotoxin's and the disinfection of the reverse osmosis central water plant.</p> <p>The administrative documents failed to evidence nightly hot water disinfection of the loop which carried the permeate.</p> |               | <p>The distribution system is disinfected at least weekly." Hot water-disinfected direct feed systems utilize chemicals for the RO and hot water for the distribution system. The water distribution system is disinfected daily using heat (policy only requires weekly). Chemical disinfection is only used for the RO system which is not connected to the water outlets during chemical disinfection. The RO system is not connected to the first and last water outlets of the distribution loop during chemical disinfection. Therefore, the chemical disinfection is not related to the timing of drawing the water cultures and endotoxins. The facility's Daily CWP logs (Attachment D) indicate that the system is heat disinfected daily. This was provided to the surveyor at the time of the survey. We request removal of this citation.</p> <p><b>ABM in-serviced 100% of clinical teammates on 3/31/14 on Policy 2-04-02B "Daily CWP Water Log" and "Daily CWP Water Log Explanation". Verification of attendance at in- service is evidenced by a signature sheet. Teammates were instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) document daily on the Daily CWP Water Log the time that the hot water disinfection was started, 2) record any "Low Disinfection Temperature Alarms"</b></p> |                      |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:<br><br>152615 | X2) MULTIPLE CONSTRUCTION<br>A. BUILDING 00<br>B. WING _____ | X3) DATE SURVEY COMPLETED<br><br>03/17/2014 |
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| NAME OF PROVIDER OR SUPPLIER<br><br>GREENSBURG DIALYSIS | STREET ADDRESS, CITY, STATE, ZIP CODE<br>1531 N COMMERCE E DR STE 6<br>GREENSBURG, IN 47240 |
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| (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 |
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| V000217            | <p>494.40(a)<br/>HOT H2O DISINF<br/>SYS-TEMP/TIME/FOLLOW DFU/PIPE<br/>5.3.4.3 Hot water disinfection systems: temp/time/follow DFU/piping<br/>Refer to RD62:2001, 4.3.14 Hot water disinfection systems: When used to control bacterial proliferation in water treatment, storage, and distribution systems, the water heater of a hot water disinfection system shall be capable of delivering hot water at the temperature and for the exposure time specified by the manufacturer.</p> <p>5.3.4.3 Hot water disinfection systems<br/>Hot water disinfection systems can be used only in systems constructed from heat-resistant materials, such as crosslinked polyethylene, polypropylene, and stainless steel (see [AAMI] 5.3.3).</p> <p>The manufacturer's instructions for using hot</p> |               | <p>on the Daily CWP Water Log, and 3) if any "Low Disinfection Temperature Alarms" occurred to notify biomed. The absence of "Low Disinfection Temperature Alarms" indicates that the CWP reached the minimum temperature required for disinfection of the loop. FA or designee will audit the Daily CWP Water Log each treatment day x 2 weeks, and then weekly x 2 to ensure that disinfection is appropriately documented. FA will review findings with the Medical Director in the monthly FHM. The FA is responsible for ongoing compliance with this POC.</p> <p>Completion date: 4/16/14</p> |                      |

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|                    | <p>water disinfection systems should be followed. If no manufacturer's instructions are available, the effectiveness of the system can be demonstrated by verifying that the system maintains a specified temperature for a specified time and by performing ongoing surveillance with bacterial cultures and endotoxin testing.</p> <p>Based on facility maintenance log review and interview, the facility failed to ensure the minimum requirements for disinfection of the reverse osmosis product water loop was met by means of documentation or the minimum temperature was reached for the heat disinfection of the loop for 1 of 3 months reviewed, February 12, 2014, through March 17, 2014.</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>On 3/13/14 at 12 PM while in the water room, employee E indicated, when asked, there was no documentation that minimum temperature was reached following the heat disinfection of the permeate loop at least monthly. He indicated the digital panel on the CWP could not give him the information.</li> <li>The monitoring logs for the Central Water Plant (CWP) evidenced documentation that on February 12, 14, 19, and 26 and March 5, and 12, 2014, integrated heat disinfection was initiated for disinfection of the permeate and the dialysis machines which were connected to the loop at stations 1, 3, 4, 5, 6, 7, 8, 9, and the bio med room. The logs failed to evidence monitoring to ensure the minimum temperature required for disinfection of the loop during integrated heat was reached at least monthly.</li> </ol> | V000217       | <p><b>217</b></p> <p>ABM in-serviced 100% of clinical teammates on 3/31/14 on <i>Policy 2-04-02B "Daily CWP Water Log"</i> and <i>"Daily CWP Water Log Explanation"</i>. Verification of attendance at in- service is evidenced by a signature sheet. Teammates were instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) document daily on the Daily CWP Water Log the time that the hot water disinfection was started, 2) record any "Low Disinfection Temperature Alarms" on the Daily CWP Water Log, and 3) if any "Low Disinfection Temperature Alarms" occurred to notify biomed. The absence of "Low Disinfection Temperature Alarms" indicates that the CWP reached the minimum temperature required for disinfection of the loop. FA or designee will audit the Daily CWP Water Log each treatment day x 2 weeks, and then weekly x 2 to ensure that disinfection is appropriately documented. FA will review findings with the Medical Director in the monthly FHM. The FA is responsible for ongoing</p> | 04/16/2014           |

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| V000407            | <p>3. On 3/13/14 at 5:15 PM, a telephone interview was conducted with the biomedical regional area manager. She indicated the facility's Reverse Osmosis water treatment system, a CWP (central Water Plant), was to automatically go into heat disinfection every night at approximately 2 AM.</p> <p>The facility documentation failed to evidence the CWP went into a nightly heat disinfection nor did documentation reflect monitoring of the automated system to ensure the minimum temperature required for disinfection of the loop, 85 degrees Celsius, was reached at a minimum of once a month.</p> <p>4. On 3/14/14 at 6 AM, employee F indicated she was not sure of how to monitor for the temperature following heat disinfection.</p> <p>494.60(c)(4)<br/>PE-HD PTS IN VIEW DURING TREATMENTS<br/>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, policy review, and interview, the facility failed to ensure all access site were visible during the hemodialysis treatment for 1 of 5 patients observed on 3/14/14, during observation 1, with the potential to affect all in-center patients.</p> <p>The findings include:</p> <p>1. On 3/14/14 at 7:10 AM, observed employee F initiate hemodialysis for patient 3 via a central venous catheter in station 8.</p> | V000407       | <p>compliance with this POC.</p> <p>Completion date: 4/16/14</p> <p><b>V407</b><br/>100% of clinical teammates were in-serviced on 3/28/14 on <i>Policy 1-03-09 "Intradialytic Treatment Monitoring"</i>. Verification of attendance at in-service is evidenced by a signature sheet. Teammates were instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) each patient, including his/her face, vascular access site, and blood line connections, needs to be seen by a staff member</p> |                      |

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|                    | <p>Following the intimation of treatment, the patient began to cover self with blankets, head to toe, covering face and access.</p> <p>A. At 7:20 AM, observed the registered dietician sitting to the left of the patient and discussing the patient's laboratory values. Throughout the conversation between the patient and the registered dietician, the patient's access was not visible. Neither the registered dietician, nor the direct care staff on the floor at the time, employees F and G, verbally cued or otherwise informed or requested of the patient to keep the access visible during the hemodialysis treatment.</p> <p>B. At 7:38 AM, the patient's access was not visible and no staff had requested of the patient to keep the access visible to staff during treatment or advised of the potential risks.</p> <p>C. At 7:40 AM employee G entered station 8, spokes to the patient, adjusted the lines, and did not move the blanket to view the patient's access. The patient readjusted the blankets over his / her head and body. The employee left the station without requesting the patient to leave their face and access visible.</p> <p>D. At 7:42 AM, there are three patients dialyzing, one is patient 3. The dialysis machine in station 8 alarms, employee G enters station 8 and pulls back the patient's blanket, then recovers the access with the blanket and walked away.</p> <p>E. At 7:43 AM, the dialysis machine in station 8 alarmed. Employee F entered station 8 to trouble shoot the alarms. The patient's access was covered with the blanket and not visible to the staff. Employee F left</p> |               | <p>throughout the dialysis treatment. 100% of patients have been provided handouts and patient education regarding consequences of having access and/or face covered. Education materials have been signed and dated by patients and placed into their medical record. Teammates understand that visible access must be documented at every thirty minute treatment check, and patient refusal to keep access visible must be documented each time. The FA or designee will conduct observational treatment prescription audits on random shifts each treatment day X 2 weeks, and then weekly X 4. Instances of non-compliance will be addressed with the teammate responsible immediately. Results will be reviewed with the Medical Director during the FHM and continued frequency of audits determined by the team with supporting documentation included in the meeting minutes. The FA is responsible for ongoing compliance with this POC.</p> <p>Completion date; 4/16/14</p> |                      |

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|                    | <p>the patient with access covered with blankets.</p> <p>F. At 7:53 AM, patient's face is visible, the patient's access is not visible.</p> <p>G. At 8:10 AM, employees F and G are in stations 5 and 6. Patient 3 in station 8 is observed with head, face, and access covered with blanket.</p> <p>H. At 8:14 AM, patient 3 in station 8 is observed with head, face, and access covered, not visible to staff. Observed patient independently moving in reclined chair.</p> <p>G. At 8:16 AM, patient 3 uncovered their face, the rest of the patient is covered with blankets. No verbal cues from any staff present to keep the access visible during treatment.</p> <p>2. At 8:35 AM, employee D indicated the face and access are not to be covered during treatment and the staff are to request of patient and remind of potential risk if not compliant.</p> <p>3. At 8:55 AM, employee G indicated she was aware the patient's access and face were to be visible and said, "[Patient] is always cold."</p> <p>4. The facility policy titled "Intradialytic Treatment Monitoring" number 1-03-09, revision date March 2012 stated, "Treatment checks should be completed at least every thirty (30) minutes. At a minimum, obtain and document the following: Vascular access visible and line connections intact, ... Patient's face visible."</p> |               |                                                                                                                 |                      |