

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152511	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  08/08/2014
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NAME OF PROVIDER OR SUPPLIER  LAWRENCEBURG DIALYSIS CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 721 RUDOLPH WAY GREENDALE, IN 47025
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V000000	<p>This visit was a federal ESRD complaint investigation that resulted in an expanded survey.</p> <p>Complaint IN00152306 - Substantiated: Federal deficiencies related to the allegation are cited. Unrelated deficiencies are also cited.</p> <p>Date: August 4, 5, 6, 7, and 8, 2014</p> <p>Facility #: 005156</p> <p>Medicaid # 200471780</p> <p>Surveyor: Susan Sparks, RN, PHNS</p> <p>Census</p> <p>In-center 41 Peritoneal 16</p> <p>Lawrenceburg Dialysis Center was found to be out of compliance with Condition of Coverage 494.40:Water and Dialysate Quality, 494.60 Physical Environment, and 494.110 Quality assessment and performance improvement.</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN August 19, 2014</p>	V000000		

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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V000175	<p>494.40 CFC-WATER &amp; DIALYSATE QUALITY</p> <p>Based on water bacteriology report and QA (Quality Assessment) document, manufacturer's instructions, and policy review and interview, it was determined the facility failed to ensure water bacteriology at or above the action level was addressed in 4 of 7 Microbiology reports reviewed with the possibility to affect 41 patients (See V 178), failed to ensure water bacteriology above the corrected action level was monitored for future compliance and failed to ensure the reverse osmosis feed water treatment and monitoring operated within the manufacturer's design parameters for 18 of 18 months in 1 of 1 water rooms with the potential to affect all 41 in-center patients (See V 179), and failed to ensure the reverse osmosis feed water treatment and monitoring operated within the manufacturers design parameters for 18 of 18 months in 1 of 1 water rooms with the potential to effect all 41 in-center patients (See V 199).</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to provide safe water and</p>	V000175	<p><b>V175</b> 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 water bacteriology at or above the action level is addressed and monitored for future compliance, and ensuring that the reverse osmosis feed water treatment and monitoring is operated within the manufacturer's design parameters. 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</p>	09/05/2014

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V000178	<p>dialysate as required by the Condition for Coverage 494.40:Water and Dialysate Quality.</p> <p>494.40(a) BACT OF H2O-MAXIMUM &amp; ACTION LEVELS 4.1.2 Bacteriology of water: max &amp; action levels Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse, shall contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration lower than 2 EU/mL</p> <p>The action level for the total viable microbial count in the product water shall be 50 CFU/mL, and the action level for the endotoxin concentration shall be 1 EU/mL. If those action levels are observed in the product water, corrective measures shall promptly be taken to reduce the levels. Based on water bacteriology report and QA (Quality Assessment) document review and interview, the facility failed to ensure water bacteriology at or above the action level was addressed in 4 of 7 Microbiology reports reviewed with the possibility to affect 41 patients. (March 2013, September 2013, April 2014, and May 2014)</p> <p>Findings:</p>	V000178	<p>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. Completion date: 9/5/14</p> <p><b>V 178</b> The Facility Administrator (FA) and Biomedical Technician (BMT) were in-serviced on <i>Policy2-06-01 "Water Culture Policy"</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) The Facility Administrator or designee is responsible for verifying that cultures are obtained, results</p>	09/05/2014

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	<p>1. Microbiology report for March 2013 evidenced the 2 Bicarb H2O Out port tested at action level, April 2013 the 2 Bicarb H2O Out port tested 0.26 (not at action level but high), May 2013 the 2 Bicarb H2O Out port tested 0.09 (not at action level but high), September 2013 2 Reuse Disinf Out port tested at action level, December 2013 the 2 Bicarb H2O out port tested 0.23 (not at action level but high), 2 Bicarb H2O Out ports in April 2014 tested at action level, and May 2014 tested at action level.</p> <p>2. On 8/8/14 at 11 AM, the Facility Manager, Employee A, was asked for the Quality Assurance monitoring of these results. At 11:30 AM, she returned with a single sheet from the QA reports evidencing that each month the water results were signed off on but no discussion of the water testing and why consistently the same ports were testing high was evidenced.</p>		<p>recorded, reviewed, and necessary actions taken, as applicable, 2) Required responses to action or unacceptable culture results if single site is at or above action level: Notify Medical Director of results within 48 hours of receiving the result. Reculture of the site within 7 days of the original sample collection date. If repeat sampling result is below the action level, no further action is required. If repeat sampling result is at or above the action level, notify the Facility Administrator/designee, Biomedical Services, Medical Director, and enter Troubleshooting Mode. If more than one site is at or above the action level or any site is at or above unacceptable level: Notify Facility Administrator/designee, Biomedical Services, and Medical Director within 48 hours of receiving the results. Disinfect affected equipment at the end of the treatment day in which results are received/reported or as recommended by the Medical Director. Reculture of all affected sites within 7 days of original sample collection date. If repeat sampling result(s) is at or above action level, notify the Facility Administrator/designee, Biomedical Services, Medical Director and enter Troubleshooting Mode. BMT will bring results of all scheduled water and dialysate testing to monthly FHM meetings for review with Medical Director and team. FHM committee will review results,</p>		

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V000179	<p>494.40(a) BACT OF H2O-MEDICAL DIRECTOR RESPONSIBLE 4.1.2 Bacteriology of water: med dir resp The facility medical director is responsible to ensure the manufacturer or supplier of a complete water treatment and distribution system demonstrates that the complete water treatment, storage, and distribution system is capable of meeting these requirements at the time of installation</p> <p>Following installation of a water treatment, storage, and distribution system, the user is responsible for continued monitoring of the water bacteriology of the system and for complying with the requirements of this standard, including those requirements related to action levels.</p> <p>Based on water bacteriology report, QA (Quality Assessment) document, Manufacturer's instructions, and policy review and interview, the Medical Director failed to ensure water bacteriology above the corrected action level was monitored for future</p>	V000179	<p>responses and trends, FA will be responsible for ensuring all water and dialysate testing results are signed by the Medical Director. Area BioMed Manager (ABM) will audit water and dialysate cultures monthly x3 to ensure that the testing has been completed and results reviewed with the medical director during FHM. The FA is responsible for ongoing compliance with this Plan of Correction (POC). Completion date: 9/5/14</p> <p><b>V179</b> The FA and BMT were in-serviced on <i>Policy2-06-01 "Water Culture Policy"</i> and <i>Policy 2-01-09 "Preventative Maintenance Schedules for Equipment"</i>. 100% of facility's teammates were in-serviced on <i>Policy 2-04-02 "Daily Water</i></p>	09/05/2014	

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	<p>compliance and failed to ensure the reverse osmosis (RO) feed water treatment and monitoring operated within the manufacturer's design parameters for 18 of 18 months in 1 of 1 water rooms with the potential to affect all 41 in-center patients.</p> <p>Findings.</p> <p>1. Mar Cor Purification Instruction (2011 Mar Cor Purification. All rights reserved. P/N-3027274 Rev. B) for use-for filters sold in the United States of America. Applications &amp; Intended Use "The Mar Cor Purification (Mar Cor) Posiclear filter is intended to remove bacteria, endotoxin, and particulate matter from water used for dialysis. It is intended for use in dialysis water treatment systems as a final stage of filtration after RO or DI treatment to help control bacteria and endotoxin levels in purified water distribution systems. This filter is not intended as a primary means of water purification. ... 6. CAUTION: The Mar Cor Posiclear filter should be replaced every 6 months or whenever the pressure drop across the filter exceeds 15 PSI."</p> <p>2. A policy titled "Preventive Maintenance Schedules for Equipment", dated Revision Date March 2013, Policy</p>		<p><i>Treatment System Monitoring</i>" and <i>Policy 2-04-02B "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) The Medical Director documents a review of all water cultures monthly 2) Results and trends are reviewed during the Facility Health Meeting (FHM) and documented in the meeting minutes 3) Preventative maintenance (PM) schedules must be made in accordance with the manufacturer's recommendation for all equipment used to perform a patient treatment. A copy of the equipment PM schedule must be filed in the appropriate Equipment Maintenance Manual, and 4) All observations and test results will be within the limits specified on the <i>Daily Water Treatment Log</i>. If observations or test results are found outside the specified limits, follow the instructions given on the <i>Daily Water Treatment Log</i> for the parameter(s) in question. In addition to following the log form instructions, the teammate completing the log will notify the Facility Administrator/designee and Biomed teammate assigned to the facility of any observation or test result found outside the limit specified on the <i>Daily Water Treatment Log</i>. The MarCor</p>				

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	<p>2:2-01-09, states, "1. Preventive maintenance (PM) schedules must be made in accordance with the manufacturer's recommendation for all equipment used to perform a patient treatment. A copy of the equipment PM schedule must be filed in the appropriate Equipment Maintenance Manual."</p> <p>3. A work ticket for Diasafe Filter # 1206-00938-4121500 evidenced the Marcor filter was changed on 12/6/12 and ticket #1217-00938-5405498 evidenced the Marcor filter was changed on 12/7/13.</p> <p>On 8/8/14 at 1:55 PM, the Biomedical Technician, Employee D, indicated there were no other tickets in the system to indicate the filter had been changed indicating the filter changing was not in compliance with the manufacturer's instructions.</p> <p>4. A facility document titled "Daily Water Treatment Sheet-CWP" when presented on 8/7/14 had "Manufacturer Specifics" for line 24, 25, and 26.</p> <p>A. On 8/7/14 at 1:30 PM, the Facility Manager, Employee A was asked to present the Manufacturer Specifics for lines 24 (&gt;40 psi), 25 (&lt;100 psi), and 26 (&lt;15 psi). She returned with the specific</p>		<p>Posiclear filter was changed on 8/8/14 as evidenced by BART ticket. The <i>Daily Water Treatment Log</i> was updated with the manufacturer's specific parameters for line 24, 25, and 26 on 8/8/14. BMT will bring results of all scheduled water and dialysate testing to monthly FHM meetings for review with Medical Director and team. FHM committee will review results, responses and trends, FA will be responsible for ensuring all water and dialysate testing results are signed by the Medical Director. ABM will audit water and dialysate cultures monthly x3 to ensure that the testing has been completed and results reviewed with the medical director during FHM. BMT will bring <i>Daily Water Treatment Log</i> to the monthly FHM meeting for the next 3 months for review with the Medical Director and team. ABM will audit the <i>Daily Water Treatment Log(s)</i> monthly x 3 months to verify that testing has been completed and is operating within the manufacturer's design parameters. The FA is responsible for ongoing compliance with this POC.</p> <p>Completion date: 9/5/14</p>	

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	<p>numbers at 2:20 PM.</p> <p>B. On 8/8/14 at 1:55 PM, the Regional Biomedical Supervisor, Employee B indicated line 25 is subtracted from line 24 to get line 26. If line 26 is higher then 15 psi then the biotech should be called and the filter changed.</p> <p>C. The sheets were reviewed from January 2013 to July 2014 and the manufacturer numbers were not in line 24, line 25, and line 26. The techs were putting the numbers in the blocks, but had no reason to call the bio tech as the bio tech had not filled in the numbers to be concerned with.</p> <p>D. A ticket #1217-00938-5405498 evidenced the Marcor filter was changed on 12/7/13. From that date line 26 was higher then 15 psi without the filter being changed on 1/2/14 (18), 1/6/14 (20), 1/9/14 (20), 1/15/14 (20), 1/17/14 (20), 1/20/14 (20), 1/22/14 (20), 1/23/14 (15), 1/24/14 (20), 1/27/14 (20), 1/31/14 (20), 2/3/14 (15), 2/5/14 (20), 2/7/14 (20), 2/12/14 (20), 2/14/20 (20), 2/18/14 (20), 2/21/14 (20), 2/26/14 (19), 2/28/14 (20), 3/5/14 (20), 3/7/14 (20), 3/12/14 (20), 3/14/14 (20), 3/19/14 (20), 3/20/14 (16), 3/21/14 (20), 3/28/14 (15), 3/31/14 (20), 4/2/14 (20), 4/7/14 (15), 4/9/14 (23),</p>						

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	<p>4/11/14 (20), 4/16/14 (20), 4/21/14 (20), 4/23/14 (20), 4/30/14 (20), 5/2/14 (18), 5/5/14 (20), 5/9/14 (20), 5/14/14 (26), 5/16/14 (23), 5/19/14 (26), 5/26/14 (25), 5/28/14 (15), 6/2/14 (20), 6/23/14 (20), 6/27/14 (16), 6/30/14 (20), 7/2/14 (20), 7/4/14 (19), 7/7/14 (20), 7/9/14 (20), 7/11/14 (15), 7/14/14 (20), 7/16/14 (15), 7/18/14 (20), 7/24/14 (15) , 7/25/14 (20), 7/28/14 (16) and 7/30/14 (20).</p> <p>5. On 8/8/14 at 2:30 PM, the bio medical technician, Employee D, was questioned as to why the filter had not been changed and the appropriate parameters put on the water treatment sheet for the patient care technicians to call and his response was, "I'm not Jesus."</p> <p>6. Microbiology report for March 2013 evidenced the 2 Bicarb H2O Out port tested at action level, April 2013 the 2 Bicarb H2O Out port test 0.26 (not at action level but high), May 2013 the 2 Bicarb H2O Out port test 0.09 (not at action level but high), September 2013 2 Reuse Disinf Out port tested at action level, December 2013 the 2 Bicarb H2O out ports tested 0.23 (not at action level but high), April 2014 2 Bicarb H2O Out port tested at action level, and May 2014 tested at action level.</p> <p>7. On 8/8/14 at 11 AM, the Facility</p>			

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V000199	<p>Manager, Employee A, was asked for the Quality Assurance monitoring of these results. At 11:30 AM, she returned with a single sheet from the QA reports evidencing that each month the water results were signed off on but no discussion of the water testing and why consistently the same ports were testing high was evidenced.</p> <p>494.40(a) RO-MEETS AAMI/MONITORED, RECORDED ON LOG 5.2.7 Reverse osmosis: meets AAMI/monitored/recorded on log Refer to RD62:2001, 4.3.7 Reverse osmosis: When used to prepare water for hemodialysis applications, either alone or as the last stage in a purification cascade, reverse osmosis systems shall be shown to be capable, at installation, of meeting the requirements of Table 1, when tested with the typical feed water of the user, in accordance with the methods of [AAMI] 5.2.2.</p> <p>5.2.7 Reverse osmosis Users should carefully follow the manufacturer's instructions for feed water treatment and monitoring to ensure that the RO is operated within its design parameters.</p> <p>6.2.7 Reverse osmosis All results of measurements of RO performance should be recorded daily in an operating log that permits trending and</p>			

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	<p>historical review.</p> <p>Based on document review, manufacturer instructions review, policy review, and interview, the facility failed to ensure the reverse osmosis feed water treatment and monitoring operated within the manufacturers design parameters for 18 of 18 months in 1 of 1 water rooms with the potential to effect all 41 in-center patients.</p> <p>Findings.</p> <p>1. Mar Cor Purification Instruction (2011 Mar Cor Purification. All rights reserved. P/N-3027274 Rev. B) for use-for filters sold in the United States of America. Applications &amp; Intended Use "The Mar Cor Purification (Mar Cor) Posiclear filter is intended to remove bacteria, endotoxin, and particulate matter from water used for dialysis. It is intended for use in dialysis water treatment systems as a final stage of filtration after RO or DI treatment to help control bacteria and endotoxin levels in purified water distribution systems. This filter is not intended as a primary means of water purification. ... 6. CAUTION: The Mar Cor Posiclear filter should be replaced every 6 months or whenever the pressure drop across the filter exceeds 15 PSI."</p>	V000199	<p><b>V199</b></p> <p>The FA and BMT were in-serviced on <i>Policy 2-01-09 "Preventative Maintenance Schedules for Equipment"</i>. 100% of facility's teammates were in-serviced on <i>Policy 2-04-02 "Daily Water Treatment System Monitoring"</i> and <i>Policy 2-04-02B "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) Preventative maintenance (PM) schedules must be made in accordance with the manufacturer's recommendation for all equipment used to perform a patient treatment. A copy of the equipment PM schedule must be filed in the appropriate Equipment Maintenance Manual, and 2) All observations and test results will be within the limits specified on the <i>Daily Water Treatment Log</i>. If observations or test results are found outside the specified limits, follow the instructions given on the <i>Daily Water Treatment Log</i> for the parameter(s) in question. In addition to following the log form instructions, the teammate completing the log will notify the Facility Administrator/designee and Biomed teammate assigned to the facility of any observation or test result found outside the limit</p>	09/05/2014			

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	<p>2. A policy titled "Preventive Maintenance Schedules for Equipment", dated Revision Date March 2013, Policy 2:2-01-09, states, "1. Preventive maintenance (PM) schedules must be made in accordance with the manufacturer's recommendation for all equipment used to perform a patient treatment. A copy of the equipment PM schedule must be filed in the appropriate Equipment Maintenance Manual."</p> <p>3. A work ticket for Diasafe Filter # 1206-00938-4121500 evidenced the Marcor filter was changed on 12/6/12 and ticket #1217-00938-5405498 evidenced the Marcor filter was changed on 12/7/13.</p> <p>On 8/8/14 at 1:55 PM, the Biomedical Technician, Employee D, indicated there were no other tickets in the system to indicate the filter had been changed indicating the filter changing was not in compliance with the manufacturer's instructions.</p> <p>4. A facility document titled "Daily Water Treatment Sheet-CWP" when presented on 8/7/14 had "Manufacturer Specifics" for line 24, 25, and 26.</p> <p>A. On 8/7/14 at 1:30 PM, the Facility Manager, Employee A was asked to</p>		<p>specified on the <i>Daily Water Treatment Log</i>. The MarCor Posiclear filter was changed on 8/8/14 as evidenced by BART ticket. The <i>Daily Water Treatment Log</i> was updated with the manufacturer's specific parameters for line 24, 25, and 26 on 8/8/14. BMT will bring <i>Daily Water Treatment Log</i> to the monthly FHM meeting for the next 3 months for review with the Medical Director and team. ABM will audit the <i>Daily Water Treatment Log(s)</i> monthly x 3 months to verify that testing has been completed and is operating within the manufacturer's design parameters. The FA is responsible for ongoing compliance with this POC.</p> <p>Completion date: 9/5/14</p>	

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	<p>present the Manufacturer Specifics for lines 24 (&gt;40 psi), 25 (&lt;100 psi), and 26 (&lt;15 psi). She returned with the specific numbers at 2:20 PM.</p> <p>B. On 8/8/14 at 1:55 PM, the Regional Biomedical Supervisor, Employee B indicated line 25 is subtracted from line 24 to get line 26. If line 26 is higher then 15 psi then the biotech should be called and the filter changed.</p> <p>C. The sheets were reviewed from January 2013 to July 2014 and the manufacturer numbers were not in line 24, line 25, and line 26. The techs were putting the numbers in the blocks, but had no reason to call the bio tech as the bio tech had not filled in the numbers to be concerned with.</p> <p>D. A ticket #1217-00938-5405498 evidenced the Marcor filter was changed on 12/7/13. From that date line 26 was higher then 15 psi without the filter being changed on 1/2/14 (18), 1/6/14 (20), 1/9/14 (20), 1/15/14 (20), 1/17/14 (20), 1/20/14 (20), 1/22/14 (20), 1/23/14 (15), 1/24/14 (20), 1/27/14 (20), 1/31/14 (20), 2/3/14 (15), 2/5/14 (20), 2/7/14 (20), 2/12/14 (20), 2/14/20 (20), 2/18/14 (20), 2/21/14 (20), 2/26/14 (19), 2/28/14 (20), 3/5/14 (20), 3/7/14 (20), 3/12/14 (20),</p>			

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V000400	<p>3/14/14 (20), 3/19/14 (20), 3/20/14 (16), 3/21/14 (20), 3/28/14 (15), 3/31/14 (20), 4/2/14 (20), 4/7/14 (15), 4/9/14 (23), 4/11/14 (20), 4/16/14 (20), 4/21/14 (20), 4/23/14 (20), 4/30/14 (20), 5/2/14 (18), 5/5/14 (20), 5/9/14 (20), 5/14/14 (26), 5/16/14 (23), 5/19/14 (26), 5/26/14 (25), 5/28/14 (15), 6/2/14 (20), 6/23/14 (20), 6/27/14 (16), 6/30/14 (20), 7/2/14 (20), 7/4/14 (19), 7/7/14 (20), 7/9/14 (20), 7/11/14 (15), 7/14/14 (20), 7/16/14 (15), 7/18/14 (20), 7/24/14 (15), 7/25/14 (20), 7/28/14 (16) and 7/30/14 (20).</p> <p>5. On 8/8/14 at 2:30 PM, the bio medical technician, Employee D, was questioned as to why the filter had not been changed and the appropriate parameters put on the water treatment sheet for the patient care technicians to call and his response was, "I'm not Jesus."</p> <p>494.60 CFC-PHYSICAL ENVIRONMENT Based on facility document, manufacturer's instructions, and policy review, observation, and interview, it was determined the facility failed to ensure preventive maintenance had been</p>	V000400	<p><b>V400</b> 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</p>	09/05/2014

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V000403	<p>performed for the bacteria/endotoxin filter after the RO water treatment system and various pieces of machinery in 1 of 1 dialysis centers reviewed with the potential to effect all 41 patients(See V 403) and failed to maintain the dialysis unit at a comfortable temperature for 1 of 1 dialysis unit with the potential to effect all 41 patients (See V 405).</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to be in compliance with this condition as required by the Condition for Coverage 494.60 Physical Environment.</p> <p>494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment,</p>		<p>Physical Environment (V400) 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 a safe, functional, and comfortable treatment environment including but not limited to: ensuring preventative maintenance is performed for the bacteria/endotoxin filter for the RO water treatment system as well as other pieces of machinery, and maintaining the temperature at a comfortable temperature. 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> <p>Completion date: 9/5/14</p>	

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	<p>dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.</p> <p>Based on facility document, manufacturer's instructions, and policy review, and interview, the facility failed to ensure preventive maintenance had been performed for the bacteria/endotoxin filter after the RO water treatment system and various pieces of machinery in 1 of 1 dialysis centers reviewed with the potential to effect all 41 patients.</p> <p>Findings:</p> <p>1. A policy titled "Preventive Maintenance Schedules for Equipment", dated March 2013, Policy:2-01-09, states, "1. Preventive maintenance (PM) schedules must be made in accordance with the manufacturer's recommendation for all equipment used to perform a patient treatment. A copy of the equipment PM schedule must be filed in the appropriate Equipment Maintenance Manual. 2. Dialysis delivery systems will receive PM performed by trained Biomed teammates according to the manufacturer's recommendations."</p> <p>2. . Mar Cor Purification Instruction (2011 Mar Cor Purification. All rights</p>	V000403	<p><b>V403</b></p> <p>The FA and BMT were in-serviced on <i>Policy 2-01-09 "Preventative Maintenance Schedules for Equipment"</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) Preventative maintenance (PM) schedules must be made in accordance with the manufacturer's recommendation for all equipment used to perform a patient treatment. A copy of the equipment PM schedule must be filed in the appropriate Equipment Maintenance Manual, and 2) Dialysis delivery systems will receive PM performed by trained Biomed teammates according to the manufacturer's recommendations. The MarCor Posiclear filter was changed on 8/8/14 as evidenced by BART ticket. BMT conducted required preventative maintenance (PM) on 90 XL Pressure Module, 90XL Conductivity Module, and centrifuge per manufacturer recommendations. ABM or designee will conduct observational audits and review of facility PM logs and monitor compliance with PM schedule monthly x 3. Results of audit will be reviewed with Medical</p>	09/05/2014

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	<p>reserved. P/N-3027274 Rev. B) for use-for filters sold in the United States of America. Applications &amp; Intended Use "The Mar Cor Purification (Mar Cor) Posiclear filter is intended to remove bacteria, endotoxin, and particulate matter from water used for dialysis. it is intended for use in dialysis water treatment systems as a final stage of filtration after RO or DI treatment to help control bacteria and endotoxin levels in purified water distribution systems. This filter is not intended as a primary means of water purification. ... 6. CAUTION: The Mar Cor Posiclear filter should be replaced every 6 months or whenever the pressure drop across the filter exceeds 15 PSI."</p> <p>A. A work ticket for Diasafe Filter # 1206-00938-4121500 evidenced the Marcor filter was changed on 12/6/12 and a ticket #1217-00938-5405498 evidenced the Marcor filter was changed on 12/7/13.</p> <p>B. On 8/8/14 at 1:55 PM, the Biomedical Technician, Employee D, indicated there were no other tickets in the system to indicate the filter had been changed indicating the filter changing was not in compliance with the manufacturer's instructions.</p>		<p>Director during monthly FHM. The FA is responsible for ongoing compliance with this POC. Completion date: 9/5/14</p>				

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	<p>3. A document titled "Certificate of Calibration" for 90 XL Pressure Module, Serial No. DP 301219 was dated 12/30/10. The record failed to evidence any other preventive maintenance before or after that date.</p> <p>A. A document titled "Certificate of Calibration" for 90 XL Conductivity Module, Serial No. DCT01296 was dated 1/5/11. The record failed to evidence any other preventive maintenance.</p> <p>B. A document titled "Probe Calibration Certificate" for 90 XL Condo/Temp, Serial No. DCT03292 was dated 2/12/14. The record failed to evidence any other preventive maintenance.</p> <p>C. A document titled "Centrifuge" Drucker 614B, Serial No. F98-149 was dated 10/13. The record failed to evidence any other preventive maintenance. On 8/8/14 at 2 PM, the Biomed technician indicated the centrifuge had been in the office for a while but he didn't know where it came from.</p> <p>D. On 8/8/14 at 2 PM, the Biomed technician indicated the above equipment should have preventive maintenance yearly, and, if new, an installation ticket</p>			

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V000405	<p>should be in the file.</p> <p>494.60(c)(2) PE-COMFORTABLE TEMPERATURE The dialysis facility must: (i) Maintain a comfortable temperature within the facility; and (ii) Make reasonable accommodations for the patients who are not comfortable at this temperature. Based on interview and observation, the facility failed to maintain the dialysis unit at a comfortable temperature for 1 of 1 dialysis unit with the potential to effect all 41 patients.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>On 8/8/14 at 2 PM, the Biomed Technician indicated when the building was built the temperature was set at 70 degrees. If the patients say they are cold someone gets them a blanket.</li> <li>On 8/8/14 at 8 AM, a confidential interview with a patient indicated the patient had complained about the cold but nothing had been done.</li> <li>On 8/8/14 from 7 AM to 10:30 AM, the dialysis unit floor was observed. The patient at station 14 had a sweatshirt hood over the head, zipped as much as possible to leave the access visible, and</li> </ol>	V000405	<p><b>V405</b> 100% of clinical teammates were in-serviced on <i>Policy 8-04-01 "Physical Environment"</i>. Verification of attendance at in- service will be evidenced by a signature sheet. Teammates will be instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) the dialysis facility will be designed, constructed, equipped, and maintained to provide dialysis patients, teammates, and the public a safe, functional, and comfortable treatment environment, and 2) The dialysis facility will take reasonable steps to maintain a comfortable temperature within the facility. The dialysis facility will make reasonable accommodations for the patients who are not comfortable at this temperature, for example suggesting that the patient bring his/her own blanket in for use during treatment. The facility has posted a notice to patients that the facility temperature is kept between</p>	09/05/2014

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V000452	<p>several blankets on. The patient at station 12 had several blankets on. The patient at station 11 had a heavy blanket on that kept sliding to the floor.</p> <p>494.70(a)(1) PR-RESPECT &amp; DIGNITY The patient has the right to- (1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD Based on clinical record, document, and policy review and interview, the facility failed recognize the individuality of the patient's needs in 1 of 4 records reviewed of deceased patients with the potential to effect all 41 patients.</p> <p>Findings:</p> <p>1. Patient 7, Admit Date 4/26/13, left dialysis to home on 7/4/14 via a medical taxi. Medical taxi's do not provide</p>	V000452	<p>70-73° F. The patients have been told that they may bring blankets to treatment as long as the patient's access remains visible. The thermostats have lockboxes on them and only the charge nurse and/or Administrative Assistant (AA) has the ability to change the temperature. The FA or designee will audit the temperature in the treatment area daily x 3 weeks to verify that temperature is between 70-73° F. Audit results will be reported and reviewed with the Medical Director during the monthly FHM. The FA is responsible for compliance with this POC. Completion date: 9/5/14</p> <p><b>V452</b> 100% of teammates were in-serviced on Policy 3-01-07 "Patient Rights and Responsibilities" and Policy 1-03-09 "Intradialytic Treatment Monitoring". 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) Patients are entitled to be treated with respect, dignity, and recognition of their individuality and</p>	09/05/2014

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	<p>medical support and are not trained for medical emergencies.</p> <p>A. 7/4/14 run sheet evidenced the patient's blood pressure elevated to 173/69 at 12:01 and the pulse elevated to 115. The blood pressure decreased to the high normal blood pressure of the patient for the next two hours. The pulse, however, stayed well into the 100's for the rest of the treatment which was unusual for the patient. The previous eight run sheets trended the pulse approximately 20 points lower.</p> <p>B. The run sheet failed to evidenced the registered nurse, Employee E recognized and took measures at 12:01 and 12:31 PM.</p> <p>C. The run sheet failed to evidenced the patient care technician, Employee F, recognized, took measures, or notified the registered nurse at 13:01, 13:34, and 14:02 PM.</p> <p>D. The run sheet evidenced the registered nurse, Employee G, called the physician and received orders for an antibiotic since the patient had a 100.4 fever and chills, but did not monitor the blood pressure and pulse to inform the physician.</p>		<p>personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD, including the need for privacy and confidentiality in all aspect of treatment, 2) Treatment checks should be completed at least every thirty (30) minutes, 3) At a minimum, obtain and document the following, blood pressure, heart rate.... 4) Significant changes are reported to the licensed nurse and documented, and 5) The licensed nurse notifies the physician as needed of changes in patient status. The FA or designee will audit 25% of post treatment flow sheets daily for two weeks and then 1 x a week for one month to verify that significant changes in patient status are reported to the physician. Ongoing compliance will be monitored by 10% of flow sheets monthly per the medical record audit. FA will review findings with Medical Director in the monthly FHM. The FA is responsible for ongoing compliance with this POC.</p> <p>Completion date: 9/5/14</p>				

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	<p>E. Treatment ended at 14:55 PM.</p> <p>2. Family had patient taken, by ambulance, to the local hospital emergency room and was admitted by 1700 PM. Records indicate the patient had an acute myocardial infarction.</p> <p>Hospital records indicate the patient suffered a Type II Myocardial Infarction seen in dialysis patients with cardiac problems. The patient did not present with pain, often will have a fever, have high blood pressure, and pulse. <a href="http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0084285">http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0084285</a></p> <p>3. The patient was transferred to a speciality hospital to receive more specialized services. The patient returned home and decided to go in hospice rather than return to dialysis according to the spouse (8/8/14 at 11:00 AM).</p> <p>4. On 8/6/14 at 10:40 AM, patient care technician, Employee F, indicated she asks the patients if they are okay if the machine alarms, if they say okay then they are okay. If the patient says no, then she alerts the registered nurse. There was no documentation she asked the patient if the patient was okay or of notifying the nurse.</p>						

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	<p>A. On 8/6/14 at 11:45, the registered nurse, Employee E, indicated she had not noticed anything wrong and had not noticed the trending on the pulse.</p> <p>B. On 8/6/14 at Noon, the registered nurse, Employee G, indicated she called the doctor for the chills and temperature but did not notice the elevated pressure and pulse to tell the doctor.</p> <p>5. On 8/5/14 at 3 PM, the Facility Manager, Employee A, was asked for the policy and parameters for the machine settings for the blood pressure and pulse.</p> <p>A. On 8/5/14 at 4:30 PM, the Facility Manager, Employee A, was asked for the policy and parameters for the machine settings for the blood pressure and pulse. She indicated she could not find who sets them and who approves them.</p> <p>B. On 8/6/14 at 11:00 AM, the Facility Manager, Employee A, was asked for the policy and parameters for the machine settings for the blood pressure and pulse. She indicated there was still not an answer. A copy of the Instruction manual for the machine indicated Fresenius sets the goals when they pre program the Fresenius 2008K machines.</p>			

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V000544	<p>C. On 8/6/14 at 2:15 PM, the Facility Manager, Employee A, was asked for the policy and parameters for the machine settings for the blood pressure and pulse. She indicated there was still not an answer.</p> <p>494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. Based on clinical record and policy review and interview, the facility failed to follow the plan of care with (1) ensured patients achieved the prescribed dose of dialysis by ensuring continuous heparin was administered as ordered for 6 of 7 hemodialysis records reviewed of patients receiving incenter dialysis with orders for continuous heparin bolus (2, 4, 5, 6 7, 8) , the patient dialyzed with the incorrect blood flow rate 2 of 7 hemodialysis records reviewed of patients receiving incenter dialysis (3 and 7) and the patient dialyzed with the incorrect dialysate flow rate in 1 of 7</p>	V000544	<p><b>V544</b> 100% of teammates were in-serviced on Policy 1-03-08 "Treatment Initiation Patient Assessment". 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) Patient prescription machine settings are verified by teammate prior to initiation of treatment and confirmed by a licensed nurse teammate within one (1) hour of treatment initiation as part of the patient assessment. Prescription components include</p>	09/05/2014

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	<p>hemodialysis records reviewed of patients receiving incenter dialysis (4) with the potential to affect all 41 patients.</p> <p>Findings:</p> <p>1. Clinical record 2, Admit Date 1/7/14, evidenced physician orders for blood flow rate (BFR) 350 ML/min, Dialysate Flow Rate (DFR) 600 ML/min, no heparin orders, and duration 180 minutes. On 1/27/14, a new Heparin Maintenance order for 1500 units of Heparin. The clinical record evidenced 2000 units was administered starting at 15:20.</p> <p>2. Clinical record 3, Admit Date 9/18/10, evidenced physician orders for 450 ML/min BFR, 600 DFR, no heparin orders, and duration 210 minutes. On 3/28/14, the BFR was 252 at 10:16 and 10:17; 201 at 10:29; 204 at 11:02; 201 at 11:32 and 12:02; 204 at 12:03; 199 at 12:31; 201 at 13:01; 199 at 13:31; and 200 at 13:45 without documentation as to why the BFR was not met.</p> <p>On 4/7/14 the BFR was 250 at 10:06; 150 at 10:35, 11:02, 11:32, 12:02, 12:33, and 13:02; and 200 at 13:32 without documentation as to why the BFR was not met.</p> <p>3. Clinical record 4, Admit date 1/20/14,</p>		<p>and are not limited to: patient identity, dialyzer make and model, reuse status, treatment time, target weight, UFR and Max UFR, UF Profiling, all accesses evaluated, correct dialysate composition (potassium, calcium, base sodium and bicarb) settings, and heparinization (intradialytic infusion). The FA or designee will audit 25% of post treatment flow sheets daily for two weeks and then 1 x a week for one month to verify that dialysis prescription is followed. Ongoing compliance will be monitored by 10% of flow sheets monthly per the medical record audit. FA will review findings with Medical Director in the monthly FHM. The FA is responsible for ongoing compliance with this POC. Completion date: 9/5/14</p>	

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	<p>evidenced physician orders for 400 ML/min BFR, 800 ML/min DFR, Heparin Bolus 2000 units, Heparin Maintenance 3000 units (1000 units/hr) to end 60 minutes before the end of dialysis, and duration of 240 minutes. The record evidenced on 7/18/14 the patient requested to run 3 hours or 180 minutes. The heparin dosage was not adjusted for the time change. Instead of 2000 units for a 3 hour run, the patient received 3000 units for a 4 hour run. On 7/21/14 the BFR was 333 at 7:01; 330 at 7:31 and 8:01; 335 at 8:31 and 9:01; 333 at 9:31; 327 at 10:01; 333 at 10:04; 335 at 10:35; and 330 at 10:38 without documentation as to why the BFR was not met.</p> <p>On 7/23/14 the DFR was 600 the entire treatment without documentation as to why the DFR was not met.</p> <p>4. Clinical record 5, evidenced physician orders for 400 ML/min BFR, 600 ML/min DFR, Heparin Bolus 4000 units, Heparin Maintenance 2750 (1000 units/hr) ending 60 minutes before the end of dialysis, and duration 225 minutes. On 7/14/14, the record evidenced the heparin bolus ended 90 minutes before the end of treatment. On 7/18/14, the heparin maintenance was 2400 units instead of 2750 units.</p>			

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	<p>5. Clinical record 6, evidenced physician orders for 400 ML/min BFR, 600 ML/min DFR, Heparin Bolus 2000 units, Heparin Maintenance 1800 (600 units/hr), heparin to stop 60 minutes before treatment ends, and 180 minutes duration.</p> <p>The clinical record failed to evidence heparin maintenance was administered on 7/14/14 and 7/16/14. On 7/18/14, the record evidenced the BFR was 300 at 15:04 and 15:31 and 265 at 16:49 with no documentation as to why the BFR was not met. On 7/23/14, the record evidenced the heparin maintenance ended 40 minutes early.</p> <p>6. Clinical record 7, Admit Date 4/26/13, evidenced physician orders for blood flow rate (BFR) 400 ML/min, dialysate flow rate (DFR) 600 ML/min, Heparin Bolus 2000 units, Heparin Maintenance 1800 units (600 units/hr) to stop 60 minutes before the end of dialysis, and duration of 240 minutes.</p> <p>A. On 6/18/14 the BFR ran 327 at 9:52 AM, 251 at 10:00 AM, and 348 at 10:31 AM. The Heparin Maintenance stopped 90 minutes before the end of dialysis.</p>			

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V000625	<p>494.110</p> <p>B. On 6/20/14, the record evidenced the Heparin Maintenance was stopped 35 minutes before the end of dialysis.</p> <p>C. On 6/25/14, the record evidenced the Heparin maintenance was stopped 80 minutes before the end of dialysis.</p> <p>D. On 7/4/14, the record evidenced the DFR was run at 500 the entire dialysis. The heparin maintenance was turned off 1 hour and 54 minutes before the end of dialysis.</p> <p>7. Clinical record 8, Admit Date 11/20/13, evidenced physician orders for BFR 400, DFR 800, Heparin Bolus 2000 units, Heparin Maintenance 2250 (600 units/hr) to end 0 minutes before the end of dialysis, and duration 225 minutes. The clinical record evidenced the heparin maintenance was turned off 1 hour before the end of dialysis on 4/7/14.</p> <p>8. On 8/7/14 at 3 PM, the Facility Manager, Employee A, indicated there was not any more documentation for the records.</p>				

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V000627	<p><b>CFC-QAPI</b></p> <p>Based on clinical record, water bacteriology reports, and QA (Quality Assessment) document review and interview, it was determined the facility failed to ensure the quality assurance program reviewed the facility's deaths to determine if there were any trends, medical errors, or adverse events the facility should address in 4 of 4 records reviewed of deceased patients with the potential to affect all 41 patients. (See V 627 and V 634) and failed to ensure the facility monitored the water bacteriology above the corrected action level for future compliance in 1 of 1 water rooms with the possibility to effect 41 patients (See V 638).</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to meet the requirements of this Condition for Coverage 494.110 Quality assessment and performance improvement.</p>	V000625	<p><b>V625</b> The Governing Body (GB) has met to review the Statement of Deficiencies (SOD) and formulate the Plan of Correction (POC). The standards under Condition –QAPI (V625) 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 QAPI including but not limited to: 1) Ensuring the quality assurance program reviews facility deaths to identify trends, medical errors or adverse events that should be addressed and monitoring the water bacteriology when it is above the action level. 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. Completion date: 9/5/14</p>	09/05/2014

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	<p><b>QAPI-ONGOING;USES INDICATORS=IMPROVEMENT</b></p> <p>The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.</p> <p>Based on clinical record review and interview, the facility failed to ensure the quality assurance program reviewed the facility's deaths to determine if there were any trends, medical errors, or adverse events the facility should address in 4 of 4 records reviewed of deceased patients with the potential to affect all 41 patients. (#2, 3, 7, and 8)</p> <p>Findings.</p> <ol style="list-style-type: none"> <li>1. Clinical record 2, admit date 1/7/14, failed to evidence discharge documentation or a review of the clinical record for possible medical errors or adverse events while on dialysis.</li> <li>2. Clinical record 3, admit date 9/18/10, failed to evidence discharge documentation or a review of the clinical record for possible medical errors or adverse events while on dialysis.</li> <li>3. Clinical record 7, admit date 4/26/13, failed to evidence a review of the clinical</li> </ol>	V000627	<p><b>V627</b></p> <p>The interdisciplinary team (IDT) was in-serviced on <i>Policy 1-14-06 "Continuous Quality Improvement Program"</i>. Verification of attendance is evidenced by a signature sheet. Teammates were instructed with emphasis on, but not limited to, the following: 1) the facility will measure, analyze, and track quality indicators or other aspects of performance. The program must include, but not be limited to, the following...mortality- review of deaths...other indicators as reflected in the Facility Health Record. Patient mortality will be discussed and reviewed during the Facility Health Meeting, to analyze for trending in the cause(s) of patient deaths. The DaVita Mortality Review Form will be completed for each patient death, with all deaths for the month summarized on the Mortality Review Summary sheet. All patient deaths and mortality review/summary forms will be reviewed in the monthly FHM. The Clinical Services Specialist (CSS) will review the FHR</p>	09/05/2014

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V000634	<p>record for possible medical errors or adverse events while on dialysis before electing hospice.</p> <p>4. Clinical record 8, admit date 11/20/13, failed to evidence discharge documentation or a review of the clinical record for possible medical errors or adverse events while on dialysis.</p> <p>5. On 8/6/14 at 2 PM the Medical Director, Employee H, indicated they had not been evaluating the deaths at the facility to see if the facility could have provided different or better care, if there were trends, if the documentation was appropriate, and if all the appropriate people knew.</p> <p>494.110(a)(2)(vi) QAPI-INDICATOR-MEDICAL INJURIES/ERRORS The program must include, but not be limited to, the following: (vi) Medical injuries and medical errors identification. Based on clinical record review and interview, the facility failed to ensure the quality assurance program reviewed the facility's deaths to determine if there were any trends, medical errors, or adverse events the facility should address in 4 of</p>	V000634	<p>meeting minutes monthly for three months to verify that the committee reviews patient deaths. The FA is responsible for ongoing compliance with this POC.</p> <p>Completion date: 9/5/14</p> <p><b>V634</b> The interdisciplinary team (IDT) was in-serviced on <i>Policy 1-14-06 "Continuous Quality Improvement Program"</i>. Verification of attendance is evidenced by a signature sheet. Teammates were instructed with emphasis on,</p>	09/05/2014			

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	<p>4 records reviewed of deceased patients with the potential to effect all 41 patients.</p> <p>Findings.</p> <ol style="list-style-type: none"> <li>1. Clinical record 2, admit date 1/7/14, failed to evidence discharge documentation or a review of the clinical record for possible medical errors or adverse events while on dialysis.</li> <li>2. Clinical record 3, admit date 9/18/10, failed to evidence discharge documentation or a review of the clinical record for possible medical errors or adverse events while on dialysis.</li> <li>3. Clinical record 7, admit date 4/26/13, failed to evidence a review of the clinical record for possible medical errors or adverse events while on dialysis before electing hospice.</li> <li>4. Clinical record 8, admit date 11/20/13, failed to evidence discharge documentation or a review of the clinical record for possible medical errors or adverse events while on dialysis.</li> <li>5. On 8/6/14 at 2 PM the Medical Director, Employee H, indicated they had not been evaluating the deaths at the facility to see if the facility could have provided different or better care, if there</li> </ol>		<p>but not limited to, the following: 1) the facility will measure, analyze, and track quality indicators or other aspects of performance. The program must include, but not be limited to, the following...mortality- review of deaths and patient safety including review of sentinel events as well as trends of adverse patient occurrences including falls and blood loss...other indicators as reflected in the Facility Health Record. FA will review all Adverse Occurrence Reports monthly for accuracy. FA will track/trend all events monthly in comparison based on previous 12 month data. Root Cause Analysis (RCA) to be used for negative trends and plan of corrections to be developed in effort to minimize the number of occurrences and limit the number of patients involved. FA will review Root Cause Analysis and plan of correction with Medical Director during monthly FHM. The Clinical Services Specialist (CSS) will review the FHR meeting minutes monthly for three months to verify that the committee reviews patient deaths and AORs. The FA is responsible for ongoing compliance with this POC.</p> <p>Completion date: 9/5/14</p>				

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V000638	<p>were trends, if the documentation was appropriate, and if all the appropriate people knew.</p> <p>494.110(b) QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time. Based on water bacteriology reports and QA (Quality Assessment) document review and interview, the facility failed to ensure the facility monitored the water bacteriology above the corrected action level for future compliance in 1 of 1 water rooms with the possibility to effect 41 patients.</p> <p>Findings:</p> <p>1. Microbiology report for March 2013 evidenced the 2 Bicarb H2O Out port tested at action level, April 2013 the 2 Bicarb H2O Out port tested 0.26 (not at action level but high), May 2013 the 2 Bicarb H2O Out port tested 0.09 (not at action level but high), September 2013 2 Reuse Disinf Out port tested at action</p>	V000638	<p><b>V638</b> The interdisciplinary team (IDT) was in-serviced on <i>Policy 1-14-06 "Continuous Quality Improvement Program"</i>. Verification of attendance is evidenced by a signature sheet. Teammates were instructed with emphasis on, but not limited to, the following: 1) the facility will measure, analyze, and track quality indicators or other aspects of performance. The program must include, but not be limited to, the following...water and dialysate cultures ...other indicators as reflected in the Facility Health Record, and 2) Any area identified as underperforming will be reviewed to identify root causes for underperformance, will have an action plan identified that will result in performance improvement, and will track this change in performance over time</p>	09/05/2014

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V000712	<p>level, December 2013 the 2 Bicarb H2O out port tested 0.23 (not at action level but high), 2 Bicarb H2O Out ports in April 2014 tested at action level, and May 2014 tested at action level.</p> <p>2. On 8/8/14 at 11 AM, the Facility Manager, Employee A, was asked for the Quality Assurance monitoring of these results. At 11:30 AM, she returned with a single sheet from the QA reports evidencing that each month the water results were signed off on but no discussion of the water testing and why consistently the same ports were testing high was evidenced.</p> <p>494.150(a) MD RESP-QAPI PROGRAM Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program. Based on water bacteriology report, QA (Quality Assessment) document, manufacturer's instructions, clinical record, and policy review and interview, the Medical Director failed to ensure the quality assurance program reviewed the facility's deaths to determine if there were any trends, medical errors, or adverse events the facility should address in 4 of</p>	V000712	<p>to verify improvements are sustained. The committee will review and analyze the facility data and trends monthly. Action plans will be developed in response to data analysis with documentation in meeting minutes, and will be reviewed and revised as required. The CSS will review the FHR meeting minutes monthly for three months to verify that water bacteriology is reviewed with action plans developed as appropriate. The FA is responsible for ongoing compliance with this POC.</p> <p>Completion date: 9/5/14</p> <p><b>V712</b> Governing Body meeting was held on 8/22/2014. Immediate steps were taken to ensure Medical Director over sight and involvement in executing his roles and responsibilities for the operational responsibility for the QAPI program. QAPI Program must be monitored/ reviewed by GB including Medical</p>	09/05/2014

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	<p>4 records reviewed of deceased patients, water bacteriology above the corrected action level was monitored for future compliance, and the reverse osmosis (RO) feed water treatment and monitoring operated within the manufacturers design parameters for 18 of 18 months in 1 of 1 water rooms with the potential to effect all 41 in-center patients.</p> <p>Findings.</p> <p>Regarding review of facility deaths</p> <p>1. Clinical record 2, admit date 1/7/14, failed to evidence discharge documentation or a review of the clinical record for possible medical errors or adverse events while on dialysis.</p> <p>2. Clinical record 3, admit date 9/18/10, failed to evidence discharge documentation or a review of the clinical record for possible medical errors or adverse events while on dialysis.</p> <p>3. Clinical record 7, admit date 4/26/13, failed to evidence a review of the clinical record for possible medical errors or adverse events while on dialysis before electing hospice.</p> <p>4. Clinical record 8, admit date 11/20/13,</p>		<p>Director who assumes operational responsibility to ensure QAPI Program analyzes data, develops plans/interventions for improvement of care, and re-evaluates focusing on health outcomes and safety of patients. The Medical Director reviewed <i>Policy 3-03-71 "Medical Director Qualifications and Responsibilities"</i> and <i>Policy 3-03-77 "Facility Health Meeting Process"</i>. This review included the importance of responsibilities related to ensuring that all policies and procedures are adhered to and responsibilities of oversight of the hemodialysis and peritoneal dialysis programs. Verification of review is evidenced by signature on the policies reviewed. The Medical Director is having weekly calls/meetings with the FA to review any issues that are occurring or have occurred in the facility. These are evidenced by the Governing Body meeting minutes. These calls/meetings will continue until facility has reached compliance with this POC. FA/Designee will ensure any variances from policy are addressed immediately and will be reviewed with the Medical Director. The dialysis facility will conduct monthly QAPI meetings known as Facility Health Meeting (FHM). The GB will meet monthly for 3 months to monitor the FHM minutes documenting, but not limited to the following: 1) mortality reviews, 2) AORs reviewed and trended, 3)</p>	

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	<p>failed to evidence discharge documentation or a review of the clinical record for possible medical errors or adverse events while on dialysis.</p> <p>5. On 8/6/14 at 2 PM the Medical Director, Employee H, indicated they had not been evaluating the deaths at the facility to see if the facility could have provided different or better care, if there were trends, if the documentation was appropriate, and if all the appropriate people knew.</p> <p>Regarding reverse osmosis (RO) feed water treatment and monitoring operated within the manufacturers design parameters</p> <p>6. Mar Cor Purification Instruction (2011 Mar Cor Purification. All rights reserved. P/N-3027274 Rev. B) for use-for filters sold in the United States of America. Applications &amp; Intended Use "The Mar Cor Purification (Mar Cor) Posiclear filter is intended to remove bacteria, endotoxin, and particulate matter from water used for dialysis. It is intended for use in dialysis water treatment systems as a final stage of filtration after RO or DI treatment to help control bacteria and endotoxin levels in purified water distribution systems. This filter is not intended as a primary means</p>		<p>water and dialysate cultures, and 4) water monitoring within the manufacturers design parameters. The CQI committee will identify root causes for underperformance, will have an action plan identified that will result in performance improvement, and will track this change in performance over time to verify improvements are sustained. The FA and Medical Director are responsible for ongoing compliance with this POC.</p> <p>Completion date: 9/5/14</p>	

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NAME OF PROVIDER OR SUPPLIER  LAWRENCEBURG DIALYSIS CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 721 RUDOLPH WAY GREENDALE, IN 47025
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	<p>of water purification. ... 6. CAUTION: The Mar Cor Posiclear filter should be replaced every 6 months or whenever the pressure drop across the filter exceeds 15 PSI."</p> <p>7. A policy titled "Preventive Maintenance Schedules for Equipment", dated Revision Date March 2013, Policy 2:2-01-09, states, "1. Preventive maintenance (PM) schedules must be made in accordance with the manufacturer's recommendation for all equipment used to perform a patient treatment. A copy of the equipment PM schedule must be filed in the appropriate Equipment Maintenance Manual."</p> <p>8. A work ticket for Diasafe Filter # 1206-00938-4121500 evidenced the Marcor filter was changed on 12/6/12 and ticket #1217-00938-5405498 evidenced the Marcor filter was changed on 12/7/13.</p> <p>On 8/8/14 at 1:55 PM, the Biomedical Technician, Employee D, indicated there were no other tickets in the system to indicate the filter had been changed indicating the filter changing was not in compliance with the manufacturer's instructions.</p> <p>9. A facility document titled "Daily</p>			

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	<p>Water Treatment Sheet-CWP" when presented on 8/7/14 had "Manufacturer Specifics" for line 24, 25, and 26.</p> <p>A. On 8/7/14 at 1:30 PM, the Facility Manager, Employee A was asked to present the Manufacturer Specifics for lines 24 (&gt;40 psi), 25 (&lt;100 psi), and 26 (&lt;15 psi). She returned with the specific numbers at 2:20 PM.</p> <p>B. On 8/8/14 at 1:55 PM, the Regional Biomedical Supervisor, Employee B indicated line 25 is subtracted from line 24 to get line 26. If line 26 is higher then 15 psi then the biotech should be called and the filter changed.</p> <p>C. The sheets were reviewed from January 2013 to July 2014 and the manufacturer numbers were not in line 24, line 25, and line 26. The techs were putting the numbers in the blocks, but had no reason to call the bio tech as the bio tech had not filled in the numbers to be concerned with.</p> <p>D. A ticket #1217-00938-5405498 evidenced the Marcor filter was changed on 12/7/13. From that date line 26 was higher then 15 psi without the filter being changed on 1/2/14 (18), 1/6/14 (20), 1/9/14 (20), 1/15/14 (20), 1/17/14 (20),</p>			

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	<p>1/20/14 (20), 1/22/14 (20), 1/23/14 (15), 1/24/14 (20), 1/27/14 (20), 1/31/14 (20), 2/3/14 (15), 2/5/14 (20), 2/7/14 (20), 2/12/14 (20), 2/14/20 (20), 2/18/14 (20), 2/21/14 (20), 2/26/14 (19), 2/28/14 (20), 3/5/14 (20), 3/7/14 (20), 3/12/14 (20), 3/14/14 (20), 3/19/14 (20), 3/20/14 (16), 3/21/14 (20), 3/28/14 (15), 3/31/14 (20), 4/2/14 (20), 4/7/14 (15), 4/9/14 (23), 4/11/14 (20), 4/16/14 (20), 4/21/14 (20), 4/23/14 (20), 4/30/14 (20), 5/2/14 (18), 5/5/14 (20), 5/9/14 (20), 5/14/14 (26), 5/16/14 (23), 5/19/14 (26), 5/26/14 (25), 5/28/14 (15), 6/2/14 (20), 6/23/14 (20), 6/27/14 (16), 6/30/14 (20), 7/2/14 (20), 7/4/14 (19), 7/7/14 (20), 7/9/14 (20), 7/11/14 (15), 7/14/14 (20), 7/16/14 (15), 7/18/14 (20), 7/24/14 (15), 7/25/14 (20), 7/28/14 (16) and 7/30/14 (20).</p> <p>10. On 8/8/14 at 2:30 PM, the bio medical technician, Employee D, was questioned as to why the filter had not been changed and the appropriate parameters put on the water treatment sheet for the patient care technicians to call and his response was, "I'm not Jesus."</p> <p>Regarding water bacteriology above the corrected action level was monitored for future compliance</p> <p>11. Microbiology report for March 2013</p>			

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	<p>evidenced the 2 Bicarb H2O Out port tested at action level, April 2013 the 2 Bicarb H2O Out port tested 0.26 (not at action level but high), May 2013 the 2 Bicarb H2O Out port tested 0.09 (not at action level but high), September 2013 2 Reuse Disinf Out port tested at action level, December 2013 the 2 Bicarb H2O out port tested 0.23 (not at action level but high), 2 Bicarb H2O Out ports in April 2014 tested at action level, and May 2014 tested at action level.</p> <p>12. On 8/8/14 at 11 AM, the Facility Manager, Employee A, was asked for the Quality Assurance monitoring of these results. At 11:30 AM, she returned with a single sheet from the QA reports evidencing that each month the water results were signed off on but no discussion of the water testing and why consistently the same ports were testing high was evidenced.</p>			