

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152507	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 11/16/2012
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NAME OF PROVIDER OR SUPPLIER BATESVILLE DIALYSIS CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 232 SR 129 S BATESVILLE, IN 47006
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V0000	<p>This visit was an ESRD recertification survey.</p> <p>Survey dates: November 13, 14, 15, and 16, 2012.</p> <p>Facility #: 005152</p> <p>Medicaid #: 200024860A</p> <p>Surveyor: Susan E. Sparks, RN, PH Nurse Surveyor Dawn Snider, RN, PH Nurse Surveyor ESRD Trainee</p> <p>Batesville Dialysis Center was found to be out of compliance with the Conditions for Coverage 42 CFR 494.40 Water & Dialysate Quality; 494.110 Quality Assessment & Performance Improvement; and 494.150 Responsibilities of the Medical Director.</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN November 21, 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 Based on observations, staff interview, and review of facility record and policy, it was determined the facility failed to ensure there was a method to identify whether valves were open or closed in 1 of 1 water treatment rooms reviewed with the potential to affect all 23 patients (See V 187), failed to ensure a contingency plan was in place to ensure an adequate supply of acid was available for dialysis and the bio-medical technician maintained the appropriate level of sodium metabisulfite in the acid feed system to avoid the chloramine level rising to breakthrough levels in 1 of 1 acid feed systems reviewed (See V 198), failed to ensure a monthly system disinfection occurred between the months of January 2012 and May 2012 resulting in out of parameter water cultures for 5 of the 7 months reviewed with the potential to affect all 23 patients (See V 219), failed to ensure additional staff were trained to ensure the appropriate level of sodium metabisulfite were maintained in the acid feed system to avoid the chloramine level rising to breakthrough levels in 1 of 1 acid feed systems reviewed with the potential to affect all 23 patients (See V 260), failed to ensure corrective actions were taken after the the bio-medical technician failed to maintain</p>			V0175	<p>V175 CONDITION Batesville Dialysis takes the conditions of coverage very seriously; immediate steps were taken to ensure that the facility's Water & Dialysate used for dialysis treatments is safe. These actions are outlined in depth in the Plan of Correction (POC) for V187, V198, V219, V260, V273, and V274. The facility Governing Body (GB) met on 11/30/2012 to review the deficiencies received as a result of a survey concluded on 11/16/2012. Members of the GB including the Medical Director, Facility Administrator (FA), Assistant FA (AFA), and Regional Operations Director (ROD) have agreed to meet weekly to monitor the facility's progress towards compliance with ensuring 1) method is available to identify valves in water treatment room are open/closed; 2) facility teammates (TMs) are trained to maintain appropriate levels of sodium metabisulfite in acid feed system to avoid increase in chloramines levels, and contingency plan is in place to maintain adequate supply; 3) water treatment system is disinfected, and water & dialysate testing is completed according to</p>		12/08/2012

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	<p>the appropriate level of sodium metabisulfite in the acid feed system to avoid the chloramine level rising to breakthrough levels on two different occasions in 1 of 1 acid feed systems reviewed with the potential to affect all 23 patients (See V 273), and failed to ensure an action plan was put in place after the monthly water results trended out of parameters between the months of April 2012 and November 2012 in 1 of 1 water rooms reviewed with the potential to affect all 23 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>		<p>policies & procedures; 4) water & dialysate testing is trended and actions in place for levels falling outside of parameters; GB will review Quality Improvement Facility Management Meeting (QIFMM) minutes to ensure minutes reflect, action plans are evaluated for effectiveness, and new plans developed as applicable. Once compliance is achieved, POC will be monitored during GB meetings at a minimum of quarterly. This POC will also be reviewed during QIFMM and the FA will report progress, as well as any barriers to maintaining compliance, with supporting documentation included in the meeting minutes.</p> <p>FA and Medical Director are responsible for compliance with the POC</p> <p>Completion date: 12/8/2012</p>		

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V0187	<p>494.40(a) ENVIRONMENT-SCHEMATIC DIAGRAMS/LABELS 8 Environment: schematic diagrams/labels Water systems should include schematic diagrams that identify components, valves, sample ports, and flow direction.</p> <p>Additionally, piping should be labeled to indicate the contents of the pipe and direction of flow.</p> <p>If water system manufacturers have not done so, users should label major water system components in a manner that not only identifies a device but also describes its function, how performance is verified, and what actions to take in the event performance is not within an acceptable range.</p> <p>Based on observation and staff interview, the facility failed to ensure there was a method to identify whether valves were open or closed in 1 of 1 water treatment rooms reviewed with the potential to affect all 23 patients.</p> <p>Findings:</p> <p>On November 13, 2012, at 2:30 PM, observation failed to identify there was a drawing present that identified whether valves were open or closed. The Biomedical Technician, Employee A, indicated there was not a method or a schematic drawing that identified whether the valves were to open or closed.</p>	V0187	<p>V187</p> <p>Biomedical Technician (BMT) updated water room schematic and placed in water room on 11/14/2012 that accurately identifies location of all water room treatment components, flow of water through all components, and valve legend. TMs in-serviced on 11/20/2012 to review components and monitoring of the water treatment system, including, but not limited to, postings, schematics, and valve legends. BMT will be responsible for updating schematic if and when changes occur and relaying to FA. Any changes to water treatment components and water room schematic will be reviewed with</p>	12/08/2012			

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			<p>FA and Medical Director during monthly QIFMM and documented in the meeting minutes. QIFMM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance, minutes will reflect.</p> <p>FA & Medical Director are responsible for compliance with this POC.</p> <p>Completion date: 12/8/2012</p>		

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V0198	<p>494.40(a) CHEMICAL INJECTION SYSTEMS 5.2.6 Chemical injection systems Chemical injection systems consist of a reservoir that contains the chemical to be injected, a metering pump, and a mixing chamber located in the main water line. Chemical injection systems also include some means of regulating the metering pump to control the addition of a chemical. This system should be designed to tightly control the addition of the chemical. The control system should ensure that a chemical is added only when water is flowing through the pretreatment cascade and that it is added in fixed proportion to the water flow or based on some continuously monitored parameter, such as pH, using an automated control system. If an automated control system is used to inject the chemical, the controlling parameter should be independently monitored. There should also be a means of verifying that the concentrations of any residuals arising from the chemical added to the water are reduced to a safe level before the water reaches its point of use.</p> <p>When acid is added to adjust pH, a mineral acid should be used.</p> <p>6.2.6 Chemical injection systems Systems for chemical injection should be monitored according to the manufacturer's instructions. If a facility designs its own system, procedures should be developed to ensure proper preparation of the chemical, adequate mixing of the injected chemical with the water flowing through the pretreatment cascade, and reduction to a safe level of the concentration of any chemical residuals before the point of water</p>						

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	<p>use. The facility should also verify that the injected chemical does not degrade the performance of downstream devices, including the primary purification process. The adequacy of these procedures must be verified using an independent laboratory. Verification can be accomplished by testing samples from the chemical reservoir and the water line after the point of injection for at least three batches of chemical.</p> <p>When the chemical to be injected is prepared at a facility from powder or by dilution of a liquid concentrate, the chemical injection reservoir must be labeled with the name of the chemical and its concentration, the date the solution was prepared, and the name of the person who mixed the solution.</p> <p>Each batch of chemical should be tested for correct formulation before use. A batch of chemical must not be used or transferred to the injection system reservoir until all tests are completed. The test results-and verification that they meet all applicable criteria-should be recorded and signed by the individual performing the tests.</p> <p>Protective clothing and an appropriate environment, including ventilation adequate to meet applicable OSHA environmental exposure limits, should be provided when chemicals for injection are prepared in a dialysis facility.</p> <p>Based on staff interview and review of facility documents, the facility failed to ensure a contingency plan was in place to ensure an adequate supply of acid was available for dialysis and the bio-medical technician maintained the appropriate</p>	V0198	<p>V198 Sodium Metabisulfite Tank marked with a low level limit, which, if reached, will provide greater than 1 day operation level of chemical in the tank.</p> <p>BMT conducted in-service for</p>	12/08/2012

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	<p>level of sodium metabisulfite in the acid feed system to avoid the chloramine level rising to breakthrough levels in 1 of 1 acid feed systems reviewed.</p> <p>Findings:</p> <p>1. November 13, 2012, at 12:00 PM, the Registered Nurse (RN), Employee B, was observed doing a water test. An acid feed system add-on was observed and a "funky" smell was noticed. When questioned, the RN indicated the acid feed system smell was due to the high chlorine level in the local water. She indicated the Bio-medical technician, Employee A, was responsible for mixing and filling the acid-feed tank. She indicated that, on two occasions, the tank had run empty and the chloramines had risen to .08 after the second worker tank. The first time, 10/10/12, the patients were on and they had notified Employee A to please come and fill the tank and had monitored closely till he fixed the problem. The second time, 11/5/12, was the morning water test, the tank was empty, and they elected not to place the patients on dialysis with a .08 level of chloramines. The first shift of patients were not dialyzed.</p> <p>2. November 13, 2012, at 4:15 PM, the Bio-medical technician, Employee B,</p>		<p>additional TMs responsible for water treatment monitoring within the facility on 11/20/2012. In-service included reviewing components and operations of chemical injection system, facility specific policy and procedure and manufacturer directions for use in proper mixing, testing, transfer, labeling, and documentation for preparation of Sodium Metabisulfite. Validation of skills will be conducted on each TM ensuring proper procedures are followed for preparation of sodium metabisulfite solution. Attendance of in-service is evidenced by TMs signature on the In-Service Form.</p> <p>BMT held mandatory in-service for all TMs responsible for water treatment monitoring on 11/20/2012. In-service included review of <i>Policy & Procedure 2-03-01 Water Treatment Systems Minimum Component Requirements, Policy & Procedure 2-07-02 Daily Water Treatment System Monitoring, Policy & Procedure # 2-07-04 Daily Water System Total Chlorine Monitoring, Policy & Procedure 2-07-04A Routine Total Chlorine</i>. 1) TMs educated on components and operations of chemical injection system; 2) TMs educated on daily monitoring of sodium metabisulfite levels in tank and proper documentation on daily monitoring log, 3) TMs instructed that should sodium</p>		

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	<p>indicated that, in November, he knew the tank was running low and was on the way to the facility when he remembered all the timers needed changed on the tank heads and he went to the other facilities he's in charge of first and by the time he reached this facility the tank had run empty.</p> <p>3. November 15, 2012, at 1:00 PM, the regional Bio-Medical technician, Employee L, indicated there was not a back-up plan if Employee B was unable to meet his responsibilities. He indicated another employee at that facility had not been trained for the sodium metabisulfite infiltration system.</p> <p>4. Facility document titled "Routine Total Chlorine Testing Log 2-07-04 A" evidenced on 10/10/12 and 11/5/12 the facility implemented their carbon tank breakthrough procedures due to their chlorine testing results.</p> <p>5. The facility's "Quality Improvement & Facility Management Meeting (QIFMM) Minutes" dated 11/13/2012 stated, "[Name Registered Nurse H] reviewed chlorine breakthrough 1 tank but not 2nd in October. Patients did not have to be taken off. MD (medical director) aware, no other problems in October. [RN H] did homeroom with team on chlorine breakthrough so team</p>		<p>metabisulfite tank reach low level limit marked on tank the BMT and FA must be immediately notified. BMT or trained TM will be assigned to take appropriate actions to prepare and fill tank to prevent potential rise in total chlorine levels. Re-validation of skills conducted on all clinical TMs on water treatment monitoring using the Dialysis Quality Water Monitoring and Testing Skills Checklist.</p> <p>FA or designee will monitor Daily Water Treatment Log audits weekly x4 weeks, then monthly to assure compliance and proper notifications, should they be necessary. Results of audits will be reviewed with the Medical Director during monthly QIFMM, continued frequency of audits will be determined by the team. QIFMM Minutes will reflect. QIFMM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance, minutes will reflect.</p> <p>FA & Medical Director are responsible for compliance with this POC.</p> <p>Completion date: 12/8/2012</p>				

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	<p>know what to do. [RN H] reviewed what she thought the reason was because the tank was dry. Team reviewed importance of looking at tank daily. [RN H] reported a breakthrough in November 1st thing in morning. Patients not put on until biomed notified and chlorine normal. Plan: the tank must be filled each week. Team to record reading everyday. CC to follow up weekly." The plan failed to provided guidance to the bio-medical technician to prevent the tank running dry and failed to provide for training other staff to prevent the tank running dry.</p>			

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V0219	<p>494.40(a) BACT CONTROL-DISINFECT 1X/MO/DWELL 7 Strategies for bacterial control 7.1 General: disinfect monthly/disinfection dwell Routine low-level disinfection of the pipes should be performed to control bacterial contamination of the distribution system. The frequency of disinfection will vary with the design of the system and the extent to which biofilm has already formed in existing systems, but disinfection must be performed at least monthly.</p> <p>A mechanism should be incorporated in the distribution system to ensure that disinfectant does not drain from pipes during the disinfection period.</p> <p>Based on staff interview, facility record and policy review, the facility failed to ensure a monthly system disinfection occurred between the months of January 2012 and May 2012 resulting in out of parameter water cultures for 5 of the 7 months reviewed with the potential to affect all 23 patients.</p> <p>Findings:</p> <p>1. Facility document dated August 2006, titled "Monthly Water Treatment Log", evidenced Date of Last System Disinfection for Monthly was 1/9/12, 2/9/12, 3/1/12, and 5/10/12. Contradicting documentation "DaVita Batch Ticket Summary" says scheduled routine disinfection was completed</p>	V0219	<p>V219 Area Biomedical Supervisor (ABS) will hold mandatory in-service for BMT and all TMs responsible for water treatment system monitoring on 12/4/2012. In-service will include but not be limited to: review of <i>Policy & Procedure #2-05-01 Water System Disinfection</i>, <i>Policy & Procedure #2-06-01 Water Culture Policy</i> emphasizing 1) water treatment system must be disinfected and documented monthly and include both the reverse osmosis machine and distribution system; 2) Interpreting culture results: Acceptable level below 50 cfu/ml, Action level 50-199cfu/ml, Unacceptable level 200cfu/ml or greater, 3) Required response to action level culture results: If single site at or above</p>	12/08/2012			

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	<p>3/1/12, 4/26/12, and 5/10/12.</p> <p>2. On November 16, 2012, at 12 Noon, the regional Bio-medical technician, Employee L, indicated the policy says monthly for disinfection and there were 7 weeks between the March and April disinfect and then 14 days between April and May.</p> <p>3. Water results for 4/6/12 First H2O Out 50 cfu, 4/13/12 First H2O 10 cfu, 5/03/2012 Last H2O Out results at 230 cfu H (high) Reuse Disinfect Out 680 cfu (H), 5/11/12 the Last H2O Out results at 160 cfu H and Reuse Disinfect Out is 10 cfu, 5/17/12 Last H2O results at <10 cf, 6/13/2012 the Last H2O Out results at 80 cfu, 6/19/12 at 10 cfu, 7/5/2012 the Last H2O Out results at 10 cfu and Pre BD Inlet # 1 220 cfu H, 7/9/12 the Pre BD Inlet # 1 <10 cfu, 7/17/2012 at <10 cfu, 7/24/2012 at 20 cfu, 7/30/12 at 10 cfu.</p> <p>A. August testing was within guidelines. 9/7/12 First H2O at 320 cfu H, 10/3/12 First H2O at 450 cfu H and PRE BD Inlet # 2 150 cfu, 10/10/12 First H2O at <10 cfu and PRE BD Inlet # 2 <10 cfu.</p> <p>B. November testing was within guidelines.</p>		<p>action level and all other results in acceptable range, notify medical director of results within 48 hours of receiving result, and site must be re-cultured within 7 days of original sample collection date, 4) Required response to more than one site at or above action level or any site at or above unacceptable level: Notify FA, Biomedical Services and Medical Director, Disinfect affected equipment at end of treatment day in which results are received/reported or as recommended by Medical Director, Re-culture of all affected sites within 7 days of original sample collection date. 5) ABS must be notified of all actionable results. Attendance of in-service is evidenced by TM signature on In-Service Form.</p> <p>ABS will conduct monthly audits of facility system disinfection and culture and endotoxin results x 3 months, then quarterly thereafter to ensure compliance with all required disinfection, testing, and response. BMT will bring results of all monthly water and dialysate testing to QIFMM meetings for review with Medical Director and team, QIFMM committee will review all results, responses and trends during monthly QIFMM, minutes will reflect. QIFMM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance</p>		

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	<p>4. A policy dated March 2012, titled "Water Treatment System Disinfection", Policy: 2-05-01, states, "4. Chemically-disinfected direct feed systems are disinfected monthly."</p> <p>5. November 13, 2012, at 12:00 PM, the Regional CSS presented the only Action Plan the facility had in place. The Action Plan covered supplies and maintenance to the water room floor. The Action Plan failed to address the Water Cultures.</p>		<p>FA & Medical Director are responsible for compliance with this POC.</p> <p>Completion date: 12/8/2012</p>		

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V0260	<p>494.40(a) PERSONNEL-TRAINING PROGRAM/PERIODIC AUDITS 9 Personnel: training program/periodic audits A training program that includes quality testing, the risks and hazards of improperly prepared concentrate, and bacterial issues is mandatory.</p> <p>Operators should be trained in the use of the equipment by the manufacturer or should be trained using materials provided by the manufacturer.</p> <p>The training should be specific to the functions performed (i.e., mixing, disinfection, maintenance, and repairs).</p> <p>Periodic audits of the operators' compliance with procedures should be performed.</p> <p>The user should establish an ongoing training program designed to maintain the operator's knowledge and skills.</p> <p>Based on staff interview and facility record review, the facility failed to ensure additional staff were trained to ensure the appropriate level of sodium metabisulfite were maintained in the acid feed system to avoid the chloramine level rising to breakthrough levels in 1 of 1 acid feed systems reviewed with the potential to affect all 23 patients.</p> <p>Findings:</p> <p>1. November 13, 2012, at 12:00 PM, the Registered Nurse (RN), Employee B, was</p>	V0260	<p>V260 Sodium Metabisulfite Tank marked with a low level limit, which, if reached, will provide greater than 1 day operation level of chemical in the tank.</p> <p>BMT conducted in-service for additional TMs responsible for water treatment monitoring within the facility on 11/20/2012. In-service included reviewing components and operations of chemical injection system, facility specific policy and procedure and manufacturer directions for use in</p>	12/08/2012			

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	<p>observed doing a water test. An acid feed system add-on was observed and a "funky" smell was noticed. When questioned, the RN indicated the acid feed system smell was due to the high chlorine level in the local water. She indicated the Bio-medical technician, Employee A, was responsible for mixing and filling the acid-feed tank. She indicated that, on two occasions, the tank had run empty and the chloramines had risen to .08 after the second worker tank. The first time, 10/10/12, the patients were on and they had notified Employee A to please come and fill the tank and had monitored closely till he fixed the problem. The second time, 11/5/12, was the morning water test, the tank was empty, and they elected not to place the patients on dialysis with a .08 level of chloramines. The first shift of patients were not dialyzed.</p> <p>2. November 13, 2012, at 4:15 PM, the Bio-medical technician, Employee B, indicated that, in November, he knew the tank was running low and was on the way to the facility when he remembered all the timers needed changed on the tank heads and he went to the other facilities he's in charge of first and by the time he reached this facility the tank had run empty.</p> <p>3. November 15, 2012, at 1:00 PM, the</p>		<p>proper mixing, testing, transfer, labeling, and documentation for preparation of Sodium Metabisulfite. Validation of skills will be conducted on each TM ensuring proper procedures are followed for preparation of sodium metabisulfite solution. Attendance of in-service is evidenced by TMs signature on the In-Service Form.</p> <p>BMT held mandatory in-service for all TMs responsible for water treatment monitoring on 11/20/2012. In-service included review of <i>Policy & Procedure 2-03-01 Water Treatment Systems Minimum Component Requirements, Policy & Procedure 2-07-02 Daily Water Treatment System Monitoring, Policy & Procedure # 2-07-04 Daily Water System Total Chlorine Monitoring, Policy & Procedure 2-07-04A Routine Total Chlorine</i>. 1) TMs educated on components and operations of chemical injection system; 2) TMs educated on daily monitoring of sodium metabisulfite levels in tank and proper documentation on daily monitoring log, 3) TMs instructed that should sodium metabisulfite tank reach low level limit marked on tank the BMT and FA must be immediately notified. BMT or trained TM will be assigned to take appropriate actions to prepare and fill tank to prevent potential rise in total chlorine levels. Re-validation of</p>		

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	<p>regional Bio-Medical technician, Employee L, indicated there was not a back-up plan if Employee B was unable to meet his responsibilities. He indicated another employee at that facility had not been trained for the sodium metabisulfite infiltration system.</p> <p>4. Facility document titled "Routine Total Chlorine Testing Log 2-07-04 A" evidenced on 10/10/12 and 11/5/12 the facility implemented their carbon tank breakthrough procedures due to their chlorine testing results.</p> <p>5. The facility's "Quality Improvement & Facility Management Meeting (QIFMM) Minutes" dated 11/13/2012 stated, "[Name Registered Nurse H] reviewed chlorine breakthrough 1 tank but not 2nd in October. Patients did not have to be taken off. MD (medical director) aware, no other problems in October. [RN H] did homeroom with team on chlorine breakthrough so team know what to do. [RN H] reviewed what she thought the reason was because the tank was dry. Team reviewed importance of looking at tank daily. [RN H] reported a breakthrough in November 1st thing in morning. Patients not put on until biomed notified and chlorine normal. Plan: the tank must be filled each week. Team to record reading everyday. CC to</p>		<p>skills conducted on all clinical TMs on water treatment monitoring using the Dialysis Quality Water Monitoring and Testing Skills Checklist.</p> <p>FA or designee will monitor Daily Water Treatment Log audits weekly x4 weeks, then monthly to assure compliance and proper notifications, should they be necessary. Results of audits will be reviewed with the Medical Director during monthly QIFMM, continued frequency of audits will be determined by the team. QIFMM Minutes will reflect. QIFMM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance, minutes will reflect.</p> <p>FA & Medical Director are responsible for compliance with this POC.</p> <p>Completion date: 12/8/2012</p>		

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	follow up weekly." The plan failed to provided guidance to the bio-medical technician to prevent the tank running dry and failed to provide for training other staff to prevent the tank running dry.			

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V0273	<p>494.40(b)(2)(ii) CH/CHL BREAKTHROUGH-ACTION=CORRECTIO N (ii) If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must-</p> <p>(D) Take corrective action to ensure ongoing compliance with acceptable chlorine and chloramine levels as described in paragraph (b)(2)(i) of this section. Based on staff interview and facility record review, the facility failed to ensure corrective actions were taken after the the bio-medical technician failed to maintain the appropriate level of sodium metabisulfite in the acid feed system to avoid the chloramine level rising to breakthrough levels on two different occasions in 1 of 1 acid feed systems reviewed with the potential to affect all 23 patients.</p> <p>Findings:</p> <p>1. November 13, 2012, at 12:00 PM, the Registered Nurse (RN), Employee B, was observed doing a water test. An acid feed system add-on was observed and a "funky" smell was noticed. When questioned, the RN indicated the acid feed system smell was due to the high chlorine level in the local water. She indicated the Bio-medical technician, Employee A, was</p>	V0273	<p>V273 Sodium Metabisulfite Tank marked with a low level limit, which, if reached, will provide greater than 1 day operation level of chemical in the tank. BMT assigned to take training courses titled Water Monitoring & Testing Conventional System, A Water Review including skills checklist, documentation confirming completion of course will be placed in personnel file. ABS will hold mandatory in-service for BMT on 12/4/2012. In-service will include but not be limited to: review of <i>Policy & Procedure #2-05-01 Water System Disinfection, Policy & Procedure #2-06-01 Water Culture Policy</i>, BMT Role and Responsibilities in the facility including ensuring TMs remain educated and current on water treatment components and water treatment monitoring, maintaining</p>	12/08/2012			

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	<p>responsible for mixing and filling the acid-feed tank. She indicated that, on two occasions, the tank had run empty and the chloramines had risen to .08 after the second worker tank. The first time, 10/10/12, the patients were on and they had notified Employee A to please come and fill the tank and had monitored closely till he fixed the problem. The second time, 11/5/12, was the morning water test, the tank was empty, and they elected not to place the patients on dialysis with a .08 level of chloramines. The first shift of patients were not dialyzed.</p> <p>2. November 13, 2012, at 4:15 PM, the Bio-medical technician, Employee B, indicated that, in November, he knew the tank was running low and was on the way to the facility when he remembered all the timers needed changed on the tank heads and he went to the other facilities he's in charge of first and by the time he reached this facility the tank had run empty.</p> <p>3. November 15, 2012, at 1:00 PM, the regional Bio-Medical technician, Employee L, indicated there was not a back-up plan if Employee B was unable to meet his responsibilities. He indicated another employee at that facility had not been trained for the sodium metabisulfite infiltration system.</p>		<p>water treatment system, monitoring daily water treatment logs, and taken appropriate actions to ensure Water & Dialysate used for dialysis treatments is safe. BMT instructed of responsibility on ensuring facility maintains appropriate levels of sodium metabisulfite in chemical injection system, if notified of low level limit an unable to prepare sodium metabisulfite within 24 hours BMT is responsible to notify FA and assign trained TM to prepare. Attendance of in-service is evidenced by TMs signature on the In-Service Form.</p> <p>ABS will be responsible to monitor BMT responsibilities and conduct monthly audits of facility system disinfection and culture/endotoxin results x 3 months, then quarterly thereafter to ensure compliance with all required disinfection, testing, and response. Results of audits will be reviewed with the Medical Director during monthly QIFMM, continued frequency of audits will be determined by the team. QIFMM Minutes will reflect. QIFMM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance, minutes will reflect.</p> <p>FA & Medical Director are responsible for compliance with this POC.</p>		

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	<p>4. Facility document titled "Routine Total Chlorine Testing Log 2-07-04 A" evidenced on 10/10/12 and 11/5/12 the facility implemented their carbon tank breakthrough procedures due to their chlorine testing results.</p> <p>5. The facility's "Quality Improvement & Facility Management Meeting (QIFMM) Minutes" dated 11/13/2012 stated, "[Name Registered Nurse H] reviewed chlorine breakthrough 1 tank but not 2nd in October. Patients did not have to be taken off. MD (medical director) aware, no other problems in October. [RN H] did homeroom with team on chlorine breakthrough so team know what to do. [RN H] reviewed what she thought the reason was because the tank was dry. Team reviewed importance of looking at tank daily. [RN H] reported a breakthrough in November 1st thing in morning. Patients not put on until biomed notified and chlorine normal. Plan: the tank must be filled each week. Team to record reading everyday. CC to follow up weekly." The plan failed to provided guidance to the bio-medical technician to prevent the tank running dry and failed to provide for training other staff to prevent the tank running dry.</p>		<p>Completion date: 12/8/2012</p>				

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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. Based on staff interview and facility record and policy review, the facility failed to ensure an action plan was put in place after the monthly water results trended out of parameters between the months of April 2012 and November 2012 in 1 of 1 water rooms reviewed with the potential to affect all 23 patients.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. Facility document dated August 2006, titled "Monthly Water Treatment Log", evidenced Date of Last System Disinfection for Monthly was 1/9/12, 2/9/12, 3/1/12, and 5/10/12. Contradicting documentation "DaVita Batch Ticket Summary" says scheduled routine disinfection was completed 3/1/12, 4/26/12, and 5/10/12. 2. On November 16, 2012, at 12 Noon, the regional Bio-medical technician, Employee L, indicated the policy says monthly for disinfection and there were 7 weeks between the March and April disinfect and then 14 days between April 	V0274	<p>V274</p> <p>ABS will hold mandatory in-service for BMT and all TMs responsible for water treatment system monitoring on 12/4/2012. In-service will include but not be limited to: review of <i>Policy & Procedure #2-05-01 Water System Disinfection</i>, <i>Policy & Procedure #2-06-01 Water Culture Policy</i> emphasizing 1) water treatment system must be disinfected and documented monthly and include both the reverse osmosis machine and distribution system; 2) Interpreting culture results: Acceptable level below 50 cfu/ml , Action level 50-199cfu/ml, Unacceptable level 200cfu/ml or greater, 3) Required response to action level culture results: If single site at or above action level and all other results in acceptable range, notify medical director of results within 48 hours of receiving result, and site must be re-cultured within 7 days of original sample collection date, 4) Required response to more than one site at or above action level or any site at or above unacceptable level: Notify FA,</p>	12/08/2012

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	<p>and May.</p> <p>3. Water results for 4/6/12 First H2O Out 50 cfu, 4/13/12 First H2O 10 cfu, 5/03/2012 Last H2O Out results at 230 cfu H (high) Reuse Disinfect Out 680 cfu (H), 5/11/12 the Last H2O Out results at 160 cfu H and Reuse Disinfect Out is 10 cfu, 5/17/12 Last H2O results at <10 cf, 6/13/2012 the Last H2O Out results at 80 cfu, 6/19/12 at 10 cfu, 7/5/2012 the Last H2O Out results at 10 cfu and Pre BD Inlet # 1 220 cfu H, 7/9/12 the Pre BD Inlet # 1 <10 cfu, 7/17/2012 at <10 cfu, 7/24/2012 at 20 cfu, 7/30/12 at 10 cfu.</p> <p>A. August testing was within guidelines. 9/7/12 First H2O at 320 cfu H, 10/3/12 First H2O at 450 cfu H and PRE BD Inlet # 2 150 cfu, 10/10/12 First H2O at <10 cfu and PRE BD Inlet # 2 <10 cfu.</p> <p>B. November testing was within guidelines.</p> <p>4. A policy dated March 2012, titled "Water Treatment System Disinfection", Policy: 2-05-01, states, "4. Chemically-disinfected direct feed systems are disinfected monthly."</p> <p>5. November 13, 2012, at 12:00 PM, the Regional CSS presented the only Action</p>		<p>Biomedical Services and Medical Director, Disinfect affected equipment at end of treatment day in which results are received/reported or as recommended by Medical Director, Re-culture of all affected sites within 7 days of original sample collection date. 5) ABS must be notified of all actionable results. Attendance of in-service is evidenced by TM signature on In-Service Form.</p> <p>ABS will conduct monthly audits of facility system disinfection and culture and endotoxin results x 3 months, then quarterly thereafter to ensure compliance with all required disinfection, testing, and response. Biomedical Technician will bring results of all monthly water and dialysate testing to QIFMM meetings for review with Medical Director and team, QIFMM committee will review all results, responses and trends during monthly QIFMM, minutes will reflect. QIFMM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance</p> <p>FA & Medical Director are responsible for compliance with this POC.</p> <p>Completion date: 12/8/2012</p>		

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	<p>Plan the facility had in place. The Action Plan covered supplies and maintenance to the water room floor. The Action Plan failed to address the Water Cultures.</p> <p>6. A policy dated September 2012, titled "Water Culture Policy", Policy: 2-06-01" states, "4. Routine water cultures are collected monthly and within 72 hours prior to scheduled system disinfection. Monthly is defined as within a calendar month. "</p>			

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V0625	<p>494.110 CFC-QAPI</p> <p>Based on staff interview and review of facility documents and policy, it was determined the facility failed to ensure a contingency plan was in place to ensure an adequate supply of acid was available for dialysis, the bio-medical technician maintained the appropriate level of sodium metabisulfite in the acid feed system to avoid the chloramine level rising to breakthrough levels in 1 of 1 acid feed systems reviewed, and an action plan was in place after the monthly water culture results trended out of parameters between the months of April 2012 and November 2012 with the potential to affect all 23 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>	V0625	<p>V625 CONDITION</p> <p>Batesville Dialysis takes the conditions of coverage very seriously; immediate steps were taken to ensure facility provides safe provision and monitoring of ESRD services to its patients. These actions are outlined in depth in the POC for V638.</p> <p>GB meeting was held on 11/30/2012 to review the deficiencies received as a result of a survey concluded on 11/16/2012. Members of the GB including the Medical Director, FA, AFA, and ROD have agreed to meet weekly to monitor the facility's ongoing progress towards compliance including but not limited to: 1) ensuring facility has contingency plan to maintain appropriate levels of sodium metabisulfite in acid feed system to avoid increase in chloramines levels 2) QAPI program identifies problems and is comprehensive including evaluation of indicators not meeting facility goals, developing plans of action, intervention, and those plans are re-evaluated for effectiveness with new interventions initiated as needed; 3) QAPI program analyzes, reviews, and trends water & dialysate testing, actions in place for levels falling outside of parameters. GB will review QIFMM minutes to ensure</p>	12/08/2012	

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			minutes accurately reflect items discussed, action plans are evaluated for effectiveness, new plans developed as applicable. Once compliance is achieved, POC will be monitored during GB meetings at a minimum of quarterly. This POC will also be reviewed during QIFMM and the FA will report progress, as well as any barriers to maintaining compliance, with supporting documentation included in the meeting minutes. <u>FA and Medical Director are responsible for this POC</u> Completion date: 12/8/2012		

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V0638	<p>494.110(b) QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE</p> <p>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 staff interview and review of facility documents and policy, the facility failed to ensure a contingency plan was in place to ensure an adequate supply of acid was available for dialysis, the bio-medical technician maintained the appropriate level of sodium metabisulfite in the acid feed system to avoid the chloramine level rising to breakthrough levels in 1 of 1 acid feed systems reviewed, and an action plan was in place after the monthly water culture results trended out of parameters between the months of April 2012 and November 2012 with the potential to affect all 23 patients.</p> <p>Findings:</p> <p>1. November 13, 2012, at 12:00 PM, the Registered Nurse (RN), Employee B, was observed doing a water test. An acid feed system add-on was observed and a "funky" smell was noticed. When questioned, the RN indicated the acid feed system smell was due to the high chlorine level in the local water. She indicated the Bio-medical technician, Employee A, was</p>	V0638	<p>V638</p> <p>CSS will conduct mandatory in-service for all QIFMM members by 12/01/2012. In-service will include but will not be limited to: Review of <i>Policy & Procedure #1-02-01: Continuous Quality Improvement Program</i> with emphasis that facility must review water treatment system documentation ensuring water system is disinfected and components monitored according to <i>Policy & Procedure</i>. Team must review water culture and endotoxin testing results monthly, evaluate actions taken and trends. Underperformance will be reviewed to identify root cause, will have action plan identified that will result in performance improvement, and will track change in performance overtime to ensure improvements are sustained. Team educated on actions taken and contingency plan to ensure adequate supply of sodium metabisulfite is available at all times for dialysis, monitoring in place to ensure appropriate levels and avoid increase in chloramines levels, team must monitor water treatment logs and</p>	12/08/2012

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NAME OF PROVIDER OR SUPPLIER BATESVILLE DIALYSIS CENTER				STREET ADDRESS, CITY, STATE, ZIP CODE 232 SR 129 S BATESVILLE, IN 47006			
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	<p>responsible for mixing and filling the acid-feed tank. She indicated that, on two occasions, the tank had run empty and the chloramines had risen to .08 after the second worker tank. The first time, 10/10/12, the patients were on and they had notified Employee A to please come and fill the tank and had monitored closely till he fixed the problem. The second time, 11/5/12, was the morning water test, the tank was empty, and they elected not to place the patients on dialysis with a .08 level of chloramines. The first shift of patients were not dialyzed.</p> <p>A. November 13, 2012, at 4:15 PM, the Bio-medical technician, Employee B, indicated that, in November, he knew the tank was running low and was on the way to the facility when he remembered all the timers needed changed on the tank heads and he went to the other facilities he's in charge of first and by the time he reached this facility the tank had run empty.</p> <p>B. November 15, 2012, at 1:00 PM, the regional Bio-Medical technician, Employee L, indicated there was not a back-up plan if Employee B was unable to meet his responsibilities. He indicated another employee at that facility had not been trained for the sodium metabisulfite infiltration system.</p>		<p>other water treatment audits during QIFMM meetings. BMT will results of all monthly water and dialysate testing to QIFMM meetings for review with Medical Director and team, QIFMM committee will review all results, responses and trends during monthly QIFMM, minutes will reflect. QIFMM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this POC.</p> <p>- Completion date: 12/8/2012</p>				

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	<p>C. Facility document titled "Routine Total Chlorine Testing Log 2-07-04 A" evidenced on 10/10/12 and 11/5/12 the facility implemented their carbon tank breakthrough procedures due to their chlorine testing results.</p> <p>D. The facility's "Quality Improvement & Facility Management Meeting (QIFMM) Minutes" dated 11/13/2012 stated, "[Name Registered Nurse H] reviewed chlorine breakthrough 1 tank but not 2nd in October. Patients did not have to be taken off. MD (medical director) aware, no other problems in October. [RN H] did homeroom with team on chlorine breakthrough so team know what to do. [RN H] reviewed what she thought the reason was because the tank was dry. Team reviewed importance of looking at tank daily. [RN H] reported a breakthrough in November 1st thing in morning. Patients not put on until biomed notified and chlorine normal. Plan: the tank must be filled each week. Team to record reading everyday. CC to follow up weekly." The plan failed to provided guidance to the bio-medical technician to prevent the tank running dry and failed to provide for training other staff to prevent the tank running dry.</p>				

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	<p>2. Facility document dated August 2006, titled "Monthly Water Treatment Log", evidenced Date of Last System Disinfection for Monthly was 1/9/12, 2/9/12, 3/1/12, and 5/10/12. Contradicting documentation "DaVita Batch Ticket Summary" says scheduled routine disinfection was completed 3/1/12, 4/26/12, and 5/10/12.</p> <p>A. On November 16, 2012, at 12 Noon, the regional Bio-medical technician, Employee L, indicated the policy says monthly for disinfection and there were 7 weeks between the March and April disinfect and then 14 days between April and May.</p> <p>B. Water results for 4/6/12 First H2O Out 50 cfu, 4/13/12 First H2O 10 cfu, 5/03/2012 Last H2O Out results at 230 cfu H (high) Reuse Disinfect Out 680 cfu (H), 5/11/12 the Last H2O Out results at 160 cfu H and Reuse Disinfect Out is 10 cfu, 5/17/12 Last H2O results at <10 cf, 6/13/2012 the Last H2O Out results at 80 cfu, 6/19/12 at 10 cfu, 7/5/2012 the Last H2O Out results at 10 cfu and Pre BD Inlet # 1 220 cfu H, 7/9/12 the Pre BD Inlet # 1 <10 cfu, 7/17/2012 at <10 cfu, 7/24/2012 at 20 cfu, 7/30/12 at 10 cfu.</p> <p>1.) August testing was within guidelines. 9/7/12 First H2O at 320 cfu</p>			

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	<p>H, 10/3/12 First H2O at 450 cfu H and PRE BD Inlet # 2 150 cfu, 10/10/12 First H2O at <10 cfu and PRE BD Inlet # 2 <10 cfu.</p> <p>2.) November testing was within guidelines.</p> <p>C. A policy dated March 2012, titled "Water Treatment System Disinfection", Policy: 2-05-01, states, "4. Chemically-disinfected direct feed systems are disinfected monthly."</p> <p>D. November 13, 2012, at 12:00 PM, the Regional CSS presented the only Action Plan the facility had in place. The Action Plan covered supplies and maintenance to the water room floor. The Action Plan failed to address the Water Cultures.</p>			

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V0710	<p>Based on staff interview and review of facility documents and policy, it was determined the medical director failed to ensure a contingency plan was in place to ensure an adequate supply of acid was available for dialysis, the bio-medical technician maintained the appropriate level of sodium metabisulfite in the acid feed system to avoid the chloramine level rising to breakthrough levels in 1 of 1 acid feed systems reviewed, and an action plan was in place after the monthly water culture results trended out of parameters between the months of April 2012 and November 2012 with the potential to affect all 23 patients (See V 712) and failed to ensure the policy for monthly system disinfection occurred between the months of January 2012 and May 2012 was implemented resulting in out of parameter water cultures for 5 of the 7 months reviewed with the potential to affect all 23 patients (See V 715).</p> <p>The cumulative effect of these systemic problem resulted in the facility's inability to meet the requirements of this Condition for Coverage 494.150 Responsibilities of the Medical Director.</p>	V0710	<p>V710 CONDITION</p> <p>Batesville Dialysis takes the conditions of coverage very seriously: immediate steps were taken to ensure Medical Director's active involvement and oversight regarding the provisions of patients care, facility processes, and outcomes in the facility. These actions are outlined in depth in the POC for V712, and V715.</p> <p>Governing body meeting held on 11/30/2012 to review the deficiencies received as a result of a survey concluded on 11/16/2012. Members of the Governing Body that included the FA, Assistant Facility Administrator, Medical Director and ROD have agreed to meet weekly to monitor the facility's ongoing progress towards compliance including but not limited to 1) Water and Dialysate used for patient dialysis treatments is safe and testing is completed according to policies and procedures and all regulatory requirements 2) Teammates adhere to policies and procedures to ensure provision of safe patient care. GB will review QIFMM minutes to ensure minutes accurately reflect items discussed, action plans are evaluated for effectiveness, new plans developed as applicable.</p>	12/08/2012			

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			<p>Once compliance is achieved, POC will be monitored during GB meetings at a minimum of quarterly. This POC will also be reviewed during QIFFM and the FA will report progress, as well as any barriers to maintaining compliance, with supporting documentation included in the meeting minutes.</p> <p>FA & Medical Director are responsible for this POC</p> <p>Completion date: 12/8/2012</p>		

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V0712	<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.</p> <p>Based on staff interview and review of facility documents and policy, the medical director failed to ensure a contingency plan was in place to ensure an adequate supply of acid was available for dialysis, the bio-medical technician maintained the appropriate level of sodium metabisulfite in the acid feed system to avoid the chloramine level rising to breakthrough levels in 1 of 1 acid feed systems reviewed, and an action plan was in place after the monthly water culture results trended out of parameters between the months of April 2012 and November 2012 with the potential to affect all 23 patients.</p> <p>Findings:</p> <p>1. November 13, 2012, at 12:00 PM, the Registered Nurse (RN), Employee B, was observed doing a water test. An acid feed system add-on was observed and a "funky" smell was noticed. When questioned, the RN indicated the acid feed system smell was due to the high chlorine level in the local water. She indicated the Bio-medical technician, Employee A, was responsible for mixing and filling the</p>	V0712	<p>V712</p> <p>Governing Body meeting was held on 11/30/2012. Immediate steps were taken to ensure Medical Director oversight and involvement in executing his roles and responsibilities for the delivery of patient care, outcomes in the facility, and accountability to the GB for the quality of medical care provided to patients. Members of GB have agreed to meet weekly to review progress and compliance with this plan of correction including 1) Sodium Metabisulfite Tank is marked with a low level limit, additional TMs are trained and validation of skills conducted on components and operations of chemical injection system, facility specific policy & procedure and manufacturer directions for use in proper mixing, testing, transfer, labeling, and documentation for preparation of Sodium Metabisulfite; 2) All TMs responsible for water treatment monitoring are trained and re-validation of skills completed on water system disinfection, water cultures, water system components including operations of chemical injection system; daily monitoring of sodium</p>	12/08/2012			

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	<p>acid-feed tank. She indicated that, on two occasions, the tank had run empty and the chloramines had risen to .08 after the second worker tank. The first time, 10/10/12, the patients were on and they had notified Employee A to please come and fill the tank and had monitored closely till he fixed the problem. The second time, 11/5/12, was the morning water test, the tank was empty, and they elected not to place the patients on dialysis with a .08 level of chloramines. The first shift of patients were not dialyzed.</p> <p>A. November 13, 2012, at 4:15 PM, the Bio-medical technician, Employee B, indicated that, in November, he knew the tank was running low and was on the way to the facility when he remembered all the timers needed changed on the tank heads and he went to the other facilities he's in charge of first and by the time he reached this facility the tank had run empty.</p> <p>B. November 15, 2012, at 1:00 PM, the regional Bio-Medical technician, Employee L, indicated there was not a back-up plan if Employee B was unable to meet his responsibilities. He indicated another employee at that facility had not been trained for the sodium metabisulfite infiltration system.</p>		<p>metabisulfite levels in tank, proper documentation on daily monitoring log, proper notification of BMT and FA if tank reaches low limit and contingency plan if BMT is unavailable to prepare and fill tank of trained TMs to prevent potential rise in total chlorine levels; 3) BMT completes additional training courses and in-services provided by ABS for BMT roles and responsibilities, water monitoring and testing, including skills checklist, 4) FA or designee monitors Daily Water Treatment Logs weekly x4 weeks, then monthly to assure appropriate sodium metabisulfite levels remain in tank and proper notifications occur, if necessary, and ABS monitors BMT responsibilities and conducts monthly audits of facility system disinfection and culture/endotoxin results x 3 months, then quarterly thereafter to ensure compliance with all required disinfection, testing, and response; 5) QAPI Program analyzes data, develops plans/interventions for improvement of care, and re-evaluates focusing on health outcomes and safety of patients. QIFMM team reviews water treatment system documentation ensuring water system is disinfected and components monitored according to Policy & Procedure. Team reviews water culture and endotoxin testing results monthly, evaluate actions taken and trends.</p>		

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	<p>C. Facility document titled "Routine Total Chlorine Testing Log 2-07-04 A" evidenced on 10/10/12 and 11/5/12 the facility implemented their carbon tank breakthrough procedures due to their chlorine testing results.</p> <p>D. The facility's "Quality Improvement & Facility Management Meeting (QIFMM) Minutes" dated 11/13/2012 stated, "[Name Registered Nurse H] reviewed chlorine breakthrough 1 tank but not 2nd in October. Patients did not have to be taken off. MD (medical director) aware, no other problems in October. [RN H] did homeroom with team on chlorine breakthrough so team know what to do. [RN H] reviewed what she thought the reason was because the tank was dry. Team reviewed importance of looking at tank daily. [RN H] reported a breakthrough in November 1st thing in morning. Patients not put on until biomed notified and chlorine normal. Plan: the tank must be filled each week. Team to record reading everyday. CC to follow up weekly." The plan failed to provided guidance to the bio-medical technician to prevent the tank running dry and failed to provide for training other staff to prevent the tank running dry.</p> <p>2. Facility document dated August 2006,</p>		<p>Underperformance is reviewed to identify root cause, action plan identified that results in performance improvement, and team tracks change in performance overtime to ensure improvements are sustained. GB will review QIFMM minutes during meetings, GB meeting minutes will reflect.</p> <p>FA & Medical Director are responsible for compliance with this POC.</p> <p>Completion date: 12/8/2012</p>		

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	<p>titled "Monthly Water Treatment Log", evidenced Date of Last System Disinfection for Monthly was 1/9/12, 2/9/12, 3/1/12, and 5/10/12. Contradicting documentation "DaVita Batch Ticket Summary" says scheduled routine disinfection was completed 3/1/12, 4/26/12, and 5/10/12.</p> <p>A. On November 16, 2012, at 12 Noon, the regional Bio-medical technician, Employee L, indicated the policy says monthly for disinfection and there were 7 weeks between the March and April disinfect and then 14 days between April and May.</p> <p>B. Water results for 4/6/12 First H2O Out 50 cfu, 4/13/12 First H2O 10 cfu, 5/03/2012 Last H2O Out results at 230 cfu H (high) Reuse Disinfect Out 680 cfu (H), 5/11/12 the Last H2O Out results at 160 cfu H and Reuse Disinfect Out is 10 cfu, 5/17/12 Last H2O results at <10 cf, 6/13/2012 the Last H2O Out results at 80 cfu, 6/19/12 at 10 cfu, 7/5/2012 the Last H2O Out results at 10 cfu and Pre BD Inlet # 1 220 cfu H, 7/9/12 the Pre BD Inlet # 1 <10 cfu, 7/17/2012 at <10 cfu, 7/24/2012 at 20 cfu, 7/30/12 at 10 cfu.</p> <p>1.) August testing was within guidelines. 9/7/12 First H2O at 320 cfu H, 10/3/12 First H2O at 450 cfu H and</p>						

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	<p>PRE BD Inlet # 2 150 cfu, 10/10/12 First H2O at <10 cfu and PRE BD Inlet # 2 <10 cfu.</p> <p>2.) November testing was within guidelines.</p> <p>C. A policy dated March 2012, titled "Water Treatment System Disinfection", Policy: 2-05-01, states, "4. Chemically-disinfected direct feed systems are disinfected monthly."</p> <p>D. November 13, 2012, at 12:00 PM, the Regional CSS presented the only Action Plan the facility had in place. The Action Plan covered supplies and maintenance to the water room floor. The Action Plan failed to address the Water Cultures.</p> <p>3. A policy dated September 2010, titled "Medical Director Qualifications and Responsibilities", Policy: 3-03-71, states, "2. MD (Medical Director) responsibilities include, but are not limited to: a. The Quality Assurance (QA)/Quality Improvement (QI) program. b. Staff education, training and performance; ... d. Ensuring that all policies and procedures relative to patient admissions, patient care, infection control, and safety and adhered to by all individuals who treat patients in the</p>				

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	facility, ... g. Complying with all federal, state, and local laws, including the conditions for coverage."			

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V0715	<p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (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; Based on staff interview and review of facility record and policy, the medical director failed to ensure the policy for monthly system disinfection occurred between the months of January 2012 and May 2012 was implemented resulting in out of parameter water cultures for 5 of the 7 months reviewed with the potential to affect all 23 patients.</p> <p>Findings:</p> <p>2. Facility document dated August 2006, titled "Monthly Water Treatment Log", evidenced Date of Last System Disinfection for Monthly was 1/9/12, 2/9/12, 3/1/12, and 5/10/12. Contradicting documentation "DaVita Batch Ticket Summary" says scheduled routine disinfection was completed 3/1/12, 4/26/12, and 5/10/12.</p> <p>2. On November 16, 2012, at 12 Noon, the regional Bio-medical technician, Employee L, indicated the policy says monthly for disinfection and there were 7</p>	V0715	<p>V715 ABS will hold mandatory in-service for BMT and all TMs responsible for water treatment system monitoring on 12/4/2012. In-service will include but not be limited to: review of <i>Policy & Procedure #2-05-01 Water System Disinfection</i>, <i>Policy & Procedure #2-06-01 Water Culture Policy</i> emphasizing 1) water treatment system must be disinfected and documented monthly and include both the reverse osmosis machine and distribution system; 2) Interpreting culture results: Acceptable level below 50 cfu/ml , Action level 50-199cfu/ml, Unacceptable level 200cfu/ml or greater, 3) Required response to action level culture results: If single site at or above action level and all other results in acceptable range, notify medical director of results within 48 hours of receiving result, and site must be re-cultured within 7 days of original sample collection date, 4) Required response to more than one site at or above action level or any site at or above</p>	12/08/2012			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152507		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 11/16/2012	
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	<p>weeks between the March and April disinfect and then 14 days between April and May.</p> <p>3. Water results for 4/6/12 First H2O Out 50 cfu, 4/13/12 First H2O 10 cfu, 5/03/2012 Last H2O Out results at 230 cfu H (high) Reuse Disinfect Out 680 cfu (H), 5/11/12 the Last H2O Out results at 160 cfu H and Reuse Disinfect Out is 10 cfu, 5/17/12 Last H2O results at <10 cf, 6/13/2012 the Last H2O Out results at 80 cfu, 6/19/12 at 10 cfu, 7/5/2012 the Last H2O Out results at 10 cfu and Pre BD Inlet # 1 220 cfu H, 7/9/12 the Pre BD Inlet # 1 <10 cfu, 7/17/2012 at <10 cfu, 7/24/2012 at 20 cfu, 7/30/12 at 10 cfu.</p> <p>A. August testing was within guidelines. 9/7/12 First H2O at 320 cfu H, 10/3/12 First H2O at 450 cfu H and PRE BD Inlet # 2 150 cfu, 10/10/12 First H2O at <10 cfu and PRE BD Inlet # 2 <10 cfu.</p> <p>B. November testing was within guidelines.</p> <p>4. A policy dated March 2012, titled "Water Treatment System Disinfection", Policy: 2-05-01, states, "4. Chemically-disinfected direct feed systems are disinfected monthly."</p>		<p>unacceptable level: Notify FA, Biomedical Services and Medical Director, Disinfect affected equipment at end of treatment day in which results are received/reported or as recommended by Medical Director, Re-culture of all affected sites within 7 days of original sample collection date. 5) ABS must be notified of all actionable results. Attendance of in-service is evidenced by TM signature on In-Service Form.</p> <p>ABS will conduct monthly audits of facility system disinfection and culture and endotoxin results x 3 months, then quarterly thereafter to ensure compliance with all required disinfection, testing, and response. BMT will bring results of all monthly water and dialysate testing to QIFMM meetings for review with Medical Director and team, QIFMM committee will review all results, responses and trends during monthly QIFMM, minutes will reflect. QIFMM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance</p> <p>FA & Medical Director are responsible for compliance with this POC.</p> <p>Completion date: 12/8/2012</p>				

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	5. November 13, 2012, at 12:00 PM, the Regional CSS presented the only Action Plan the facility had in place. The Action Plan covered supplies and maintenance to the water room floor. The Action Plan failed to address the Water Cultures.			