

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152617	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 07/27/2012
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NAME OF PROVIDER OR SUPPLIER DSI KOKOMO DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP CODE 3760 S REED ST KOKOMO, IN 46902
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V0000	<p>This visit was an ESRD recertification survey.</p> <p>Survey dates: July 23, 24, 25, and 27, 2012</p> <p>Facility #: 006659</p> <p>Medicaid Vendor #: NA</p> <p>Surveyor: BridgetBoston, RN, PHNS - Team Leader Marty Coons, RN, PHNS Team Member</p> <p>DSI Dialysis of Kokomo was found to be out of compliance with the Condition for Coverage 494.40:Water and Dialysate Quality.</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN August 2, 2012</p>	V0000		

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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V0175	<p>494.40 CFC-WATER & DIALYSATE QUALITY</p> <p>Based on documents, lab results, and policy and procedure review and interview, it was determined the facility failed to ensure the product water used to prepare dialysate and concentrates was below action level for 3 of 6 months reviewed with the potential to affect all 20 patients (See V 178); failed to ensure the the ultraviolet radiation device was maintained according to manufactures instructions for 1 of 1 UV light maintenance record reviewed with the potential to affect water product quality and all current patients (See V 214); failed to ensure the bacteria level of the product water was below action level for 3 of 6 months reviewed with the potential to affect all 20 patients (See V 252); failed to ensure that the monthly water samples sent for culture levels were collected prior to the disinfection of the water treatment system in 1 of the last 6 monthly water cultures reviewed with the potential to affect all 20 patients (See V 254); failed to ensure repeat water and dialysate cultures were completed on a weekly basis until the bacterial count and concentrate was below action level for 3 of 6 months reviewed with the potential to affect all 20 patients (See V 255); and failed to ensure an action plan was developed and implemented and repeat</p>	V0175	Cross reference V178; V214; V252; V254; V255; V274	08/27/2012			

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	<p>water and dialysate cultures were completed on a weekly basis until the bacterial count and concentrate was below action level for 3 of 6 months reviewed with the potential to affect all 20 patients (See V 274);</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to provide safe water and dialysate as required by the Condition for Coverage 494.40:Water and Dialysate Quality.</p>			

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V0178	<p>494.40(a) BACT OF H2O-MAXIMUM & ACTION LEVELS 4.1.2 Bacteriology of water: max & 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.</p> <p>Based on agency document, lab results, and policy and procedure review and interview, the facility failed to ensure the product water used to prepare dialysate and concentrates was below action level for 3 of 6 months reviewed with the potential to affect all 20 patients of the facility. (February, March, and April)</p> <p>Findings:</p> <p>1. Agency document titled "Environmental CQI Report" evidenced the monthly water quality results and a collection date of 2/7/12. The document evidenced a print date of 3/15/12 and signature of the medical director, void of date. The report evidenced the test results</p>	V0178	The BT (Biomed Technician) has been in-serviced on Policy & Procedure: 494.40 Corrective actions for positive water colony counts & endotoxin levels; 494.40; Reviewing colony counts & endotoxin results; 494.40 Microbial & Endotoxin standards for water used in hemodialysis. If results exceed AAMI action levels, they will be addressed within 48 hours of receipt of results and the Medical Director will be notified via fax, phone, in person or email within 24 hours. If results exceed AAMI maximum allowable limits, they will be addressed within 24 hours of receipt of results and the Medical Director will be notified via fax, phone, in person, or email within 24 hours. If results exceeding action level persist, actions taken	08/27/2012	

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	<p>were 1) Loop beginning was 162 CFU (colony forming units) and 2) R O (Reverse Osmosis) Permeate was 246 CFU. A redraw was completed on 2/13/12 and the results were 1) loop beginning 40 CFU and 2) RO Permeate was 52 CFU.</p> <p>2. Agency document titled "Environmental CQI Report" included the monthly water quality results and evidenced signatures of the Medical Director and the Interim Clinical Manager dated 4/20/12. The report evidenced a collection date of 3/8/12 and evidenced the results were RO Permeate 70 CFU and 1.520 LAL (limulus ameocyte lysate) endotoxin units (EU). The document contained a hand written note and stated, "Will do weekly [cultures] carbon tanks - to make sure it is." The report evidenced the following results:</p> <p>A. Redraw dated 3/13/12 and the results were 1) Post Carbon # 2 Tank 634 CFU, 2) R O sample port #1 was 168 CFU, 3) RO sample port #2 was 154 CFU, and 4) RO sample port #3 was 294 CFU.</p> <p>B. Redraw dated 3/15/12 and the results were 1) RO sample port #2 - 106 CFU and 2) RO permeate was 86 CFU.</p>		<p>must escalate. The Medical Director will be notified within 24 hours of receipt of results. Action plans will be initiated for any results exceedign action & allowable limits levels. These action plans will be update/revised as needed per results of initial/ redraws of cultures /endotoxins. Action plans will be initiated for any results exceeding action & allowable limits levels. These action plans will be updated/revised as needed per results of initial/redraws of cultures/endotoxins.ATM (Area Technical Manager) will monitor all colony count and endotoxin results and notification of the Medical Director if any results are exceeding the AAMI recommended practice x 6 months or until compliance has been established, then per quarterly technical audit. VP of technical services or designee will review all audit results bi-weekly until compliance has been established.Anyone found not to be in compliance with policy & procedure will face immediate disciplinary action up to and including termination. ATM or designee will review all education, audits, action plans and discipline in monthly QAPI and bi-weekly LGB.</p>				

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	<p>C. A redraw dated 3/20/12 of only two sample ports and the results were 1) RO Permeate 106 CFU and 2) RO sample port #1 - 114 CFU.</p> <p>3. Agency document titled "Environmental CQI Report" evidenced the monthly water quality results and signature of the environmental technician dated 5/17/12. The report evidenced the first water sample collected for the month of April was a RO water sample collected on 4/17/12. No other port was sampled for water and dialysate on 4/17/12. The RO water sample result was zero. The report evidenced the next sample collected was on 4/26/12 and evidenced a result of 106 CFU for water source "Loop beginning."</p> <p>4. On July 24, 2012, at 12:50 PM, employee D, the environmental technician, indicated he did not collect any water or dialysate samples for colony counts after March 20, 2012, and before April 17, 2012, from any ports. He indicated he increased the number of disinfections of the loop and reverse osmosis and indicated with his experience, he had determined the problem was in the carbon tanks and they needed to be rebeded. He indicated he was not authorized to complete the rebed and the facility vendor could not complete</p>						

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	<p>the work until April 12, 2012. He indicated with his experience he was confident after the carbon tanks were rebeded, the CFU and EU values would come into acceptable levels. Reviewed the lab result dates with employee I and he indicated there was only one collection of water and dialysate in May on 5/1/12, one in June on June 5/12, and one for July on 7/5/12.</p> <p>5. On July 27, 2012, at 10:20 AM, the clinical manager indicated there was no written and approved facility Action Plans found to evidence the facility developed and implemented an Action Plan once the water and dialysate cultures were above acceptable levels beginning in February 2012 and no further action plan found that addressed any follow up and monitoring.</p> <p>6. On July 27, 2012, at 2:15 PM, employee D indicated there was no "Action Plan" developed before 3/27/12 and he indicated there was no other written and approved Action Plan to follow up and monitor the water and dialysate CFU and EU results. He indicated the Action Plan dated 3/27/12 was created as part of the report to be presented at the April QAPI meeting but he did not bring the report to the meeting. He indicated he created the Action Plan electronically and it was available to the</p>						

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	<p>Clinical Manager to print and incorporate into the monthly QAPI meeting. He indicated his chain of command was to report all water and dialysate cultures outside acceptable values to the Clinical Manager and he did not report to the medical director and stated, "Unless she asked me directly."</p> <p>7. On July 27, 2012, at 2:15 PM, the QAPI minutes were reviewed with employee D. The minutes dated April 20, 2012, contained a hand written note and stated, "Continue to have high cultures - carbon tank with high results. Both carbon tanks rebedded last week. + disinfected Culture results currently 0 - will cont [continue] to disinfect weekly until trend developed + culture." Employee D stated, "I never knew that was written." He indicated he does not review the notes written on the QAPI report during the meeting.</p> <p>8. The agency policy titled "Microbiological Testing Policy and Procedure" policy # 40.42 effective date 2/7/09 stated, "It is the responsibility of the technician and the medical director to ensure that the microbiological testing is being completed per policy. ... Bacterial colony counts of product water and dialysate shall be less than 200 CFU / mL [colony forming units / milliliter] with an</p>						

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	action level of 50 CFU / mL. The endotoxin LAL concentration of product water and dialysate shall be less than 2 EU / mL [Endotoxin Units / milliliter] with an action level of 1 EU / mL. ... If there is a result that is at or above an action level, but below the maximum allowable level, action will be taken per AAMI standards action tree within 48 hours of receiving the results."			

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V0214	<p>494.40(a) BACT CONTROL DEVICE-UV LIGHT 5.3.4 Bacterial control devices: 5.3.4.1 Ultraviolet irradiators: UV dose Refer to RD62:2001, 4.3.13 Ultraviolet irradiators: When used to control bacterial proliferation in water storage and distribution systems, UV irradiation devices shall be fitted with a low-pressure mercury lamp that emits light at a wavelength of 254 nm and provides a dose of radiant energy of 30 milliwatt-sec/cm², [except in the case described below]. The device shall be sized for the maximum anticipated flow rate according to the manufacturer's instructions.</p> <p>5.3.4.1 Ultraviolet irradiators If the irradiator includes a meter as described above, the minimum dose of radiant energy should be at least 16 milliwatt-sec/cm².</p> <p>To prevent the use of sublethal doses of radiation that may lead to the development of resistant strains of bacteria, UV irradiators shall be equipped with a calibrated ultraviolet intensity meter ...or with an on-line monitor of radiant energy output that activates a visible alarm, which indicates that the lamp should be replaced. Alternatively, the lamp should be replaced on a predetermined schedule according to the manufacturer's instructions to maintain the recommended radiant energy output.</p> <p>6.3.4 Bacterial control devices 6.3.4.1 Ultraviolet irradiators Ultraviolet irradiators intended for use as a direct means of bacterial control shall be monitored for radiant energy output. UV irradiators should be monitored at the frequency recommended by the manufacturer. A log sheet should be used to</p>			

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	<p>indicate that monitoring has been performed.</p> <p>Based on maintenance log review and interview, the facility failed to ensure the ultraviolet radiation device was maintained according to manufacturer's instructions for 1 of 1 UV light maintenance record reviewed with the potential to affect water product quality and all current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The maintenance record for the UV light serial # A - 2486 evidenced the UV bulb was changed on 1/3/11 and 3/3/12, a period of 10,128 hours. 2. On July 24, 2012 at 2 PM, employee D indicated the lamp is always on except for during disinfection and was to be changed annually or at 9000 hours which ever is first. 	V0214	<p>The BT has been in-serviced on the UV Light manufacturers recommendations for monitoring frequency and completion of the maintenance log. ATM or designee will monitor UV light replacement during quarterly technical audits to ensure compliance. VP of technical services or designee will review all audit results until compliance has been established. Anyone found not to be in compliance with manufacturer recommendations will face immediate disciplinary action up to and including termination. ATM or designee will review all education, audits, action plans and discipline in monthly QAPI and bi-weekly LGB.</p>	08/27/2012	

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V0252	<p>494.40(a) MICROB MONITOR-MO H2O SAMPLES/METHOD 7.2 Microbial monitoring methods: monthly water samples/method 7.2.1 General Culture water ...weekly for new systems until a pattern has been established. For established systems, culture monthly unless a greater frequency is dictated by historical data at a given institution.</p> <p>Monitoring can be accomplished by direct plate counts, in conjunction with the measurement of bacterial endotoxin.</p> <p>7.2.2 Sample collection Water samples should be collected directly from outlet taps situated in different parts of the water distribution system. In general, the sample taps should be opened and the water should be allowed to run for at least 60 seconds before a sample is collected in a sterile, endotoxin-free container. A minimum of 50 mL of water, or the volume specified by the laboratory performing the test, should be collected. Sample taps should not be disinfected.</p> <p>Based on document, lab results, and policy and procedure review, and interview, the facility failed to ensure the bacteria level of the product water was below action level for 3 of 6 months reviewed with the potential to affect all 20 patients. (February, March, and April)</p> <p>Findings:</p> <p>1. Agency document titled</p>	V0252	The BT has been in-serviced on policy & procedure 494.40; Corrective actions for positive water colony counts & endotoxin levels; 494.40 Reviewing colony counts & endotoxin results; Microbial & endotoxin standards for water used in hemodialysis. If results exceed AAMI action levels, they will be addressed within 48 hours of receipt of results and the Medical Director will be notified via fax, phone, in person or email within	08/27/2012			

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	<p>"Environmental CQI Report" evidenced the monthly water quality results and a collection date of 2/7/12. The document evidenced a print date of 3/15/12 and signature of the medical director, void of date. The report evidenced the test results were 1) Loop beginning was 162 CFU (colony forming units) and 2) R O (Reverse Osmosis) Permeate was 246 CFU. A redraw was completed on 2/13/12 and the results were 1) loop beginning 40 CFU and 2) RO Permeate was 52 CFU.</p> <p>2. Agency document titled "Environmental CQI Report" included the monthly water quality results and evidenced signatures of the Medical Director and the Interim Clinical Manager dated 4/20/12. The report evidenced a collection date of 3/8/12 and evidenced the results were RO Permeate 70 CFU and 1.520 LAL (limulus amebocyte lysate) endotoxin units (EU). The document contained a hand written note and stated, "Will do weekly [cultures] carbon tanks - to make sure it is." The report evidenced the following results:</p> <p>A. Redraw dated 3/13/12 and the results were 1) Post Carbon # 2 Tank 634 CFU, 2) R O sample port #1 was 168 CFU, 3) RO sample port #2 was 154 CFU, and 4) RO sample port #3 was 294</p>		<p>24 hours. If results exceed AAMI maximum allowable limits, they will be addressed within 24 hours of receipt of results and the Medical Director will be notified via fax, phone, in person or email within 24 hours. If results exceeding action level persist, actions taken must escalate. The Medical Director will be notified within 24 hours of receipt of results. Action plans will be initiated for any results exceeding action & allowable limits levels. These action plans will be updated / revised as needed per results of initial/redraws of cultures/endotoxins. ATM or designee will monitor all colony count & endotoxin results and notification of the Medical Director if any results are exceeding the AAMI recommended practice x 6 months or until compliance has been established, then per quarterly technical audit. VP of technical services or designee will review all audit results bi-weekly until compliance has been established. Anyone found not to be in compliance with P&P will face immediate disciplinary action up to and including termination. ATM or designee will review all education, audits, action plans and discipline in monthly QAPI and bi-weekly LGB.</p>				

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	<p>CFU.</p> <p>B. Redraw dated 3/15/12 and the results were 1) RO sample port #2 - 106 CFU and 2) RO permeate was 86 CFU.</p> <p>C. A redraw dated 3/20/12 of only two sample ports and the results were 1) RO Permeate 106 CFU and 2) RO sample port #1 - 114 CFU.</p> <p>3. Agency document titled "Environmental CQI Report" evidenced the monthly water quality results and signature of the environmental technician dated 5/17/12. The report evidenced the first water sample collected for the month of April was a RO water sample collected on 4/17/12. No other port was sampled for water and dialysate on 4/17/12. The RO water sample result was zero. The report evidenced the next sample collected was on 4/26/12 and evidenced a result of 106 CFU for water source "Loop beginning."</p> <p>4. On July 24, 2012, at 12:50 PM, employee D, the environmental technician, indicated he did not collect any water or dialysate samples for colony counts after March 20, 2012, and before April 17, 2012, from any ports. He indicated he increased the number of disinfections of the loop and reverse</p>				

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	<p>osmosis and indicated with his experience, he had determined the problem was in the carbon tanks and they needed to be rebeded. He indicated he was not authorized to complete the rebed and the facility vendor could not complete the work until April 12, 2012. He indicated with his experience he was confident after the carbon tanks were rebeded, the CFU and EU values would come into acceptable levels. Reviewed the lab result dates with employee I and he indicated there was only one collection of water and dialysate in May on 5/1/12, one in June on June 5/12, and one for July on 7/5/12.</p> <p>5. On July 27, 2012, at 10:20 AM, the clinical manager indicated there was no written and approved facility Action Plans found to evidence the facility developed and implemented an Action Plan once the water and dialysate cultures were above acceptable levels beginning in February 2012 and no further action plan found that addressed any follow up and monitoring.</p> <p>6. On July 27, 2012, at 2:15 PM, employee D indicated there was no "Action Plan" developed before 3/27/12 and he indicated there was no other written and approved Action Plan to follow up and monitor the water and dialysate CFU and EU results. He</p>				

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	<p>indicated the Action Plan dated 3/27/12 was created as part of the report to be presented at the April QAPI meeting but he did not bring the report to the meeting. He indicated he created the Action Plan electronically and it was available to the Clinical Manager to print and incorporate into the monthly QAPI meeting. He indicated his chain of command was to report all water and dialysate cultures outside acceptable values to the Clinical Manager and he did not report to the medical director and stated, "Unless she asked me directly."</p> <p>7. On July 27, 2012, at 2:15 PM, the QAPI minutes were reviewed with employee D. The minutes dated April 20, 2012, contained a hand written note and stated, "Continue to have high cultures - carbon tank with high results. Both carbon tanks rebedded last week. + disinfected Culture results currently 0 - will cont [continue] to disinfect weekly until trend developed + culture." Employee D stated, "I never knew that was written." He indicated he does not review the notes written on the QAPI report during the meeting.</p> <p>8. The agency policy titled "Microbiological Testing Policy and Procedure" policy # 40.42 effective date 2/7/09 stated, "It is the responsibility of</p>				

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	the technician and the medical director to ensure that the microbiological testing is being completed per policy. ... Bacterial colony counts of product water and dialysate shall be less than 200 CFU / mL [colony forming units / milliliter] with an action level of 50 CFU / mL. The endotoxin LAL concentration of product water and dialysate shall be less than 2 EU / mL [Endotoxin Units / milliliter] with an action level of 1 EU / mL. ... If there is a result that is at or above an action level, but below the maximum allowable level, action will be taken per AAMI standards action tree within 48 hours of receiving the results."				

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V0254	<p>494.40(a) MICROB MONITOR-SAMPLE BEFORE DISINFECT 7.2 Microbial monitoring methods 7.2.1 General: samples before disinfect Samples should always be collected before sanitization/disinfection of the water treatment system and dialysis machines.</p> <p>Based on document and policy and procedure review and interview, the facility failed to ensure the monthly water samples sent for culture levels were collected prior to the disinfection of the water treatment system in 1 of the last 6 monthly water cultures reviewed (July 2012) with the potential to affect all 20 patients.</p> <p>The findings include:</p> <p>1. On July 24, 2012, at 12:40 PM employee D, the environmental technician, indicated they were following Liberty's policy's and procedures and it was not a Liberty policy to collect a water or dialysate samples prior to disinfection. The water and dialysate CFU (colony forming units) and EU (endotoxin units) results and the disinfection logs for July 2012 were reviewed with employee D. Employee D confirmed he disinfected the water treatment system on July 3, 2012, and then collected his water and dialysate samples on 7/5/12.</p>	V0254	<p>The BT has been in-serviced regarding policy & procedure 40.42; States that all colony counts and endotoxin samples must be drawn prior to disinfection. ATM or designee will monitor all colony count and endotoxin draw dates, results and disinfection logs x 6 months or until compliance has been established, then per quarterly technical audit. VP of technical services or designee will review all audit results bi-weekly until compliance has been established. Anyone found not to be in compliance with P&P will face immediate disciplinary action up to and including termination. ATM or designee will review all education, audits, and discipline in monthly QAPI and bi-weekly LGB.</p>	08/27/2012	

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	<p>2. Agency disinfection logs evidenced the Reverse Osmosis was disinfected on July 3, 2012, and a sample of the product water was sent out for CFU and EU on 7/5/12. There was no sample collected before disinfection.</p> <p>3. A disinfection log for the distribution loop evidenced the loop was disinfected on 6/30/12 and a sample was collected for CFU and EU on 7/5/12.</p> <p>4. The policy titled "Microbiological Testing Policy and Procedure" # 40.42 provided by the environmental technician on 7/24/12 for review stated, "All lab samples should be drawn prior to routine scheduled disinfections."</p>				

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V0255	<p>494.40(a) MICROB MONITOR-REPEAT CULTURES 7.2 Microbial monitoring methods 7.2.1 General: repeat cultures Cultures should be repeated when bacterial counts exceed the allowable levels. If culture growth exceeds permissible standards, the water system and dialysis machines should be cultured weekly until acceptable results are obtained. Additional samples should be collected when there is a clinical indication of a pyrogenic reaction or septicemia, and following a specific request by the clinician or the infection control practitioner.</p> <p>If repeat cultures are performed after the system has been disinfected (e.g., with formaldehyde, hydrogen peroxide, chlorine, or peracetic acid), the system should be flushed completely before collecting samples. Drain and flush storage tanks and the distribution system until residual disinfectant is no longer detected before collecting samples.</p> <p>Based on agency document, policy, and lab results review and interview, the facility failed to ensure repeat water and dialysate cultures were completed on a weekly basis until the bacterial count and concentrate was below action level for 3 of 6 months reviewed with the potential to affect all 20 patients. (February, March, and April)</p> <p>Findings:</p> <p>1. Agency document titled "Environmental CQI Report" evidenced the monthly water quality results and a</p>	V0255	<p>The BT has been in-serviced on Policy & Procedure 40.42; States that all colony counts and endotoxin samples must be drawn prior to disinfection. 494.40; corrective action for positive water colony counts & endotoxin levels; 494.40 Reviewing colony counts and endotoxin results; Microbial & endotoxin standards for water used in hemodialysis. If results exceed AAMI action levels, they will be addressed within 48 hours of receipt of results and the Medical Director will be notified via fax, phone, in person or email within 24 hours. If results exceed</p>	08/27/2012	

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	<p>collection date of 2/7/12. The document evidenced a print date of 3/15/12 and signature of the medical director, void of date. The report evidenced the test results were 1) Loop beginning was 162 CFU (colony forming units) and 2) R O(Reverse Osmosis) Permeate was 246 CFU. A redraw was completed on 2/13/12 and the results were 1) loop beginning 40 CFU and 2) RO Permeate was 52 CFU.</p> <p>2. Agency document titled "Environmental CQI Report" included the monthly water quality results and evidenced signatures of the Medical Director and the Interim Clinical Manager dated 4/20/12. The report evidenced a collection date of 3/8/12 and evidenced the results were RO Permeate 70 CFU and 1.520 LAL (limulus amebocyte lysate) endotoxin units (EU). The document contained a hand written note that stated, "Will do weekly [cultures] carbon tanks - to make sure it is." The report evidenced the following results:</p> <p>A. Redraw dated 3/13/12 and the results were 1) Post Carbon # 2 Tank 634 CFU, 2) R O sample port #1 was 168 CFU, 3) RO sample port #2 was 154 CFU, and 4) RO sample port #3 was 294 CFU.</p>		<p>AAMI maximum allowable limits, they will be addressed within 24 hours of receipt of results and the Medical Director will be notified via fax, phone, in person, or email within 24 hours. Action plans will be initiated for any results exceeding action & allowable limits levels. These action plans will be updated/revised as needed per results of initial/redraws of cultures/endotoxins. ATM or designee will monitor all colony count and endotoxin draw dates, results and disinfection logs x 6 months or until compliance has been established, then per quarterly technical audit. VP of technical services or designee will review all audit results bi-weekly until compliance has been established. Anyone found not to be in compliance with P&P will face immediate disciplinary action up to and including termination. ATM or designee will review all education, audits, and discipline in monthly QAPI and bi-weekly LGB.</p>				

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	<p>B. Redraw dated 3/15/12 and the results were 1) RO sample port #2 - 106 CFU and 2) RO permeate was 86 CFU.</p> <p>C. A redraw dated 3/20/12 of only two sample ports and the results were 1) RO Permeate 106 CFU and 2) RO sample port #1 - 114 CFU.</p> <p>3. Agency document titled "Environmental CQI Report" evidenced the monthly water quality results and signature of the environmental technician dated 5/17/12. The report evidenced the first water sample collected for the month of April was a RO water sample collected on 4/17/12. No other port was sampled for water and dialysate on 4/17/12. The RO water sample result was zero. The report evidenced the next sample collected was on 4/26/12 and evidenced a result of 106 CFU for water source "Loop beginning."</p> <p>4. Agency document titled "Environmental CQI Report" evidenced the monthly water quality results and signature of the medical director dated 6/15/12. The report evidenced the water and dialysate samples were collected one for the month of May on 5/1/12 and the results were within acceptable range.</p> <p>5. Agency folder titled "Technical QAPI</p>						

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	<p>Logs" evidenced a note attached to the folder which stated, "Please Sign" was provided by employee A on 7/24/12 at 11:20 AM. Within the folder was a one page report of water and dialysate results for the month of June and those samples were collected on 6/5/12 and were within acceptable levels.</p> <p>6. Three environmental maintenance logs titled "Equipment Repair Log ... Loop, Water Treatment," "Loop Disinfect Log," and "RO Loop Disinfection Log Sheet" evidenced documentation of disinfection of the identified equipment on 3/3/12, 4/7/12, 4/21/12, 5/5/12, 6/5/12, and 7/5/12.</p> <p>7. Environmental maintenance log titled "The Equipment Repair Log 23 G RO" evidenced documentation dated 4/14/12 and stated, "Cleaned RO with low pH cleaner. Rinse. Then high Ph cleaner. Rinse." The log evidenced documentation the RO was disinfected on 4/17/12, 5/8/12, and 7/3/12.</p> <p>8. On July 24, 2012 at 12:50 PM, employee D, the environmental technician, indicated he did not collect any water or dialysate samples for colony counts after March 20, 2012, and before April 17, 2012, from any ports. He indicated he increased the number of</p>						

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	<p>disinfections of the loop and reverse osmosis and indicated with his experience, he had determined the problem was in the carbon tanks and they needed to be rebeded. He indicated he was not authorized to complete the rebed and the facility vendor could not complete the work until April 12, 2012. He indicated with his experience he was confident after the carbon tanks were rebeded, the CFU and EU values would come into acceptable levels. Reviewed the lab result dates with employee I and he indicated there was only one collection of water and dialysate in May on 5/1/12, one in June on June 5/12, and one for July on 7/5/12.</p> <p>9. On July 25, 2012, at 12:10 PM, an individual from the facility's new owner DSI, and identified here as employee I, presented a one page document titled "QAPI Action Plan ... original date 27 - Mar - 12." He indicated the document was received from employee D by email and printed in the facility 7/25/12 for review by surveyor. He indicated the standard would be to continue weekly testing and disinfection to monitor the water and dialysate values and to contact another vendor for an earlier rebed of the carbon tanks.</p> <p>The document presented was</p>			

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	<p>reviewed on 7/25/12. The document indicated the plan was to increase disinfection and testing to bi-monthly beginning 3/25/12.</p> <p>10. On July 27, 2012, at 10:20 AM, the clinical manager indicated there was no written and approved facility Action Plans found to evidence a plan was developed and implemented once the first water and dialysate cultures were identified and no further action plan found that addressed any follow up and monitoring.</p> <p>11. On July 27, 2012, at 2:15 PM, employee D indicated there was no "Action Plan" developed before 3/27/12 and he indicated there was no other written and approved Action Plan to follow up and monitor the water and dialysate CFU and EU results. He indicated the Action Plan dated 3/27/12 was created as part of the report to be presented at the April QAPI meeting but he did not bring the report to the meeting. He indicated he created the Action Plan electronically and it was available to the Clinical Manager to print and incorporate into the monthly QAPI meeting. He indicated his chain of command was to report all water and dialysate cultures outside acceptable values to the Clinical Manager and indicated he did not report to the medical director and stated, "Unless</p>				

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	<p>she asked me directly."</p> <p>12. On July 27, 2012, at 2:15 PM, a review of the QAPI minutes were reviewed with employee D. The minutes dated April 20, 2012, contained a hand written note and stated, "Continue to have high cultures - carbon tank with high results. Both carbon tanks rebedded last week. + disinfected Culture results currently 0 - will cont to disinfect weekly until trend developed + culture." Employee D stated, "I never knew that was written." He indicated he does not review the notes written on the QAPI report during the meeting.</p> <p>13. The agency policy titled "Microbiological Testing Policy and Procedure" policy # 40.42 and effective date 2/7/09 stated, "It is the responsibility of the technician and the medical director to ensure that the microbiological testing is being completed per policy. ... Bacterial colony counts of product water and dialysate shall be less than 200 CFU / mL [colony forming units / milliliter] with an action level of 50 CFU / mL. The endotoxin LAL concentration of product water and dialysate shall be less than 2 EU / mL [Endotoxin Units / milliliter] with an action level of 1 EU / mL. ... If there is a result that is at or above an action level, but below the maximum</p>						

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	allowable level, action will be taken per AAMI standards action tree within 48 hours of receiving the results."			

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V0274	<p>494.40(c) H2O TEST-DEVIATIONS REQUIRE RESPONSE Water testing results including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards must be addressed with a corrective action plan that ensures patient safety.</p> <p>Based on document, policy, and lab result review and interview, the facility failed to ensure an action plan was developed and implemented and repeat water and dialysate cultures were completed on a weekly basis until the bacterial count and concentrate was below action level for 3 of 6 months reviewed with the potential to affect all 20 patients. (February, March, and April)</p> <p>The findings include:</p> <p>1. Agency document titled "Environmental CQI Report" evidenced the monthly water quality results and a collection date of 2/7/12. The document evidenced a print date of 3/15/12 and signature of the medical director, void of date. The report evidenced the test results were 1) Loop beginning was 162 CFU (colony forming units) and 2) R O (Reverse Osmosis) Permeate was 246 CFU. A redraw was completed on 2/13/12 and the results were 1) loop beginning 40 CFU and 2) RO Permeate</p>	V0274	<p>The BT has been in-serviced on Policy & Procedure 494.40; Corrective actions for positive water colony counts & endotoxin levels: 494.40 Reviewing colony counts and endotoxin results: Microbial & endotoxin standards for water used in hemodialysis. If results exceed AAMI action levels, they will be addressed within 48 hours of receipt of results and the Medical Director will be notified via fax, phone, in person or email within 24 hours. If results exceed AAMI maximum allowable limits, they will be addressed within 24 hours of receipt of results and the Medical Director will be notified via fax, phone, in person or email within 24 hours. Action plans will be initiated for any results exceeding action & allowable limits levels. These action plans will be updated/revised as needed per results of initial/redraws of cultures/endotoxins. ATM or designee will monitor all colony count and endotoxin draw dates, results and disinfection logs x 6 months or until compliance has been established, the per Quarterly Technical audit. VP of</p>	08/27/2012			

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	<p>was 52 CFU.</p> <p>2. Agency document titled "Environmental CQI Report" included the monthly water quality results and evidenced signatures of the Medical Director and the Interim Clinical Manager dated 4/20/12. The report evidenced a collection date of 3/8/12 and evidenced the results were RO Permeate 70 CFU and 1.520 LAL (limulus ameocyte lysate) endotoxin units (EU). The document contained a hand written note and stated, "Will do weekly [cultures] carbon tanks - to make sure it is." The report evidenced the following results:</p> <p>A. Redraw dated 3/13/12 and the results were 1) Post Carbon # 2 Tank 634 CFU, 2) R O sample port #1 was 168 CFU, 3) RO sample port #2 was 154 CFU, and 4) RO sample port #3 was 294 CFU.</p> <p>B. Redraw dated 3/15/12 and the results were 1) RO sample port #2 - 106 CFU and 2) RO permeate was 86 CFU.</p> <p>C. A redraw dated 3/20/12 of only two sample ports and the results were 1) RO Permeate 106 CFU and 2) RO sample port #1 - 114 CFU.</p> <p>3. Agency document titled</p>		<p>technical services or designee will review all audit results bi-weekly until compliance has been established. Anyone found not to be in compliance with P&P will face immediate disciplinary action up to and including termination. ATM or designee will review all education, audits, action plans and discipline in monthly QAPI and bi-weekly LGB.</p>		

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	<p>"Environmental CQI Report" evidenced the monthly water quality results and signature of the environmental technician dated 5/17/12. The report evidenced the first water sample collected for the month of April was a RO water sample collected on 4/17/12. No other port was sampled for water and dialysate on 4/17/12. The RO water sample result was zero. The report evidenced the next sample collected was on 4/26/12 and evidenced a result of 106 CFU for water source "Loop beginning."</p> <p>4. On July 24, 2012, at 12:50 PM, employee D, the environmental technician, indicated he did not collect any water or dialysate samples for colony counts after March 20, 2012, and before April 17, 2012, from any ports. He indicated he increased the number of disinfections of the loop and reverse osmosis and indicated with his experience, he had determined the problem was in the carbon tanks and they needed to be rebeded. He indicated he was not authorized to complete the rebed and the facility vendor could not complete the work until April 12, 2012. He indicated with his experience he was confident after the carbon tanks were rebeded, the CFU and EU values would come into acceptable levels. Reviewed the lab result dates with employee I and</p>			

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	<p>he indicated there was only one collection of water and dialysate in May on 5/1/12, one in June on June 5/12, and one for July on 7/5/12.</p> <p>5. On July 27, 2012, at 10:20 AM, the clinical manager indicated there was no written and approved facility Action Plans found to evidence the facility developed and implemented an Action Plan once the water and dialysate cultures were above acceptable levels beginning in February 2012 and no further action plan found that addressed any follow up and monitoring.</p> <p>6. On July 27, 2012, at 2:15 PM, employee D indicated there was no "Action Plan" developed before 3/27/12 and he indicated there was no other written and approved Action Plan to follow up and monitor the water and dialysate CFU and EU results. He indicated the Action Plan dated 3/27/12 was created as part of the report to be presented at the April QAPI meeting but he did not bring the report to the meeting. He indicated he created the Action Plan electronically and it was available to the Clinical Manager to print and incorporate into the monthly QAPI meeting. He indicated his chain of command was to report all water and dialysate cultures outside acceptable values to the Clinical Manager and he did not report to the</p>			

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	<p>medical director and stated, "Unless she asked me directly."</p> <p>7. On July 27, 2012, at 2:15 PM, the QAPI minutes were reviewed with employee D. The minutes dated April 20, 2012, contained a hand written note and stated, "Continue to have high cultures - carbon tank with high results. Both carbon tanks rebedded last week. + disinfected Culture results currently 0 - will cont [continue] to disinfect weekly until trend developed + culture." Employee D stated, "I never knew that was written." He indicated he does not review the notes written on the QAPI report during the meeting.</p> <p>8. The agency policy titled "Microbiological Testing Policy and Procedure" policy # 40.42 effective date 2/7/09 stated, "It is the responsibility of the technician and the medical director to ensure that the microbiological testing is being completed per policy. ... Bacterial colony counts of product water and dialysate shall be less than 200 CFU / mL [colony forming units / milliliter] with an action level of 50 CFU / mL. The endotoxin LAL concentration of product water and dialysate shall be less than 2 EU / mL [Endotoxin Units / milliliter] with an action level of 1 EU / mL. ... If there is a result that is at or above an</p>						

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	action level, but below the maximum allowable level, action will be taken per AAMI standards action tree within 48 hours of receiving the results."			

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V0468	<p>494.70(b)(1) PR-INFORMED-D/C & TRANS P&P INC IVD The patient has the right to-</p> <p>(1) Be informed of the facility's policies for transfer, routine or involuntary discharge, and discontinuation of services to patients;</p> <p>Based on admission document and clinical record review and interview, the facility failed to ensure all patients were advised of their right to be informed of the facility's policies for transfer, routine or involuntary discharge, and discontinuation of services to patients for 1 of 2 records reviewed of home dialysis patients admitted after the last recertification survey 7/24/09 with the potential to affect all patients of the facility. (# 1)</p> <p>Findings include:</p> <p>1. Clinical record # 1 was admitted to the facility on 9/2/11. The record failed to evidence the patient was advised of the facility's policies for transfer, routine or involuntary discharge, and discontinuation of services to patients.</p> <p>On 7/27/12 at 3:50 PM, employee C indicated that clinical record #1 failed to evidence the patient was advised of the patient right to be informed of the facility's policies for transfer, routine or involuntary discharge, and</p>	V0468	<p>The IDT team will complete an in-service on the patients rights to be informed of the facilities policies for transfer, routine or involuntary discharge, and discontinuation of services to patients hosted by the Nurse Manger or designee. The inservice will include review of the policy to inform all patients of their rights to be informed of the facilities policies for transfer, routine or involuntary discharge, and discontinuation of services to patients. The inservice will review proper notification to the patient and proper documentation. The Nurse Manager or designee will monitor the education provided by the IDT to ensure all patients are advised of their right to be informed of the facilities policies for transfer, routine or involuntary discharge, and discontinuation of services to patients. Nurse Manager or designee will perform monthly audits x 3 to ensure compliance. Education and auditing will be reviewed in QAPI & LGB meetings monthly.</p>	08/27/2012			

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	<p>discontinuation of services to patients.</p> <p>2. The document titled "Patient Right's and Responsibilities" void of effective date, provided by the clinical manager on 7/24/12 states, "Patient rights - The patient has the right to: ... Be informed of the facility policies for transfer, routine or involuntary discharge, and discontinuation of services to patients."</p>				

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V0516	<p>494.80(b)(1) PA-FREQUENCY-INITIAL-30 DAYS/13 TX An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session.</p> <p>Based on interview and review of clinical records and facility policy, the facility failed to ensure the initial comprehensive assessment of the patient's needs was completed within 13 hemodialysis treatment days or 30 calendar days in 1 of 2 records reviewed of home dialysis patients admitted after the last recertification survey 7/24/09 with the potential to affect all new admissions to the facility. (#2)</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record #2, start of care January 17, 2011, evidenced an initial comprehensive assessment completed by the registered nurse on 3/11/11 and the social worker on 1/21/11. The clinical record failed to evidence any documentation the physician or dietician had completed their part of the assessment. 2 The facility's policy titled "Patient Assessment" policy # 80.01 and effective date 12/12/08 was presented to the 	V0516	<p>The IDT team will complete assessments and plan of care in-service hosted by the Nurse Manager or designee. The in-service will include the review of the assessment / POC policy, forms, and documents. The in-service will review proper documentation of the assessment/POC to ensure individualization to specific patient needs, measureable goals, and expected outcomes. The inservice will also review the assessment / POC time line and the IDT expectations in the assessment / POC process. An assessment / POC tracker will be used to ensure the timeliness of all assessments / POCs. The tracker will include the due dates of all assessments / POCs. The Nurse Manager or designee will be responsible to oversee and update the tracker as needed. The Nurse Manager or designee will monitor the IDT involvement in the assessment / POC and monitor the assessment / POC forms for accuracy, timeliness, and proper documentation. The Nurse Manager or designee will review the assessment / POC tracker, timeliness, and accuracy</p>	08/27/2012	

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	<p>surveyor on July 7/27/12 at 4 PM by employee C who indicated the policy was current. The policy stated, "New Patients (all admissions to the dialysis facility, including patient's returning from a failed transplant or changing modalities) 30 days or 13 outpatient hemodialysis sessions."</p> <p>3. On 7/27/12 at 1 PM, employee C indicated clinical record #2 failed to evidence the comprehensive assessment had been completed within 30 calendar days of the patient's first peritoneal dialysis treatment which was on 1/17/12.</p>		<p>in QAPI & LGB meetings monthly. Education and auditing will be reviewed in QAPI & LGB meetings monthly. The Nurse Manager or designee will perform monthly audits x 3 & PRN to ensure compliance.</p>		

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V0557	<p>494.90(b)(2) POC-INITIAL IMPLEMENTED-30 DAYS/13 TX Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.</p> <p>Based on interview and review of clinical records, the facility failed to ensure the development and implementation of an initial plan of care was completed within 13 hemodialysis treatment days or 30 calendar days in 1 of 2 records reviewed of home dialysis patients admitted after the last recertification survey 7/24/09 with the potential to affect all new admissions to the facility. (#2)</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record #2, start of care January 17, 2011, evidenced an initial comprehensive assessment completed by the registered nurse on 3/11/11 and the social worker on 1/21/11. The clinical record failed to evidence a plan of care was completed within 30 days of the patient's first treatment with the home dialysis nurse on 1/17/12. 2. On 7/27/12 at 11:25 AM, employee C indicated it is the policy of the facility to complete the initial plan of care within 30 calendar days for home dialysis patients 			V0557	<p>The IDT team will complete an assessment and plan of care inservice hosted by the Nurse Manager or designee. The inservice will include the review of the assessment/POC policy, forms, and documents. The in-service will review proper documentation of the assessment / POC to ensure individualization to specific patients needs, measurable goals, and expected outcomes. The inservice will also review the assessment / POC time lines and the IDT expectations in the assessment / POC process. An assessment / POC tracker will be used to ensure the timeliness of all assessments / POCs. The tracker will include the due dates of all assessments / POCs. The Nurse Manager or designee will be responsible to oversee and update the tracker as needed. The Nurse Manager or designee will monitor the IDT involvement in the assessment / POC and monitor the assessment / POC forms for accuracy, timeliness, and proper documentation. The Nurse Manager or designee will review the assessment / POC tracker, timeliness, and accuracy</p>		08/27/2012

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	and clinical record #2 failed to evidence a plan of care was completed within 30 calendar days of the patient's first peritoneal dialysis treatment on 1/17/12.		in QAPI in LGB meetings monthly. Educaton and auditing will be reviewed in QAPI & LGB meetings monthly. Nurse Manager or designee will perform monthly audits x 3 and PRN to ensure compliance		

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V0715	<p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must-</p> <p>(2) Ensure that-</p> <p>(i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers;</p> <p>Based on clinical record and facility policy review and interview, the medical director failed to ensure initial assessments were completed by the registered nurse (RN) prior to the initiation of patient's first treatment in 1 (# 2) of 2 clinical records reviewed of home dialysis patients admitted since the last recertification survey 7/24/09 creating the potential to affect all new admissions to the facility.</p> <p>The findings include:</p> <p>1. The facility's policy titled "Patient Assessment" policy # 80.01 was presented on July 7/27/12 at 4 PM by employee C who indicated the policy was current. The policy stated, "Initial assessments will be performed by a member of the medical staff and a registered nurse prior to the patients first dialysis treatment in the facility. ... The nursing assessment will be documented on the patient's the patient's treatment record."</p>	V0715	<p>The IDT team and Medical Director will complete an inservice on completing patients initial assessments prior to initiation of their first treatment hosted by the Nurse Manager or designee. The inservice will include review of policy #80.01 stating "initial assessments will be performed by a member of the medical staff and a registered nurse prior to the patients first dialysis treatment in the facility". The inservice will review proper documentation of the initial assessment. The Nurse Manager or designee will be responsible to oversee for proper documentation and to ensure timeliness and accuracy. The Nurse Manager or designee will perform monthly audits x 3 and PRN to ensure compliance. The Medical Director will be inserviced regarding her job description and oversight of clinical operations of the facility. Education and auditing will be reviewed in QAPI and LGB meetings monthly.</p>	08/27/2012			

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	<p>2. Clinical record #2, start of care January 17, 2011, evidenced an initial comprehensive assessment completed by the registered nurse on 3/11/11 and the social worker on 1/21/11. The clinical record failed to evidence any documentation the physician or dietician had completed their part of the assessment.</p> <p>The electronic clinical record evidenced a narrative note dated 1/17/11 written by employee H, a registered nurse and terminated employee, that stated, "Spent the afternoon, practicing connections and performing manual treatments."</p> <p>3. On 7/27/12 at 1 PM, employee C indicated she was not able to find an initial assessment for patient 2.</p>			