STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152601	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING	(X3) DATE SURVEY COMPLETED 09/28/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
LIBERTY DIALYSIS LAFAYETTE II	1020 N 18TH ST LAFAYETTE, IN 47904

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V0000	This was a federal ESRD recertification survey. Survey Dates: 9/26/12 through 9/28/12 Facility #: 005140 Medicaid Vendor #: 200418720 Surveyors: Bridget Boston, RN, Public Health Nurse Surveyor - team leader Marty Coons, RN, Public Health Nurse Surveyor - team member Ingrid Miller, RN, Public Health Nurse Surveyor - team member Census by Service Type: Number of In-Center Hemodialysis Patients: 67 Number of Peritoneal Dialysis Patients: 42 Number of home hemodialysis patients: 7 Total: 116 Liberty Dialysis Lafayette was found to be out of compliance with the Conditions for Coverage 42 CFR 494.30: Infection Control, 494.40:Water and Dialysate Quality, and 494.110: Quality Assessment and Performance Improvement.	V0000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Any defiencystatement ending with an asterisk (*) denotes a deficency which the institution may be excused from correcting providing it is determined that other safegaurds 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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	Quality Review: Joyce Elder, MSN, BSN, RN October 9, 2012			

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V0110	494.30 CFC-INFECTION CONTROL Based on observation and interview and review of policy, personnel files, and documents, it was determined the facility failed to ensure that 1 of 1 dialysis facility kept sinks free of soiled equipment and supplies (See V 114); failed to ensure Patient Care Technicians (PCT) and Registered Nurses (RN) had prepared disinfectant solution in the proper ratio to be used to disinfect dialysis equipment used on patients prior to using the same equipment on another patient creating the potential to spread infection causing agents among facility staff and all 67 current in-center patients (See V 116); failed to ensure an appropriate disinfectant was used to clean equipment and contaminated surfaces and dialysis equipment was adequately cleaned between patients creating the potential for the spread of disease causing organisms among staff and the facility's 67 current in center hemodialysis patients (See V 122); and failed to ensure infection control practices were monitored and staff were adequately trained and evaluated to ensure the employees' ability for making bleach solution accurately for 1 of 1 facility with the potential to cause infectious organisms to spread among all the facility's patients and staff (See V 132).	V0110	The Governing Body acknowledges its responsibility to ensure that the Liberty Dialysis Lafayette II facility provides and monitors a sanitary environment to minimize transmission of infectious agents, provide a safe environment for patients and staff and ensure systems are in place to keep sinks free of soiled equipment and supplies, to prepare disinfectant solution in the proper ratio, to ensure an appropriate disinfectant is used to clean equipment, contaminated surfaces and dialysis equipment between patients, to ensure infection control practices are monitored and to ensure staff are adequately trained. Therefore, the Governing Body, on 10/16/12 reviewed the SOD and developed the following Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. The following action steps were implemented The Governing Body will meet weekly to monitor the progress of the Plan of Correction until the Condition level deficiencies are lifted, then monthly for an additional three months to ensure that the corrective actions have resulted in resolution of the cited issues. Once this is determined, the Governing Body will return to quarterly or as needed meetings.	10/16/2012

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	The cumulative effect of these systemic problems resulted in the facility's inability to follow accepted infection control practices as required by the Condition for Coverage 494.30: Infection control.		Effective immediately: · The Clinical Manager (CM) will analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee. · A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda. · The QAI Committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution of the issues · The Director of Operations (DO) will present a report on the Plan of Correction data and all actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. · The Governing Body, at its meeting of 10/16/12, designated the Regional Quality Manager to serve as Plan of Correction Monitor and provide additional oversight. She will actively participate in each QAI and Governing Body meeting - either personally or via conference call - and submit a status report at each of the referenced Governing Body meetings with a copy to the RVP. This additional oversight is to ensure the ongoing correction	

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			of deficiencies cited in the Statement of Deficiency through to resolution as well as ensure the Governance of the Facility is presented current and complete data to enhance their governance oversight role · Minutes of the Governing Body and QAI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's direction and oversight and the QAI Committee's ongoing monitoring of facility activities. These are available for review at the facility. · The responses provided for V 114, V 116, V 122 and V 132 describe, in detail, the processes and monitoring steps taken to ensure that all deficiencies as cited within this Condition are corrected to ensure ongoing compliance	

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V0114	494.30(a)(1)(i) IC-SINKS AVAILABLE A sufficient number of sinks with warm water and soap should be available to facilitate hand washing. Based on observation, interview, and review of policies, the dialysis facility failed to ensure the facility kept sinks free of soiled equipment and supplies for 1 of 1 facility with the potential to spread infectious disease to all the facility's patients. Findings 1. On 9/27/12 at 10:30 AM, the dirty sink at a work station at Pod #3 in the middle of the inpatient hemodialysis treatment center was observed utilized for clean and dirty cleaning. At this sink area, a sign was observed that stated, "Dirty Sink." On the front part of the right side of the sink was a white and blue container holding approximately 2 liters of clear fluid and several white wipes. This container was labeled "9/27/12 0500 AM [Employee A] Patient Care Technician Bleach 1:100." On the back right side of the sink were paper towels in a holder. On the left front side of the sink was a clean plastic container with a blue edge with the lid off. This container held several blue hemostat clamps and other white clamps in approximately 2 liter of bleach water. Two hemostat clamps were	V0114	A mandatory in-service was completed on 10/9/12 for all staff with special emphasis on the prohibition of placement of contaminated items in hand-washing sinks and review of the appropriate designation and use of sinks labeled as "Hand-Washing Only" or " Dirty". On 10/19/12, the Clinical Manager labeled each sink with the appropriate sign as indicated below: ·Sinks used for hand-washing were labeled with a sign that reads: "Hand Washing Only - Do Not Place Contaminated Items in the Sink". ·The dirty sinks were labeled with a sign that reads: "NO Hand-Washing – Saline & Other Fluid Disposal Only". Containers with clean clamps were immediately removed from the dirty sink area and relocated to a clean supply area. The Clinical Manager will ensure that infection control audits utilizing the Plan of Correction audit tool are done daily until the facility is resurveyed then weekly. Frequency of ongoing monitoring will be determined by the QAI Committee based on results of	10/19/2012

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	noted to be unclamped and the clamps were not completely submerged in the bleach water. The container was labeled "9/27/12 0500 [Employee A] Bleach 1:100." 2. On 9/27/12 at 10:30 AM, Employee L, Registered Nurse, indicated the sink was not to be used for other purposes besides handwashing. 3. The facility policy titled "Infection Control Measures" with an effective date of 7/21/2009 stated, "Environmental Practices ... c. Sinks ... ii. Handwashing sinks will be dedicated only for hand washing purposes and should remain clean ... 4. Soiled Utility Room The soiled utility room is utilized for disposal and the rinsing of soiled equipment."		monitoring and resolution of the issues. The Clinical Manager will report a summary of findings monthly in QAI and compliance will be monitored by the QAI committee.	

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V0116	494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient. -- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient. -- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.			
	Based on observation, staff interview, and review of policies and procedures and documents, the facility failed to ensure Patient Care Technicians (PCT) and Registered Nurses (RN) had prepared disinfectant solution in the proper ratio to be used to disinfect dialysis equipment used on patients prior to using the same equipment on another patient creating the potential to spread infection causing agents among facility staff and all 67 current in-center patients. The findings include: 1. The undated policy titled "Cleaning and Disinfection of Surfaces and Equipment" policy number 30.06, states, "To provide direction regarding correct	V0116	The Governing Body on October 16, 2012 met and determined to replace the existing infection control policies with the FMC Bloodborne Pathogen Manual effective immediately. This is documented within the GB Minutes of this date. All staff attended a mandatory in-service conducted by the clinic educator on 10/9/12 reviewing the following policies: · Infection Control Overview – FMS-CS-IC-II-155-060A · Dialysis Precautions – FMS-CS-IC-II-155-070A · Hand Hygiene – FMS-CS-IC-II-155-090A · PPE – FMS-CS-IC-II-155-080A · Cleaning and Disinfection – FMS-CS-IC-II-155-110A	10/16/2012

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	cleaning and disinfection of environmental surfaces and equipment to prevent transmission of dangerous pathogens. 1. Any manufacturer's guidance for sterilization or disinfectant of an item will be followed, as well as guidance from the chemical sterilant or disinfectant manufacturer, including appropriate dilution and contact time. 2. At the end of each dialysis treatment, a. All surfaces without, visible blood will be cleaned following the low level disinfection protocol using soap detergent or detergent germicide. b. For visible blood, the intermediate-level (1:10) disinfection protocol must be followed, which requires the area be immediately cleaned with a cloth soaked with tuberculocidal disinfection following the manufacturer's direction for dilution and contact time ... 6. At the end of each patient treatment, the staff will clean and disinfect the dialysis station. ... The staff will discard all fluids and clean and disinfect all surfaces of the containers associated with the prime waste (including containers attached to the machines) after each treatment. 7. After each treatment, the staff will clean and disinfect medical devices and equipment. Any shared items such as scissors, hemostats, clamps, stethoscopes, and blood pressure cuffs will be cleaned and disinfected between patient uses. If the		· Work Surface Cleaning and Disinfection – FMS-CS-IC-II-155-110C1 · Handling Contaminated Medical Records – FMS-CS-IC-II-121A · Cleaning and Disinfection BP Cuff – FMS-CS-IC-II-155-122A · Mixing Bleach Procedure – FMS-CS-IC-II-155-110C5 Emphasis was placed on ensuring the disinfection solution is mixed to the proper ratios as noted per policy, chlorine potency is verified, proper disinfection of nondisposable items occurs and any disposable items taken into the patient's station are not returned to a clean area or used on other patients. Proper disinfection will be used before returning non-disposable items to a clean area as described in policy FMS-CS-IC-II-155-070. The Clinical Manager will be responsible for ensuring proper disinfection of non-disposable equipment is performed before and after using supplies and that cross contamination is not occurring as evidenced by conducting an infection control audit utilizing the Plan of Correction Audit Tool daily until the facility is resurveyed then weekly. Frequency of ongoing monitoring will be determined by	

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	item is visibly contaminated with blood, an intermediate-level disinfectant will be used. ... 9. Dialysis machine disinfection will be documented, including testing for residual disinfectant." 2. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #25 terminated dialysis at 9:40 AM by employee P, a PCT, at station 28, dialysis machine L29. Review of post treatment dialysis documentation on 9/27/2 evidenced patient #26 initiated dialysis at 10:35 AM by the PCT, employee P at station 28, machine L29. Testing of the disinfectant solution by employee N, the administrator, and employee L a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. 3. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #23 terminated dialysis at 7:35 AM by employee P, a PCT, at station 23, dialysis machine 6. Review of post treatment dialysis documentation on 9/27/2 evidenced patient #24 initiated dialysis at 11:10 AM by the PCT, employee O, at station 23, machine L6. Testing of the disinfectant solution by		the QAI Committee based on results of monitoring and resolution of the issues. Staff compliance is further monitored by the Education Coordinators, Director of Operations, Operation Managers and Clinical Manager as follows: ·Observing staff's adherence to properly disinfect non-disposable equipment before returning to a clean area ·Ensuring that staff members do not take paper treatment sheets into the patient station. ·Immediate intervention, consisting of reeducation up to disciplinary action, to address and correct identified noncompliance with the appropriate staff member Compliance with these policies will be maintained by the Clinical Manager on an ongoing basis. The Clinical Manager is responsible to review and analyze the results of all audits and monitoring tools and present to the QAI Committee on a monthly basis. The QAI Committee is responsible to provide oversight and ensure resolution is occurring.	

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	employee N, the administrator, and employee L a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. 4. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #22 terminated dialysis at 10:19 AM by employee O, a PCT, at station 21, dialysis machine L4 . Review of post treatment dialysis documentation on 9/27/2 evidenced patient #14 initiated dialysis at 12:15 PM by the PCT, employee O, at station 21, machine L4. Testing of the disinfectant solution by employee N, the administrator, and employee L, a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. 5 Review of post treatment dialysis documentation on 9/27/12 evidenced patient #20 terminated dialysis at 10:06 AM by employee A, a PCT, at station 24, dialysis machine L3. Review of post treatment dialysis documentation on 9/27/2 evidenced patient #21 initiated dialysis at 11:10 AM by the PCT,			

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	employee A, at station 21, machine L3. Testing of the disinfectant solution by employee N, the administrator, and employee L, a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. 6. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #19 terminated dialysis at 11:02 AM by employee O, a PCT, at station 17, dialysis machine L17 . Review of post treatment dialysis documentation on 9/27/2 evidenced patient #15 initiated dialysis at 12:00 PM by the PCT, employee A, at station 25, machine L17. Testing of the disinfectant solution by employee N, the administrator, and employee L, a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. 7. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #18 terminated dialysis at 10:05 AM by employee A, a PCT, at station 19, dialysis machine L25 . Review of post treatment dialysis documentation on			

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	9/27/2 evidenced patient #16 initiated dialysis at 12:20 PM by the PCT, employee A, at station 19, machine L25. Testing of the disinfectant solution by employee N, the administrator, and employee L, a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. 8. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #11 initiated dialysis at 11:30 AM and terminated dialysis at 3:06 PM by employee P, a PCT, at station 20, dialysis machine L19. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #17 initiated dialysis at 12:05 PM by the same PCT using the same dialysis machine L19. The PCT failed to document at what station the patient was dialyzing. Testing of the disinfectant solution by employee N, the administrator, and employee L, a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients.			

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V0122	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. 3. The undated policy titled "Cleaning and Disinfection of Surfaces and Equipment" policy number 30.06, states, "To provide direction regarding correct cleaning and disinfection of environmental surfaces and equipment to prevent transmission of dangerous pathogens. 1. Any manufacturer's guidance for sterilization or disinfectant of an item will be followed, as well as guidance from the chemical sterilant or disinfectant manufacturer, including appropriate dilution and contact time. 2. At the end of each dialysis treatment, a. All surfaces without, visible blood will be cleaned following the low level disinfection protocol using soap detergent or detergent germicide. b. For visible blood, the intermediate-level (1:10) disinfection protocol must be followed, which requires the area be immediately cleaned with a cloth soaked with	V0122	On 9/28/12, the Operations Manager met with the Clinical Manager to review and reinforce her requirement to ensure that the facility is utilizing bleach disinfection solutions as required by policy and that all patient care staff members are following policies. Per the adoption of the FMCNA Bloodborne Pathogens Manual as noted in V 116 – 1:10 bleach solution is to be used for visible blood spills, 1:100 Bleach solution is used for routine disinfection within the dialysis facility. ·Effective immediately, the Clinical Manager has added the daily assignment of bleach mixing as part of the facility's patient assignment process. As noted above, the Director of Operations arranged for the Education Department to educate all staff, including the home therapies staff on 10/9/12 to the	10/09/2012

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	tuberculocidal disinfection following the manufacturer's direction for dilution and contact time ... 6. At the end of each patient treatment, the staff will clean and disinfect the dialysis station. ... The staff will discard all fluids and clean and disinfect all surfaces of the containers associated with the prime waste (including containers attached to the machines) after each treatment. 7. After each treatment, the staff will clean and disinfect medical devices and equipment. Any shared items such as scissors, hemostats, clamps, stethoscopes, and blood pressure cuffs will be cleaned and disinfected between patient uses. If the item is visibly contaminated with blood, an intermediate-level disinfectant will be used. ... 9. Dialysis machine disinfection will be documented, including testing for residual disinfectant." A. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #25 terminated dialysis at 9:40 AM by employee P, a PCT, at station 28, dialysis machine L29. Review of post treatment dialysis documentation on 9/27/2 evidenced patient #26 initiated dialysis at 10:35 AM by the PCT, employee P at station 28, machine L29. Testing of the disinfectant solution by employee N, the administrator, and employee L a RN, with "E-Z Chek"		following: ·FMS Blood Borne Pathogen Manual specifically ·Cleaning and Disinfection FMS-CS-IC-II-155-110A – ensuring that clamps are totally submersed in bleach solution ·Bleach Mixing FMS-CS-IC-II-155-115-C to include verification of chlorine potency per policy ·Bleach preparation documentation requirements emphasizing immediate documentation by the preparer. ·Competency will be demonstrated by all employees as evidenced within the employee's personnel files as noted in V 132 ·Effective immediately additional bleach containers have been obtained to ensure the appropriate number of containers are available within the facility to ensure all clamps will be submerged per policy Monitoring of staff compliance to required disinfection with prepared solution has been incorporated into the plan of correction monitoring tool. The Clinical Manager or designee will conduct an infection control audit daily until the facility is resurveyed then weekly. Frequency of ongoing monitoring will be determined by the QAI Committee based on results of monitoring and resolution of the	

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	potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. B. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #23 terminated dialysis at 7:35 AM by employee P, a PCT, at station 23, dialysis machine 6. Review of post treatment dialysis documentation on 9/27/2 evidenced patient #24 initiated dialysis at 11:10 AM by the PCT, employee O, at station 23, machine L6. Testing of the disinfectant solution by employee N, the administrator, and employee L a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. C. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #22 terminated dialysis at 10:19 AM by employee O, a PCT, at station 21, dialysis machine L4 . Review of post treatment dialysis documentation on 9/27/2 evidenced patient #14 initiated dialysis at 12:15 PM by the PCT, employee O, at station 21, machine L4. Testing of the disinfectant solution by		issues. In the event that a staff member is found to not follow the facility procedures for infection control, the Clinical Manager will be notified and is responsible to address the findings with the identified staff member. The Clinical Manager's action will be structured to reinforce by further education following through as necessary with the application of progressive disciplinary action. The Clinical Manager is responsible to review and analyze the results of all audits and monitoring tools and present to the QAI Committee on a monthly basis and the QAI Committee and the Governing Body monitor for ongoing compliance	

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	employee N, the administrator, and employee L, a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. D Review of post treatment dialysis documentation on 9/27/12 evidenced patient #20 terminated dialysis at 10:06 AM by employee A, a PCT, at station 24, dialysis machine L3. Review of post treatment dialysis documentation on 9/27/2 evidenced patient #21 initiated dialysis at 11:10 AM by the PCT, employee A, at station 21, machine L3. Testing of the disinfectant solution by employee N, the administrator, and employee L, a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. E. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #19 terminated dialysis at 11:02 AM by employee O, a PCT, at station 17, dialysis machine L17 . Review of post treatment dialysis documentation on 9/27/2 evidenced patient #15 initiated dialysis at 12:00 PM by the PCT,			

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	employee A, at station 25, machine L17. Testing of the disinfectant solution by employee N, the administrator, and employee L, a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. F. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #18 terminated dialysis at 10:05 AM by employee A, a PCT, at station 19, dialysis machine L25 . Review of post treatment dialysis documentation on 9/27/2 evidenced patient #16 initiated dialysis at 12:20 PM by the PCT, employee A, at station 19, machine L25. Testing of the disinfectant solution by employee N, the administrator, and employee L, a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. G. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #11 initiated dialysis at 11:30 AM and terminated dialysis at 3:06 PM by employee P, a PCT, at station 20, dialysis machine L19. Review of post treatment			

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	dialysis documentation on 9/27/12 evidenced patient #17 initiated dialysis at 12:05 PM by the same PCT using the same dialysis machine L19. The PCT failed to document at what station the patient was dialyzing. Testing of the disinfectant solution by employee N, the administrator, and employee L, a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. 4. On 9/28/12 at 6:45 AM, employee P, a PCT, indicated they did not mix a 1:10 bleach solution daily and she used 1:100 bleach for blood spills. 5. On 9/28/12 at 6:50 AM, employee A indicated the facility did not make a bleach solution of 1:10 bleach for blood spills and they only make one bleach solution 1:100 and use it for all blood spills regardless of the quantity. Employee I, a registered nurse, confirmed the facility did not make a 1:10 bleach solution or have it available for disinfection purposes following a blood spill. She said it was not the policy of Liberty Dialysis.			

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	6. On 9/28/12 at 7 AM, employee I, a registered nurse, indicated the facility did not have a policy to use a bleach solution with 1:10 ration to clean equipment contaminated with blood and blood spills. 7. On 9/28/12 at 9:26 AM, employee M indicated the facility did not have a policy on making 1:10 bleach water solution and when it was necesaary to use the strength of 1:10 solution. She indicated the facility only used 1:100 bleach solution for all cleaning purposes including blood spills. Based on personnel file review, document review, policy review, interview, and observation, the dialysis facility failed to ensure an appropriate disinfectant was used to clean equipment and contaminated surfaces and dialysis equipment was adequately cleaned between patients creating the potential for the spread of disease causing organisms among staff and the facility's 67 current in center hemodialysis patients.			

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	The findings include: 1. On 9/27/12 at 10:30 AM, the dirty sink at a work station at Pod #3 in the middle of the inpatient hemodialysis treatment center was observed utilized for clean and dirty cleaning. At this sink area, a sign was observed that stated, "Dirty Sink." On the front part of the right side of the sink was a white and blue container holding approximately 2 liters of clear fluid and several white wipes. This container was labeled "9/27/12 0500 AM [Employee A] Patient Care Technician Bleach 1:100." On the back right side of the sink were paper towels in a holder. On the left front side of the sink was a clean plastic container with a blue edge with the lid off. This container held several blue hemostat clamps and other white clamps in approximately 2 liter of bleach water. Two hemostat clamps were noted to be unclamped and the clamps were not completely submerged in the bleach water. The container was labeled "9/27/12 0500 [Employee A] Bleach 1:100." 2. On 9/27/12 at 11:20 AM, Employee A indicated arriving at the facility at 4:28 AM and making a bleach solution of 1:100 (1 part bleach and 100 parts water) for cleaning. Employee A was observed			

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	to reconstruct how the bleach water was made for finding #1. Employee A retrieved a 1 gallon measuring cup and 1 gallon container of Pure Bright bleach from the biohazard room at the rear of pod #3 and took the measuring cup to the dirty sink in pod #3. Employee A filled the gallon container to a line drawn on the gallon measuring cup at the 3 quart line with warm tap water. After obtaining a 10 cc (cubic centimeter) syringe from a nearby supply of syringes, Employee A used the syringe to pull up 3 cc of bleach from the bleach container and poured this bleach into the warm tap water. Then Employee A used the syringe to mix the bleach. No document was referred to when making this bleach water. A. On 9/27/12 at 11:30 AM, Employee A indicated this procedure was how the bleach water for the clean bucket and dirty clamp container was made at 5 AM. Employee A indicated training had occurred months before and he / she did not remember the names of the trainers. B. On 9/27/12 at 12:18 PM, Employee N, administrator, indicated the formula used for mixing the 1:100 bleach and had been hanging in the water room to the rear of pod #3. (Employee A had not used this formula when mixing the 1:100 bleach in finding #3.)			

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	C. At 9/27/12 at 12:40 PM a document titled "Instructions for mixing bleach" was presented by Employee N. This form stated, "Fill one gallon measuring cup to the 3 quart line with tap water (This will fill your bucket to approximately the top of the handle.) Pour water into bleach bucket container. Measure 4 mL [milliliter] of bleach (If needed you may pour some bleach into the bleach jugs from the machines so that your syringe will reach.) Add bleach to tap water in bucket. Use E - Z check strip to check potency of solution. It should measure 100 ppm (parts per million). Label bucket with identifying information - contents, person mixing, date, time and strength." D. On 9/27/12 at 12:45 PM, Employee M, the nurse manager, indicated there was no log to document that bleach water had been made per facility policy. E. On 9/27/12 at 2:20 PM, the medical director indicated Employee A diluted the bleach in the 1:100 bleach water too much. F. On 9/27/12 at 2:30 PM, Employee P, patient care technician (PCT), indicated making the 1:100 bleach water with 3 cc of bleach per 3 quarts of water and never			

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	having written instructions to make the water or a log to record making the bleach water. Employee P indicated not being able to recall who had trained him / her on making bleach water. G. On 9/27/12 at 4:10 PM, Employee N indicated that 38 cc of bleach was needed for 3 quarts of water to achieve the 1:100 ratio of 1 part bleach to 100 parts of water. H. On 9/27/12 at 4:50 PM, Employee M indicated no bleach water with a ratio of 1 part bleach to 10 parts water was being made for large spills and what constituted a large spill had not been determined. I. Employee A, date of hire 6/6/11, evidenced a personnel file which included a document titled "Orientation Checklist." This document was unsigned and not dated and failed to indicate any training had been completed. J. The agency policy titled "Procedure 01:03 ... Surface Cleaning in the hemodialysis setting" with no effective date stated, "Dialysis personnel will adhere to the following: Bleach solution (1:100) will be made every day, stored in a covered container, and labeled. Blood spills will be wiped immediately with 1:100 bleach solution."			

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V0132	494.30(a)(1)(i) IC-TRAINING & EDUCATION Infection Control Training and Education Infection control practices for hemodialysis units: intensive efforts must be made to educate new staff members and reeducate existing staff members regarding these practices. Based on observation, policy review, document review, personnel file review, and interview, the facility failed to ensure infection control practices were monitored and staff were adequately trained and evaluated to ensure the employees' ability for making bleach solution accurately for 1 of 1 facility with the potential to cause infectious organisms to spread among all the facility's patients and staff. The findings include: 1. On 9/27/12 at 10:30 AM, the dirty sink at a work station at Pod #3 in the middle of the inpatient hemodialysis treatment center was observed utilized for clean and dirty cleaning. At this sink area, a sign was observed that stated, "Dirty Sink." On the front part of the right side of the sink was a white and blue container holding approximately 2 liters of clear fluid and several white wipes. This container was labeled "9/27/12 0500 AM [Employee A] Patient Care Technician	V0132	The Operations Manager met with the facility Education Coordinator to arrange and schedule staff in-services to educate all staff members on the recently adopted Bloodborne Pathogen Program and Infection Control Manual, with special emphasis on defining what constitutes a large blood spill. Training will be completed by 10/9/12 and an in-service attendance sheet will be available in the facility for review. On 10/20/12, the Education Coordinators completed individual skills and competency checks on the newly trained BBP Manual on all patient care staff emphasizing the employees' ability to make bleach solution. Documentation is available within the facility personnel files. In addition, annual skills and competency checks are being added to the QAI Calendar to ensure they will be done on an annual basis. Effective immediately, the containers with clean wipes have been moved to a clean area away from the dirty sink.	10/20/2012

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	Bleach 1:100." On the back right side of the sink were paper towels in a holder. On the left front side of the sink was a clean plastic container with a blue edge with the lid off. This container held several blue hemostat clamps and other white clamps in approximately 2 liter of bleach water. Two hemostat clamps were noted to be unclamped and the clamps were not completely submerged in the bleach water. The container was labeled "9/27/12 0500 [Employee A] Bleach 1:100." 2. On 9/27/12 at 11:20 AM, Employee A indicated arriving at the facility at 4:28 AM and making a bleach solution of 1:100 (1 part bleach and 100 parts water) for cleaning. Employee A was observed to reconstruct how the bleach water was made for finding #1. Employee A retrieved a 1 gallon measuring cup and 1 gallon container of Pure Bright bleach from the biohazard room at the rear of pod #3 and took the measuring cup to the dirty sink in pod #3. Employee A filled the gallon container to a line drawn on the gallon measuring cup at the 3 quart line with warm tap water. After obtaining a 10 cc (cubic centimeter) syringe from a nearby supply of syringes, Employee A used the syringe to pull up 3 cc of bleach from the bleach container and poured this bleach into the warm tap water. Then		In order to monitor staff adherence to the correct application of the Bloodborne Pathogen Program, the Director of Operations incorporated the observation of the facility's requirements in the Plan of Correction Monitoring Tool. As such, the following has been implemented: □ On October 1, 2012 the Regional Quality Manager presented the developed Plan of Correction monitoring tool to the Education Coordinator and Facility Management team. □ Beginning 10/3/12, the Education Coordinators or Clinical Manager will complete the tool during each patient shift on each employee including the home therapies staff whenever they are seeing patients □ Any identified issues of staff noncompliance will have an immediate intervention by the Education Coordinator or Management team member providing oversight. The noncompliance and intervention will be documented on the POC monitoring tool. □ The Clinical Manager or Director of Operations will review the tool and administer corrective action as needed. The Clinical Manager reviews the copies of the completed monitoring tool, identified	

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	Employee A used the syringe to mix the bleach. No document was referred to when making this bleach water. A. On 9/27/12 at 11:30 AM, Employee A indicated this procedure was how the bleach water for the clean bucket and dirty clamp container was made at 5 AM. Employee A indicated training had occurred months before and he / she did not remember the names of the trainers. B. On 9/27/12 at 12:18 PM, Employee N, administrator, indicated the formula used for mixing the 1:100 bleach and had been hanging in the water room to the rear of pod #3. (Employee A had not used this formula when mixing the 1:100 bleach in finding #3.) C. At 9/27/12 at 12:40 PM a document titled "Instructions for mixing bleach" was presented by Employee N. This form stated, "Fill one gallon measuring cup to the 3 quart line with tap water (This will fill your bucket to approximately the top of the handle.) Pour water into bleach bucket container. Measure 4 mL [milliliter] of bleach (If needed you may pour some bleach into the bleach jugs from the machines so that your syringe will reach.) Add bleach to tap water in bucket. Use E - Z check strip to check potency of solution. It should measure		noncompliance and the applied interventions with the Director of Operations and Medical Director weekly. The Clinical Manager or designee will complete the infection control audits daily until the facility is resurveyed then weekly. Frequency of ongoing monitoring will be determined by the QAI Committee based on results of monitoring and resolution of the issues. The report is summarized and reviewed, during the monthly QAI meeting. The QAI will recommend procedural or operational changes that are required to prevent reoccurrence of significant events. Target dates for implementation should be included. QAI Minutes document this activity and will be available for review at the facility. The Clinical Manager is responsible and the QAI Committee monitors to ensure on going compliance.	

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NAME OF PROVIDER OR SUPPLIER LIBERTY DIALYSIS LAFAYETTE II		STREET ADDRESS, CITY, STATE, ZIP CODE 1020 N 18TH ST LAFAYETTE, IN 47904	

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	100 ppm (parts per million). Label bucket with identifying information - contents, person mixing, date, time and strength." D. On 9/27/12 at 12:45 PM, Employee M, the nurse manager, indicated there was no log to document that bleach water had been made per facility policy. E. On 9/27/12 at 2:20 PM, the medical director indicated Employee A diluted the bleach in the 1:100 bleach water too much. F. On 9/27/12 at 2:30 PM, Employee P, patient care technician (PCT), indicated making the 1:100 bleach water with 3 cc of bleach per 3 quarts of water and never having written instructions to make the water or a log to record making the bleach water. Employee P indicated not being able to recall who had trained him / her on making bleach water. G. On 9/27/12 at 4:10 PM, Employee N indicated that 38 cc of bleach was needed for 3 quarts of water to achieve the 1:100 ratio of 1 part bleach to 100 parts of water. H. On 9/27/12 at 4:50 PM, Employee M indicated no bleach water with a ratio of 1 part bleach to 10 parts water was being			

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	made for large spills and what constituted a large spill had not been determined. I. Employee A, date of hire 6/6/11, evidenced a personnel file which included a document titled "Orientation Checklist." This document was unsigned and not dated and failed to indicate any training had been completed. J. The agency policy titled "Procedure 01:03 ... Surface Cleaning in the hemodialysis setting" with no effective date stated, "Dialysis personnel will adhere to the following: Bleach solution (1:100) will be made every day, stored in a covered container, and labeled. Blood spills will be wiped immediately with 1:100 bleach solution." 3. The undated policy titled "Cleaning and Disinfection of Surfaces and Equipment" policy number 30.06, states, "To provide direction regarding correct cleaning and disinfection of environmental surfaces and equipment to prevent transmission of dangerous pathogens. 1. Any manufacturer's guidance for sterilization or disinfectant of an item will be followed, as well as guidance from the chemical sterilant or disinfectant manufacturer, including appropriate dilution and contact time. 2. At the end of each dialysis treatment, a.			

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	All surfaces without, visible blood will be cleaned following the low level disinfection protocol using soap detergent or detergent germicide. b. For visible blood, the intermediate-level (1:10) disinfection protocol must be followed, which requires the area be immediately cleaned with a cloth soaked with tuberculocidal disinfection following the manufacturer's direction for dilution and contact time ... 6. At the end of each patient treatment, the staff will clean and disinfect the dialysis station. ... The staff will discard all fluids and clean and disinfect all surfaces of the containers associated with the prime waste (including containers attached to the machines) after each treatment. 7. After each treatment, the staff will clean and disinfect medical devices and equipment. Any shared items such as scissors, hemostats, clamps, stethoscopes, and blood pressure cuffs will be cleaned and disinfected between patient uses. If the item is visibly contaminated with blood, an intermediate-level disinfectant will be used. ... 9. Dialysis machine disinfection will be documented, including testing for residual disinfectant." A. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #25 terminated dialysis at 9:40 AM by employee P, a PCT, at station 28,			

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	dialysis machine L29. Review of post treatment dialysis documentation on 9/27/2 evidenced patient #26 initiated dialysis at 10:35 AM by the PCT, employee P at station 28, machine L29. Testing of the disinfectant solution by employee N, the administrator, and employee L a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. B. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #23 terminated dialysis at 7:35 AM by employee P, a PCT, at station 23, dialysis machine 6. Review of post treatment dialysis documentation on 9/27/2 evidenced patient #24 initiated dialysis at 11:10 AM by the PCT, employee O, at station 23, machine L6. Testing of the disinfectant solution by employee N, the administrator, and employee L a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. C. Review of post treatment dialysis documentation on 9/27/12 evidenced			

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	patient #22 terminated dialysis at 10:19 AM by employee O, a PCT, at station 21, dialysis machine L4 . Review of post treatment dialysis documentation on 9/27/2 evidenced patient #14 initiated dialysis at 12:15 PM by the PCT, employee O, at station 21, machine L4. Testing of the disinfectant solution by employee N, the administrator, and employee L, a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. D Review of post treatment dialysis documentation on 9/27/12 evidenced patient #20 terminated dialysis at 10:06 AM by employee A, a PCT, at station 24, dialysis machine L3. Review of post treatment dialysis documentation on 9/27/2 evidenced patient #21 initiated dialysis at 11:10 AM by the PCT, employee A, at station 21, machine L3. Testing of the disinfectant solution by employee N, the administrator, and employee L, a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients.			

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	E. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #19 terminated dialysis at 11:02 AM by employee O, a PCT, at station 17, dialysis machine L17 . Review of post treatment dialysis documentation on 9/27/2 evidenced patient #15 initiated dialysis at 12:00 PM by the PCT, employee A, at station 25, machine L17. Testing of the disinfectant solution by employee N, the administrator, and employee L, a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. F. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #18 terminated dialysis at 10:05 AM by employee A, a PCT, at station 19, dialysis machine L25 . Review of post treatment dialysis documentation on 9/27/2 evidenced patient #16 initiated dialysis at 12:20 PM by the PCT, employee A, at station 19, machine L25. Testing of the disinfectant solution by employee N, the administrator, and employee L, a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis			

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	machines between patients. G. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #11 initiated dialysis at 11:30 AM and terminated dialysis at 3:06 PM by employee P, a PCT, at station 20, dialysis machine L19. Review of post treatment dialysis documentation on 9/27/12 evidenced patient #17 initiated dialysis at 12:05 PM by the same PCT using the same dialysis machine L19. The PCT failed to document at what station the patient was dialyzing. Testing of the disinfectant solution by employee N, the administrator, and employee L, a RN, with "E-Z Chek" potency chlorine test strips failed to show the cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients. 4. On 9/28/12 at 6:45 AM, employee P, a PCT, indicated they did not mix a 1:10 bleach solution daily and she used 1:100 bleach for blood spills. 5. On 9/28/12 at 6:50 AM, employee A indicated the facility did not make a bleach solution of 1:10 bleach for blood spills and they only make one bleach solution 1:100 and use it for all blood spills regardless of the quantity.			

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	Employee I, a registered nurse, confirmed the facility did not make a 1:10 bleach solution or have it available for disinfection purposes following a blood spill. She said it was not the policy of Liberty Dialysis. 6. On 9/28/12 at 7 AM, employee I, a registered nurse, indicated the facility did not have a policy to use a bleach solution with 1:10 ration to clean equipment contaminated with blood and blood spills. 7. On 9/28/12 at 9:26 AM, employee M indicated the facility did not have a policy on making 1:10 bleach water solution and when it was necesaary to use the strength of 1:10 solution. She indicated the facility only used 1:100 bleach solution for all cleaning purposes including blood spills.			

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V0175	494.40 CFC-WATER & DIALYSATE QUALITY Surveyor: Boston, Bridget Based on interview, observation, and review of policy and documents, it was determined the facility failed to ensure the empty bed contact time (EBCT) was evaluated and monitored and documentation evidenced a minimum of 5 minutes of EBCT for each carbon tank for a total of a minimum of 10 minutes at the maximum product water flow rate for 1 of 1 facility with the potential to have affected all dialysis patients (See V 195) and failed to ensure chlorine testing had been completed in accordance with facility policy in 2 of 3 water test observed on September 26, 2012, creating the potential to affect all of the facility's 116 current patients (See V 196). The cumulative effect of these systemic problems resulted in the facilities inability to ensure they provided safe water and dialysate as required by the Condition for Coverage 494.40:Water and Dialysate Quality.	V0175	The Governing Body acknowledges its responsibility to ensure that the Liberty Dialysis Lafayette II facility has systems that provide safe water and dialysate to all patients as required by the Conditions for Coverage emphasizing that empty bed contact time (EBCT) is evaluated and monitored and that chlorine testing is completed in accordance with facility policy. The Governing Body, on 10/16/12 reviewed the SOD and developed the following Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. The following action steps were implemented The Governing Body will meet weekly to monitor the progress of the Plan of Correction until the Condition level deficiencies are lifted, then monthly for an additional three months to ensure that the corrective actions have resulted in resolution of the cited issues. Once this is determined, the Governing Body will return to quarterly or as needed meetings. Effective immediately: · The Clinical Manager (CM) will analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee. · A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda. · The QAI Committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution of the issues	10/16/2012

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			· The Director of Operations (DO) will present a report on the Plan of Correction data and all actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. · The Governing Body, at its meeting of 10/16/12, designated the Regional Quality Manager to serve as Plan of Correction Monitor and provide additional oversight. She will actively participate in each QAI and Governing Body meeting - either personally or via conference call - and submit a status report at each of the referenced Governing Body meetings with a copy to the RVP. This additional oversight is to ensure the ongoing correction of deficiencies cited in the Statement of Deficiency through to resolution as well as ensure the Governance oversight role. · Minutes of the Governing Body and QAI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's direction and oversight and the QAI Committee's ongoing monitoring of facility activities. These are available for review at the facility. · The responses provided for V 195 and V 196 describe, in detail, the processes and monitoring steps taken to ensure that all deficiencies as cited within this Condition are corrected to ensure ongoing compliance	

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V0195	494.40(a) CARBON ADSORPTION-10 MINUTES EBCT 5.2.5 Carbon adsorption: 10 min EBCT Refer to RD62:2001, 4.3.9 Carbon adsorption media: When granulated activated carbon is used as the adsorption medium ... each adsorption bed shall have an [empty bed contact time] EBCT of at least 5 minutes at the maximum product water flow rate (a total EBCT of at least 10 minutes). Based on interview and review of policy and administrative documents, the facility failed to ensure the empty bed contact time (EBCT) was evaluated and monitored and documentation evidenced a minimum of 5 minutes of EBCT for each carbon tank for a total of a minimum of 10 minutes at the maximum product water flow rate for 1 of 1 facility with the potential to affect all dialysis patients. The findings include: 1. The policy dated 1/1/2010 and titled "Granular Activated Carbon (GAC) Filters" stated, "The granular activated carbon (GAC) filters ability to effectively remove total chlorine may be reduced if the reactive sites are masked by other substances as well as increases in pH and / or decreases in temperature. Due to these factors the GAC filter performance must be monitored regularly."	V0195	On 10/8/12, the Governing Body met and decided to replace the current water/technical policies with the Fresenius water and technical policies and logs. Policies directly related to issues noted within the survey, are being adopted effective 10/8/12. This is documented within the GB Minutes of this date. On 10/4/12, the Technical Operations Manager met with the Technical Program Manager to discuss the identified technical deficiency specific to determination of EBCT. The Technical Operations Manager and the Technical Program Manager will arrange and schedule local bio-medical staff in-service to educate on the recently adopted polices including employees D, R and M, relating to GAC monitoring and maintenance. Emphasis was placed on calculating EBCT monthly and documenting	10/12/2012

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	2. On 9/26/12 at 11:30 AM, employee D indicated he was unsure as to how to determine the EBCT and indicated it was not completed for the last three years. He indicated the carbon tanks were both rebeded in August 2012 and was not aware of the volume of carbon that was placed. He indicated he did not have the documentation from the vendor. 3. The administrative document tilted "Carbon Tank Service Log" stated, "Rebed both 1 & 2 with 14 cu [cubic] of carbon each both tested. ... 8/21/12 Both tank 1 and 2 rebeded, Aqua Systems." 4. On 9/26/2012 at 4:08 PM, employee R produced a EBCT calculation dated 9/26/12 and the time of the calculation was written as 3:50 PM, and indicated the EBCT was 5.50 with a volume of carbon of 7.35 cubic feet / tank. He indicated he entered the volume of 7.35 per tank into the calculation with the known 11 gallons of product water / minute to achieve a product number that meets the minimum requirement of 10 minute EBCT in total. He was not able to evidence there was 7.35 cubic feet of carbon in each tank. 5. On 9/26/2012 at 4:41 PM, employee M indicated she did not have the vendor information regarding the cubic feet of carbon that was placed in the carbon tanks		appropriately on the ER-1 and determining competency through a skills check. Training will be completed by 10/12/12 and an in-service attendance sheet will be available in the facility for review. Only those demonstrating competency will be assigned to this task. Ongoing, this skills checklist will be added to the QAI Calendar to ensure annual competency occurs. The Technical Program Manager (TPM) will assure that the cited deficiency does not reoccur by auditing the ER-1 weekly until the facility is resurveyed. Frequency of ongoing audits will be determined by the QAI Committee upon review of the audits and resolution of the issue. Ongoing the audits will be conducted monthly as part of the technical audit of the water logs. Any noted non-compliance with this policy will be addressed immediately with the bio-medical personnel involved including corrective action as appropriate. The TPM is responsible to meet monthly with the Clinical Manager prior to the QAI Committee to review and analyze the technical data. The Clinical Manager is responsible to report a summary of audit and log findings monthly in QAI and compliance will be monitored by the QAI Committee.	

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	in August 2012. 6. At 5 PM on 9/26/12, the facility produced another EBCT which indicated the gallons per minute was 2.70 when the gallons per minute on the RO was 11 gallon / minute. Therefore, the calculation was incorrect. The clinical manager evidenced the receipt from the vendor that was dated 8/10/12 which indicated the vendor placed 30 cubic feet of carbon total into the 2 carbon tanks, 15 per tank, and evidenced an EBCT which was adequate with the facilities current gallons per minute flow.			

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V0196	494.40(a) CARBON ADSORP-MONITOR, TEST FREQUENCY 6.2.5 Carbon adsorption: monitoring, testing freq Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours. Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet. Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N.N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L]. Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly. Based on observation, interview, and review of policy and documents, the facility failed to ensure chlorine testing had been completed in accordance with facility policy in 2 of 3 water tests observed on September 26, 2012, creating the potential to affect all of the facility's	V0196	On 9/26/12, the Operations Manager provided immediate education to all staff on existing policies on chlorine monitoring with return demonstrations completed. On 10/4/12, the Technical	10/21/2012

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	116 current patients. The findings include: 1. At 12:40 PM, employee B, a patient care technician (PCT), was observed to complete a routine water test for chlorine using a Ultra - Low Total Chlorine Test strip. She conducted the water test without a timing device to ensure the test strip was in contact with the product water sample for the required amount of time to conduct a valid test. She indicated she counted to 20 to ensure she conducted the test for the correct length of time, she then walked to the treatment floor and handed the strip and document to employee H, a registered nurse, to verify the reading and document on the flow sheet. The employee indicated the timing device in the water room did not work consistently and indicated the timer did not work days earlier when she completed the test. 2. At 1:25 PM, employee C was observed to conduct a water test to determine the availability of total chlorine in the product water. She conducted the water test without a timing device to ensure the test strip was in contact with the product water sample for the required amount of time to conduct a valid test. She indicated she counted to twenty to ensure		Operations Manager met with the Technical Program Manager to discuss the identified technical deficiency. The Technical Operations Manager and Technical Program Manager will arrange and schedule staff in-services to educate all direct patient care staff on all recently adopted Fresenius Medical Care water polices as noted in V 195, specific to chlorine monitoring. Emphasis was placed on allowing the water treatment system to run for a minimum of 15 minutes before performing the test, collecting the appropriate amount of specimen, testing the strip per policy, having a timing device present and including the RN in the reading of the strip. As part of the training a return demonstration of all staff will be done by the Technical Program Manager using the RPC test skills checklist. Training will be completed by 10/21/12 and an in-service attendance sheet will be available in the facility for review. Only those demonstrating competency will be assigned to this task. Ongoing, this skills checklist will be added to the QAI Calendar to ensure annual competency occurs. The Technical Program Manager or his designee will assure that the cited deficiency does not reoccur by directly observing a staff member	

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	she conducted the test for an ample amount of time. 3. The policy dated 3/1/09 titled RPC ULTRA - LOW Total Chlorine Test Strip Procedure" stated, "Only trained personnel will perform the tests for ultra low total chlorine. Technician performing the test and the RN verifying the test are physically present during the time of testing. ... Supplies needed: ... timer with the ability to read ins seconds." 4. The administrative document titled "Chlorine / Chloramines Log Sheet"identified employee G verified the chlorine water test dated 9/3/12 at 4:52 AM, 8:47 AM, and 12:43 PM, 9/6/12 at 9:28 AM and 1:38 PM, 9/10/12 at 8:25 AM and 12:31 PM, 9/15/12 at 5:41 and 9:55 AM and 1:42 PM, and 9/26/12 at 4:43 AM and 8:34 AM. 5. Personnel file A, a PCT, date of hire 6/6/2011, failed to evidence the employee had been trained and competency tested on her ability and accuracy of completing the chlorine water test. 6. Personnel file B, a PCT, date of hire 10/4/07, failed to evidence the employee had been trained and a competency test evaluation had been completed to determine the employee's ability and		perform a chlorine test and document the staff member's proficiency utilizing the RPC test skills checklist daily until the facility is resurveyed. The frequency of ongoing observation of the chlorine skills testing will be determined by the QAI Committee upon review of the audit results and demonstrated proficiency. Any noted non-compliance with this policy will be addressed immediately with the personnel involved including corrective action as appropriate and the staff member will be prohibited from completing the chlorine testing until competency is demonstrated. The Clinical Manager is responsible to report a summary of audit and log findings monthly in QAI and compliance will be monitored by the QAI Committee.	

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	accuracy for completing the total chlorine water testing. The file evidenced the employee participated in a discussion regarding testing the product water for chlorine on 4/25/11. 7. Personnel file C, a PCT, date of hire 6/23/08, failed to evidence the employee had been trained and a competency test evaluation had been completed to determine the employee's ability and accuracy for completing the total chlorine water testing. The file evidenced the employee participated in a discussion regarding testing the product water for chlorine on 4/28/11. 8. Personnel file G, a registered nurse, date of hire 5/7/12, failed to evidence the employee had been trained and competency tested on her ability and accuracy of completing the chlorine water test. 9. Personnel file I, a registered nurse, date of hire 6/9/10, failed to evidence the employee was determined to be competent in his ability and accuracy of completing the total chlorine water test per facility policy. The file evidenced a document titled "Orientation / Skills Checklist" dated 4/25/11 which indicated the water testing was discussed and not performed.			

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	10. On 9/26/12 at 1:25 PM, Employee C indicated Employee D, a water technician, had taught Employee C to check the water for chloramines a few months ago. Employee C indicated the timer had not worked this morning when the chloramines test was performed and was not working now. Employee C indicated counting up to 20 silently to check the time instead of looking at a watch, timer, or clock.			

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V0401	494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment. Based on observation, the facility failed to ensure medications were labeled correctly in 1 of 1 day of observation of the medication preparation area (9/27/12) and disinfection was performed accurately to maintain a safe environment for patients and staff in 1 of 3 days of observations (9/27/12) creating the potential for an unsafe or an unhealthy work environment. The findings include: 1. The undated policy titled "Cleaning and Disinfection of Surfaces and Equipment" policy number 30.06, states, "To provide direction regarding correct cleaning and disinfection of environmental surfaces and equipment to prevent transmission of dangerous pathogens. 1. Any manufacturer's guidance for sterilization or disinfectant of an item will be followed, as well as guidance from the chemical sterilant or disinfectant manufacturer, including appropriate dilution and contact time. 2. At the end of each dialysis treatment, a. All surfaces without, visible blood will be	V0401	The Governing Body met on October 16, 2012 and again on 10/19/12 to review the SOD and to adopt the Bloodborne Pathogen Program and Infection Control Manual and FMS-CS-IC-I-120-040A "Medication Preparation and Administration." On 9/26/12, the Operations Manager met with the Clinical Manager to review and reinforce her requirement to ensure that the facility is utilizing bleach disinfection solutions as required by policy and that all patient care staff members are following policies. ·Effective immediately, the Clinical Manager has added the daily assignment of bleach mixing as part of the facility's patient assignment process As noted above, the Director of Operations arranged for the Education Department to educate all staff, including the home therapies staff on 10/9/12 to the following: ·FMS Blood Borne Pathogen	10/19/2012

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	cleaned following the low level disinfection protocol using soap detergent or detergent germicide. b. For visible blood, the intermediate-level (1:10) disinfection protocol must be followed, which requires the area be immediately cleaned with a cloth soaked with tuberculocidal disinfection following the manufacturer's direction for dilution and contact time ... 6. At the end of each patient treatment, the staff will clean and disinfect the dialysis station. ... The staff will discard all fluids and clean and disinfect all surfaces of the containers associated with the prime waste (including containers attached to the machines) after each treatment. 7. After each treatment, the staff will clean and disinfect medical devices and equipment. Any shared items such as scissors, hemostats, clamps, stethoscopes, and blood pressure cuffs will be cleaned and disinfected between patient uses. If the item is visibly contaminated with blood, an intermediate-level disinfectant will be used. ... 9. Dialysis machine disinfection will be documented, including testing for residual disinfectant." A. On 9/27/12 at 1:05 PM, employee N and employee L presented the results of the testing of the disinfectant solution with "E-Z Chek" potency chlorine test strips. The 3 strips failed to show the		Manual specifically ·Bleach Mixing FMS-CS-IC-II-155-115-C Monitoring of staff compliance to required disinfection with prepared solution has been incorporated into the plan of correction monitoring tool. The Clinical Manager or designee will conduct an infection control audit daily until the facility is resurveyed then weekly. Frequency of ongoing monitoring will be determined by the QAI Committee based on results of monitoring and resolution of the issues. In the event that a staff member is found to not follow the facility procedures for infection control, the Clinical Manager will be notified and is responsible to address the findings with the identified staff member. The Clinical Manager's action will be structured to reinforce by further education following through as necessary with the application of progressive disciplinary action. The Director of Operations met with the facility's Education Coordinator to educate all staff on Medication Preparation and Administration on 10/19/12. Emphasis was placed on properly labeling syringes to include the identity of the nurse preparing the	

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	cleaning solution registered that any chlorine was in the solution used to disinfect the patient stations and dialysis machines between patients in POD 3 of the dialysis in-center unit. B. The facility staff was unable to provide any documentation as to dialysis machine disinfection, including testing for residual disinfectant. 2. Observation on 9/27/12 at 11:15 AM, evidenced 8 - 3 milliliter Heparin syringes for patients #11, 14, 15, and 16 and 5 - 10 milliliter Heparin syringes for patients # 11, 14, 15, 16 and 17 were pre-drawn and lying inside an unlocked bottom shelf of an upper cabinet in the medication preparation area. The heparin syringes failed to identify the nurse who prepared the medication or date/time drawn. 3. On 9/27/12 at 11:30 AM employee L, registered nurse, indicated the heparin must be labeled with initials, time, and date.		syringe, the medication, date/time drawn. Monitoring of staff compliance to correct syringe labeling will be done using the patient safety audit tool. The Clinical Manager or designee will conduct a patient safety audit daily until the facility is resurveyed then weekly. Frequency of ongoing monitoring will be determined by the QAI Committee based on results of monitoring and resolution of the issues. The Clinical Manager will report a summary of findings monthly in QAI with compliance monitored by the QAI Committee.	

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
LIBERTY DIALYSIS LAFAYETTE II	1020 N 18TH ST LAFAYETTE, IN 47904

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V0409	494.60(d)(1) PE-ER PREP STAFF-INITIAL/ANNUAL/INFORM PTS The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following: (i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of- (A) What to do; (B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated; (C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and (D) How to disconnect themselves from the dialysis machine if an emergency occurs. Based on interview and review of administrative documents, policy, and personnel files, the facility failed to ensure the staff were adequately and appropriately trained in emergency plans and procedures specific for the facility and geographical area for 1 of 1 facility with the potential to adversely affect all staff and patients. The findings include:	V0409	On October 16, 2012, the Governing Body met and determined to replace the current Liberty Lafayette Emergency Disaster policies with the FMCNA Emergency Disaster Policies as well as the Facility Specific Disaster Plan. This is documented within the GB Minutes of this date. The Operations Manager met with the facility's staff on 10/19/12 to review their requirements as stated in the Conditions for	10/25/2012

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	1. On 9/26/12 at 3 PM, employee H, a registered nurse, indicated he / she was not aware of a written emergency plan and specific responsibilities of the staff other than to disconnect the patients from treatment. He / she looked about the in - center unit and did not find a plan. 2. On 9/26/12 at 4 PM, the director of nursing evidenced a binder with documents titled "Staff Training and Emergency Review Checklist" and stated, "Liberty Dialysis : As part of personnel training, all staff is expected to review emergency skills quarterly including appropriate documentation of skills review." Each of the documents were initialed by the individual employee and dated. The documents failed to evidence the specific developed and implemented plan for each possible scenario identified for the facility and the responsibilities of each staff member if the emergency occurred. The documentation failed to evidence training or a demonstration of competency expected in the emergency situation. 3. On 9/26/12 at 7 PM, the clinical manager indicated there was no evidence of emergency training for the personnel files reviewed, files A, B, C, G, and H, and there was no evidence of a written emergency plan specific for the facility		Coverage and defined in policy FMS-CS-IC-II-130-014A/C, to ensure that every staff member is oriented and educated on facility specific disaster preparedness On 10/19/12, the Education Coordinator provided an in-service to all staff members reviewing the Lafayette – Facility Specific Disaster Plan. Disaster Drill Observation documentation and attendance sheet are available at the facility. Disaster drills were held on 10/19/12 and 10/25/12, to include participation by staff members' in their specific roles. Documentation of the drills is available within the facility. Ongoing, disaster drills will be held semi-annually per the QAI audit tool. As part of the admission process, each new patient will also be provided disaster education emphasizing what to do, where to go when the geographic area must be evacuated and who to contact in an emergency occurs while the patient is not on dialysis. Semi-annually, each patient will participate in the facility's Disaster Drill with participation documented on the "Patient Participation in Fire and Disaster Drill Form". This form will also be used to document review of the information if a patient was absent on the day of the facility's disaster drill, which will be	

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	and no evidence that all staff were trained in specific procedures and different emergency scenarios. 4. The undated policy titled "Disaster Plan / Emergency Preparedness" stated, "The purpose of this policy is to ensure the facility has a safety plan to follow in the event of a disaster and / or emergency occurring in or around the facility. The plan will provide all employees (to meet OSHA requirements) and patients with information, education and drills so that appropriate actions may be implemented with calm and orderly precision. ... The facility will identify specific emergency situations that may occur within or around the facility: a) The facility will determine the types of emergency situations that may arise due to the nature of the dialysis patient, the location and the nature of the business, and the recommendations of the regulatory agencies responsible for the oversight of the facility. The facility will provide training and education regarding the types of emergency responses to those emergency situations to the staff and patients under the direction of the RN facility manager. The RN facility manager will schedule drills for the types of emergency situations listed. These drills will be randomized as to type and held minimally on an annual basis, documented and critiqued for appropriate		available within the patients chart. Any patient who is not available to participate in a drill will have the drill made up through one on one review with the Clinical Manager or designee. The Clinical Manager will utilize the QAI tool for Disaster Drill Observation tracking of all patients and staff semi-annually to ensure that all patients and staff participated in the facility's disaster drill as evidenced by their participation form and timely signature. New patients will be tracked utilizing the medical record audit form for all new patients monthly to ensure that they have been educated and trained on emergency disaster preparedness within their first month on dialysis. The Clinical Manager is responsible to review the disaster drills identifying any opportunities for improvement and ensuring that all staff members are aware of their roles. This review is to be presented to the QAI Committee quarterly. The Director of Operations is responsible to ensure all documentation required as part of disaster drill process and review is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of	

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	response. "		action plans if needed. The QAI Committee is responsible to analyze the results and determine a root cause analysis then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI Committee.	

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V0410	494.60(d)(1) PE-PT CARE STAFF-CURRENT CPR CERT Staff training must be provided and evaluated at least annually and include the following: Ensuring that, at a minimum, patient care staff maintain current CPR certification Based on interview and review of personnel files, administrative document, and policy, the facility failed to ensure all staff had a current CPR certification for 1 of 3 patient care technician files reviewed (C) and 1 of 2 (H) registered nurse files reviewed of the staff who provided patient care on the in- center treatment floor on 9/26/12 with the potential to affect all patients. The findings include: 1. Personnel file C, a patient care technician, date of hire (DOH) 6/23/08, evidenced a CPR certification that expired July 28, 2012. 2. Personnel file H, a registered nurse, DOH 6/20/10, evidenced an expired CPR card. 3. On 9/26/12 at 5:30 PM, employee M evidenced a roster for a CPR a refresher training session dated 9/26/12, from 12:30 PM to 2:30 PM, with employees C and H as attendees. She indicated she was aware	V0410	The Operations Manager met with the facility's staff on 10/5/12 to review their requirements as stated in the Conditions for Coverage, to ensure that every staff member has a current CPR certification in their education file and to emphasize their responsibility to ensure the CPR certification remains current and documentation is provided to the Clinical Manager on a timely basis. On 9/28/12, the Clinical Manager performed a 100% audit of all personnel files to ensure a current CPR certification is on file. Any staff missing their CPR will be immediately placed in the next available CPR class; all will be current by 10/24/12. The Clinical Manager will utilize the Personnel file tracking tool in the QAI for all staff quarterly to ensure that all staff maintain a current CPR certification. The Clinical Manager is responsible to review the personnel tracking tool quarterly identifying any opportunities for improvement and ensuring that all	10/24/2012

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	the staff CPR were expired. 4. The facility document titled "Job Description and performance evaluation " stated, "Skills required: Registered Nurse: ... Basic Cardiac Life Support (Course C)." 5. The undated policy titled "Emergency Resuscitation (Code)" stated, "All patient care staff are expected to know the resuscitation / code status of the resuscitation statement for any patient in their care. First responder will assess the patient for pulse and respirations and as needed, call for help. The first responding RN will take charge of the resuscitation / code. Assign or assume initiation of CPR."		staff members remain current in CPR. This review is to be presented to the QAI Committee quarterly. The Director of Operations is responsible to ensure all documentation required as part of personnel tracking process and review is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans if needed. The QAI Committee is responsible to analyze the results and determine a root cause analysis then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI Committee.	

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V0411	494.60(d)(1) PE-NURS STAFF TRAINED IN ER EQUIP & MEDS Staff training must be provided and evaluated at least annually and include the following: (iii) Ensuring that nursing staff are properly trained in the use of emergency equipment and emergency drugs. Based on interview and review of personnel files, the facility failed to ensure the staff were adequately and appropriately trained in emergency equipment and use of emergency medications for 3 of 3 patient care technicians (A, B, and C) and 2 of 2 registered nurses (G and H) personnel files reviewed of staff on duty providing direct patient care on the dialysis treatment unit on 9/26/12 with the potential to adversely affect all staff and patients. The findings include: 1. Personnel file A, date of hire 5/31/11, failed to evidence proper training of emergency equipment and procedures within the scope of a patient care technician was provided. 2. Personnel file B, date of hire 10/28/07, failed to evidence proper training of emergency equipment and procedures within the scope of a patient care technician was provided.	V0411	On 10/16/12, the Governing Body met and determined to replace the current Liberty Lafayette Emergency Disaster policies with the FMCNA Emergency Equipment and Procedures. This is documented within the GB Minutes of this date. On 10/19/12, the Education Coordinator provided an in-service to all staff members reviewing the “Patient Emergency Treatment Policy” 138-020-110 and “Emergency Equipment/Supplies” 138-020-120. Mock code observation documentation and attendance sheet are available at the facility. A mock code was held on 10/19/12, to include participation by staff members’ in their specific roles including utilization of emergency equipment and mock administration of emergency drugs per the scope of the personnel. Documentation of the drill is available within the facility. Ongoing, mock codes will be held semi-annually per the QAI audit tool.	10/19/2012

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	3. Personnel file C, date of hire 6/23/08, failed to evidence proper training of emergency equipment and procedures within the scope of a patient care technician was provided. 4. Personnel file G, a registered nurse, date of hire 5/7/12, failed to evidence proper training of emergency equipment and medications. 5. Personnel file H, a registered nurse, date of hire 6/9/10, failed to evidence proper training of emergency equipment and medications. 6. On 9/26/12 at 5:25 PM, employee M indicated there was no further information available.		The Clinical Manager is responsible to review the mock code identifying any opportunities for improvement and ensuring that all staff members are aware of their roles. This review is to be presented to the QAI Committee quarterly. The Director of Operations is responsible to ensure all documentation required as part of mock code process and review is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans if needed. The QAI Committee is responsible to analyze the results and determine a root cause analysis then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI Committee.	

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V0413	494.60(d)(3) PE-ER EQUIP ON PREMISES-02, AED, SUCTION Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available. Based on observations, staff interview, and review of policies and procedures, the facility failed to ensure the emergency (ER) equipment box was updated with current supplies needed in an ER situation in 1 of 1 ER box's observed during the home dialysis tour, creating the potential to effect the 48 home dialysis patients. The findings include: 1. On 09/26/2012 at 12:35 PM, the ER equipment box, in the laboratory of the home dialysis side, evidenced a checklist for supplies such as 1-box of alcohol wipes, 10-Band-Aid, 4-Betadine swab-sticks, 3-nasal cannula, 1-blood pressure cuff (BP), 3-scissor clamps, gloves, 1-box of sterile 4 x 4 gauze, 1-box of sterile 2 x 2 gauze, 2-tourniquets, 1-box masks, 3-microspore tape, 2-1000 milliliter (ml) bags of 0.9 % normal saline, 5-IV catheters, 2-priming sets, 5-3 cc (cubic centimeter) syringes, 5-10 cc syringes, and 1 vial of diphenhydramine 50 mg/ml (milligram per milliliter). The checklist evidenced the ER container had	V0413	The Director of Operations will meet with the facility's staff on 10/5/12 to review their requirements detailed in Fresenius policy "Emergency Equipment/Supplies" to ensure that emergency supplies and medications are maintained at the dialysis facility as determined by the Governing Body under the guidance of the Medical Director. The Home Program Manager under the guidance of the Medical Director will obtain the medications and equipment that is to be kept at the facility for use in the emergency box by 9/28/12. The Home Program Manager will create a checklist by 9/28/12 containing all medications and supplies that are kept in the facility. The supplies and equipment will be checked monthly by the home therapies staff for expiration dates, quantities and that the medications and supplies are covered and locked. The Home Program Manager is responsible to review the	10/05/2012

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	not been the checked since 7/11/11. Further observation evidenced the ER container did not contain 10-Band-Aid, the 3-nasal canulas, the 1-Bp cuff, the 3-scissor clamps, the gloves, the 3-microspore tape, the 5-IV catheters, the 2-priming sets, the 5-3 cc syringes, or the 5-10 cc syringes. The ER box also evidenced 2-Gent-L-Kare IV start kits with an expiration date of 5/2012, 1 box of sterile 4 x 4 gauze with an expiration date of 01/1981, and 2 - 1000 ml bags of 0.9 % normal saline with an expiration date of 8/11. 2. On 09/26/12 at 1:10 PM, employee I, the home dialysis clinical manager, indicated the ER kit had not been checked since 7/2011 and they did not have a policy regarding how often the ER box needed to be checked. The clinical manager further indicated checking the ER box was her responsibility and she would check it now, then further stated, "I can not change the past, just go forward." 3. The facility's undated "Emergency Preparedness" policy #60.02 states, "Non-expired emergency / evacuation supplies, including site dressings, saline, IV tubing, will be available to accommodate evacuated patients."		checklist of the Home program monthly to ensure they audits are occurring. The Home Program Manager is responsible to report a summary of findings monthly to the Clinical Manager and both the Clinical Manager and Home Program Manager are responsible to analyze the data and report to the QAI Committee on a monthly basis. The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.	

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V0506	494.80(a)(3) PA-IMMUNIZATION/MEDICATION HISTORY The patient's comprehensive assessment must include, but is not limited to, the following: Immunization history, and medication history. Based on clinical record and policy review and interview, the facility failed to ensure every patient was screened and monitored for tuberculosis as part of the comprehensive assessment for 1 of 12 clinical records reviewed (10) with the potential to affect all staff and patients. The findings include: 1. Clinical record # 10 evidenced the patient began treatment on 6/29/12. The record failed to evidence the patient was screened for tuberculosis by a tuberculin skin test or chest x - ray. 2. The undated policy titled "Patient Assessment" stated, "The comprehensive assessment ... will include: ... evaluation of current health status nd medical condition, including ... c morbid conditions, ... immunization history." 3. On 9/28/12 at 1:25 PM, employee M reviewed the clinical record and indicated there was no evidence of a tuberculosis screening.	V0506	The Governing Body met on October 16, 2012 and determined to adopt FMS-CS-IC-II-155-160A "Facility Tuberculosis Risk Assessment" and FMS-CS-IC-II-155-170A "Patient Tuberculin Skin Testing Mantoux emphasizing that the facility's "risk assessment" must be determined to ensure compliance with subsequent policies. This task was given to the Operations Manager and will be documented within the GB Minutes. The Operations Manager met with the facility's Interdisciplinary Team on 10/19/12 to review their requirements as stated in the Conditions for Coverage, to ensure that every patient will have a timely, complete and current Comprehensive Assessment and Plan of Care completed and available within their medical record that meets all criteria including an assessment of the patient's immunization history emphasizing screening and monitoring for tuberculosis. The nursing staff was educated on 10/9/12 by the Education Coordinator on the recently adopted policies,	11/05/2012

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			FMS-CS-IC-II-155-160A "Facility Tuberculosis Risk Assessment" and FMS-CS-IC-II-155-170A "Patient Tuberculin Skin Testing Mantoux." Emphasis was placed on ensuring that all new admissions are tested for TB. The Clinical Manager and Home Program Manager completed 100% review of all current patients' Comprehensive Assessments by 10/19/12 to ensure that all Assessments include a medication and immunization review that is complete and current and included screening for tuberculosis. Any patient's Assessment found to be missing tuberculosis screening including patients # 10 will be presented to the IDT for completion by 11/5/12 including obtaining orders for patient testing as necessary. The Clinical Manager and Home Program Manager will utilize the QAI tool for Assessment and Care-Plan tracking of all patients monthly to ensure that timely completion of all patients' immunization history as part of their Comprehensive Assessment. The Clinical Manager and Home Program Manager are responsible to report a summary of findings monthly utilizing the tracking tool as noted above to include the number of Assessments due focusing on the immunization history, those completed and those missed to the QAI. Any patient missing any	

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			component of the Assessment will be scheduled for completion the following month and corrective action will be taken as appropriate. The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI Committee and Governing Body.	

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V0517	494.80(b)(2) PA-F/U REASSESSMENT-WITHIN 3 MO OF INITIAL A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in §494.90. Based on clinical record review, policy review, and interview, the facility failed to ensure the reassessment occurred within 3 months after the completion of the initial assessment for 1 of 12 records reviewed (#6) with the potential to affect all the facility's new patients. Findings 1. Clinical record #6, start of care 5/28/11, evidenced an initial plan of care on 6/24/11. The 90 day assessment did not occur until 12/12/11. 2. The policy titled "Patient Assessment" with no effective date stated, "New patients (all admissions to the dialysis facility, including patients returning to dialysis from a failed transplant or changing modalities) ... within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care." 3. On 9/28/12 at 3:50 PM, Employee L, Home Care Manager and Registered	V0517	The Director of Operations met with the facility's Interdisciplinary Team on 10/19/12 to review their requirements as stated in the Conditions for Coverage and detailed in Lafayette policy "Patient Assessment", to ensure that every new patient, unstable patient and any patient with a modality change will have a timely, complete and current Comprehensive Re- Assessment and New Plan of Care available within their medical record that meets all criteria emphasizing the requirement that all patients must have a Comprehensive Reassessment within 3 months after the completion of the initial assessment. On 10/8/12, the RQM met with the Clinical Manager to review the QAI Patient Assessment and Plan of Care tracking tools to ensure the CM is knowledgeable as to how to utilize the tracking tools to ensure compliance. The Clinical Manager and Operations Manager completed 100% review of all patients' Comprehensive Assessments by 10/19/12 to ensure that all re-assessments that were due have been completed and are current. Any	11/05/2012

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	Nurse, indicated the 90 day assessment and plan of care were late.		patient's reassessment found to be out of compliance including patient #6 will be presented to the IDT for completion by 11/5/12. The Clinical Manager will utilize the QAI tool for Assessment and Care-Plan tracking of all patients monthly to ensure the timely completion of any new patients, unstable patients, Re-Assessments and annual reviews for stable patients. The Clinical Manager is responsible to report a summary of findings monthly utilizing the tracking tool as noted above to include the number of Re-assessments due, completed and missed to the QAI. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.	

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V0586	494.100(b)(1) H-PT/CAREGIVER DEMO COMPREHEND TRAINING The dialysis facility must - (1) Document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training; Based on policy review and clinical record review and interview, the facility failed to ensure documentation was in the medical record that the caregivers in the extended care facility (ECF) who completed the peritoneal dialysis had received training and demonstrated adequate comprehension of the training for 2 of 2 clinical records reviewed of patients who received dialysis in the ECF with the potential to affect all 4 dialysis patients that reside in an extended care facility. (# 5 and 6) Findings include 1. Clinical record #5, start of care 2/25/12, evidenced the patient resided in an ECF and the facility staff were completing the patient's peritoneal dialysis beginning 2/25/12. The clinical record failed to evidence the staff of the ECF were trained and had adequate comprehension of the training. On 9/28/12 at 12:15 PM, Employee L, Registered Nurse and manager of the	V0586	The Director of Operations met with the facility's home therapies staff on 10/5/12 to review the requirements as stated in the Conditions for Coverage, to ensure that every home patient residing in an ECF is receiving treatments from qualified staff in PD. The Home Program Manager will be providing on-site training for the ECF staff of each facility that houses the home patients and are designated as caregivers to provide dialysis. A return demonstration will be done for each of the ECF staff and maintained by the Home Program Manager. All training will be completed by 11/3/12. The ECF agrees that only trained staff who have been signed off with skills and competency checks will provide dialysis to home patients. The Home Program Manager has created a binder with contact information for each of the ECF. The Home Program Manager will contact the ECF on a quarterly basis to obtain a list of any new staff members since the last training session. New staff	11/23/2012

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	Home Care Dialysis program, indicated the caregivers at the ECF had not completed training and demonstrated adequate comprehension of the training. 2. Clinical record #6, start of care 5/28/11, evidenced the patient resided in an ECF and the facility staff were completing the patient's peritoneal dialysis beginning 5/28/11. The clinical record failed to evidence the staff of the ECF were trained and had adequate comprehension of the training. On 9/28/12 at 3:30 PM, Employee L indicated the caregivers at the ECF had not completed training and demonstrated adequate comprehension of the training. 3. The policy titled "Medical Records - Home PD" with a review date of 12/02/07 stated, "All medical record documentation will include: ... Evidence that the patient / helper demonstrated competence in performing the home dialysis procedures."		members will not provide dialysis as caregivers until training is received and competency is documented Training classes with return demonstration will be scheduled on an as needed basis. The ECF has agreed to contact the Home Program Manager as needed if staffing issues arise within a quarter. The Home Program Manager has added to the QAI calendar the need for annual skills checks and competency exams for all ECF staff. The Home Program Manager will complete 100% chart audit of all patient's monthly visit sheets by 10/26/12 to ensure that all patients have been reviewed at a minimum of every two months and have documentation showing that their home record sheets are complete, include a signature of the ECF staff member providing care and that the signature of the staff member providing the care has been documented to have completed a skills and competency check, Any patient documentation found out of compliance, including patient's # 5 and 6 will be reviewed at the next monthly clinic visit on 11/23/12. The Home Program Manager is responsible to report a summary of findings monthly utilizing the medical record audit tool to the	

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			QAI committee. The Director of Operations is responsible to ensure that the ECF is maintaining documents timely and evidencing trained caregivers. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.	

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V0587	494.100(b)(2),(3) H-FAC RECEIVE/REVIEW PT RECORDS Q 2 MONTHS The dialysis facility must - (2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and (3) Maintain this information in the patient ' s medical record. Based on clinical record and policy review and interview, the facility failed to ensure had retrieved and reviewed the flow sheets for patient care maintained by the ECF caregivers for 2 of 2 peritoneal dialysis patients residing in the same extended care facility (ECF) with the potential to affect all the patients who reside in ECF facilities. (5 and 6) Findings 1. Clinical record #5, start of care 2/25/12, failed to evidence flow sheets after 8/2/12 and were not complete from 6/2/12 - 8/1/12. Caregiver notes were present from 6/2/11 - 6/11/12, 7/1/12 - 7/8/12, and 8/1/12 - 8/13/12, but no caregiver signature were present. On 9/28/12 at 10:25 AM, Employee L indicated there were no treatment records after 8/2/12 and the treatment records were not complete for 6/2/12 - 8/1/12. 2. Clinical record #6, start of care	V0587	The Director of Operations met with the facility's patient care staff on 10/5/12 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care", to ensure that every home patients' records/treatment sheets will be retrieved from the patients and/or the ECF providing care for the residents in the ECF at least every two months. Upon receipt of treatment documentation, the Home Program Manager is responsible to immediately review the treatment data ensuring it is appropriate and notify the physician for any abnormal findings. Emphasis was placed that the records must be complete and signed. The Home Program Manager will complete 100% chart audit of all patient's monthly visit sheets by 10/26/12 to ensure that all patients have documentation showing that their home record sheets have been retrieved at a minimum of every two months,	11/23/2012

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NAME OF PROVIDER OR SUPPLIER LIBERTY DIALYSIS LAFAYETTE II		STREET ADDRESS, CITY, STATE, ZIP CODE 1020 N 18TH ST LAFAYETTE, IN 47904	

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	5/25/11, failed to evidence flow sheets were complete from 6/2/12 - 8/13/12. Caregiver flow sheets were present from 6/6/12 - 7/11/12, 7/14/12 - 7/17/12, 8/1/12 - 8/4/12, and 8/11/12 - 8/13/12. No other flow sheets were evidenced for these time frames. No caregiver signatures were present. On 9/28/12 at 3 PM, Employee L indicated the treatment records were not complete from 6/2/12 - 8/13/12. 3. The facility policy titled "Peritoneal Dialysis Recordkeeping" with no effective date stated, "Complete self-monitoring data and other information from self-care patients or their designated caregivers will be provided to the home training nurse to review at least every 2 months; and will be filed in patient's medical record. 4. The facility policy titled "Medical Records - Home PD" with no effective date stated, "The facility is responsible to assure that records of dialysis treatments in the home setting are retrieved and reviewed by the appropriate and reviewed by the appropriate personnel at least every 2 months. Such review assists staff in monitoring home patients' status by determining if patients are following treatments and / or having problems with their dialysis at home."		are complete including the signature of the caregiver and have been reviewed by the Home Program Manager or designee upon receipt Any patients' records found out of compliance, including patient's # 5 and 6 will be retrieved and reviewed at the next monthly clinic visit on 11/23/12. The Home Program Manager is responsible to report a summary of findings monthly utilizing the medical record audit tool to the Clinical Manager prior to the monthly QAI Committee. The Clinical Manager or Home Program Manager is responsible to analyze the data and present to the monthly QAI Committee for review. If records are not available from the ECF, the Home Program Manager will escalate this to the Director of Operations who will address directly with the ECF. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.	

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V0625	494.110 CFC-QAPI Based on administrative record, clinical record, and facility policy review and interview, it was determined the facility failed to ensure a quality assessment and performance improvement program was in place that included the identification and resolution of infection control practice noncompliance and the management of patients with diagnosis of MRSA of their peritoneal access resulting in the continued noncompliance with infection control policies and procedures and the mismanagement of patients diagnosed with MRSA creating the potential to affect all of the facility's 116 current patients (See V 627); failed to ensure a quality assessment and performance improvement program was in place that identified noncompliant infection control practices and current infections of all patients to prevent the cross contamination to staff and patients with compromised immune systems and at the same time creating the potential to affect all of the facility's 116 current patients and staff (See V 637); failed to ensure a quality assessment and performance improvement program was in place that systematically monitored infection control practices, resulting in noncompliance with infection control policies and procedures creating the	V0625	The Governing Body acknowledges its responsibility to ensure that Liberty Dialysis Lafayette has an effective, data driven Comprehensive Quality Assessment and Performance Improvement program that includes participation of all members of the Interdisciplinary Team and ensures the identification and resolution of infection control practice noncompliance and the management of patients diagnosed with MRSA. The Governing Body, on 10/16/12 reviewed the SOD and developed the following Plan of Correction ensuring that the deficiencies are addressed, both immediately and with long term resolution. The following action steps were implemented The Governing Body will meet weekly to monitor the progress of the Plan of Correction until the Condition level deficiencies are lifted, then monthly for an additional three months to ensure that the corrective actions have resulted in resolution of the cited issues. Once this is determined, the Governing Body will return to quarterly or as needed meetings. Effective immediately: · The Clinical Manager (CM) will analyze and trend all data and monitoring/audit results as related	10/16/2012

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	potential to affect all the the facility's 116 current patients; and failed to ensure a quality assessment and performance improvement program was in place that systematically monitored infection control practices, resulting in noncompliance with infection control policies and procedures and staff caring active infections and susceptible patients creating the potential to affect all the the facility's 116 current incenter patients (See V 640). The cumulative effect of these systemic problems resulted in the facility's inability to meet the requirements of the Condition for Coverage 494.110: Quality Assessment and Performance Improvement.		to this Plan of Correction prior to presenting the monthly data to the QAI Committee. · A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda. · The QAI Committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution. · The Director of Operations (DO) will present a report on the Plan of Correction data and all actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. · The Governing Body, at its meeting of 10/16/12, designated the Regional Quality Manager to serve as Plan of Correction Monitor and provide additional oversight. She will actively participate in each QAI and Governing Body meeting - either personally or via conference call - and submit a status report at each of the referenced Governing Body meetings with a copy to the RVP. This additional oversight is to ensure the ongoing correction of deficiencies - as cited in the Statement of Deficiency - through to resolution as well as ensure the Governance of the facility is presented current and complete	

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			data to enhance their governance oversight role · Minutes of the Governing Body and QAI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's direction and oversight and the QAI Committee's ongoing monitoring of facility activities. These are available for review at the facility. · The responses provided for V 627, V 637, V 638 and V 640 describe, in detail, the processes and monitoring steps taken to ensure that all deficiencies as cited within this Condition are corrected to ensure ongoing compliance	

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V0627	494.110(a)(1) QAPI-ONGOING;USES INDICATORS=IMPROVEMENT The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.			
	Based on administrative record, clinical record, and facility policy review and interview, the facility failed to ensure a quality assessment and performance improvement (QAPI) program was in place that included the identification and resolution of infection control practice noncompliance and the management of patients with diagnosis of active MRSA infections of their peritoneal access sites resulting in the continued noncompliance with infection control policies and procedures and creating the potential to affect all of the facility's 116 current patients. The findings include: 1. The facility's QAPI meeting minutes dated June 2012 indicated the facility had 1 catheter infection in April and 3 catheter infections during the month of May. 2. The facility's QAPI meeting minutes dated July 2012 indicated there were no	V0627	On October 8, 2012, the Governing Body determined to replace the current Liberty Lafayette QAI Process with the adoption of the FMCNA QAI Program including the policies, templates, Minutes and audits. On October 8, 2012 the Regional Quality Manager held a meeting with all participants of the QAI Committee for the purpose of education on the FMS QAI Program. This education included but was not limited to the following: · Review of the 2012 QAPI Program including the required outcomes, QAI Calendar, use of the Minutes template · Review of the process to identify, evaluate, trend, develop plans of correction and monitor results as related to all outcomes. · Outcomes and requirements specific to o Infection tracking tool analysis o Identification and resolution of infection control practice	11/20/2012

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	infections of fistulas, grafts, or catheters. 3. The facility's QAPI meeting minutes dated August 21, 2012, stated, "In-center had 5 catheter infections, ... did an audit on the staff members and the audit was not very good. Reeducate staff about infection control. ... No infections in the home program. ... Action plan in place ... infections." A. A document titled "QAPI Action Plan" dated July 19, 2012, was attached to the QAPI minutes and stated, "Problem : Catheter Infections. Goal: To prevent any further infections. Action Plan: ... Rounds with housekeeping . ... Review P & P [policy and procedure] with staff and complete checklist with all DCP [direct care providers]. Perform weekly audits / disciplinary action to be taken for anyone not following P & P." B. The administrative documents titled "Infection And Exposure Control" were presented and reviewed. There were seven documents. 1) Two of these documents were not dated and there was no identifier for the auditor and the individual being evaluated. The tool did indicate 9 patient		noncompliance o Analysis and tracking of catheter infections o Proper use and documentation of monitoring tools o Follow up with created action plans The QAI Committee will analyze the last 6 months of infection analysis and infection control practice noncompliance at the QAI Meeting on 11/20/12 to update the Minutes with the current status as evidenced by trends and log reports including re-evaluation of catheter infections and tracking systems and home patients diagnosed with MRSA. The Governing Body will also perform an audit of the QAI minutes from 2012 to ensure that there are no other areas in need of improvement and to recognize any negative trends of any outcomes. If identified, the Governing Body will ensure that a root cause analysis of these trends is completed and an action plan developed. This will be evidenced in both the QAI and Governing Body Minutes within the facility. The Clinical Manager is responsible to report a summary of trending and analysis of infections, infection control practice non-compliance and	

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	care technicians were observed and 7 of the nine did not complete hand hygiene when necessary and other non specific infection control breaks. 2) Three of these "tools" were dated 7/23/12 through 7/25/12 and did not reveal who completed the audit and who was evaluated. The tool revealed the auditor observed a break in infection control practices, but it was not clear what those breaks were. 3) Another tool was dated 7/23/12 and identified the breaks in infection control practices during patient care was hand hygiene. This tool did not identify the auditor or the individual evaluated. 4) Another tool was dated 7/24/12 and 7/26/12 and identified the auditor was employee I and indicated 3 unnamed staff were observed and problems with infection control practices was identified. 4. An undated administrative document titled "Meeting Agenda" stated, "Infection Control: result of infection control audit - poor." An attached sign in sheet indicated		action plan follow up to the QAI and Medical Director. The Director of Operations is responsible to monitor the QAI data monthly to ensure the Clinical Manager is presenting all trending and documentation as required. The QAI Committee and Medical Director are responsible to analyze the data, determine a root cause analysis if trending identifies infections or infection control practices that are outside of target and ensure action plans are in place and resolution is occurring. The Governing Body is responsible to provide oversight to the QAI Committee to ensure the Committee is fulfilling its role in the identification, analysis, development of actions plans and monitoring improvement for all desired outcomes.	

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	this meeting occurred on 7/26/12. 5. On 9/28/12 at 11:10 AM, employee M indicated there was an audit of the infection control practices of the staff in July 2012 and problems were identified. She said there was no documentation to evidence the problems and concerns had been addressed. 6. Clinical record # 8 evidenced the patient was a home dialysis patient and had visited the clinic routinely for clinic visits 1 - 2 times a month for the past 9 months, January through September 2012. A visit note dated 9/17/12, documented by employee U, a home program registered nurse, stated, "Pt [patient] here for nurse visit. [Employee M] to see and to complete care plan assessment. When exit site assessed, writer called into room. Pt. [patient] reported no problems with exit site, but is red and has small amount of drainage." The record evidenced a laboratory report dated 9/22/12 that stated, "Culture Wound ... MRSA." 7. Clinical record # 9 evidenced a visit note dated 6/11/12, documented by employee U, a home program registered			

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	nurse, that stated, "Pt [patient] here ... for flush. ... Exit site pink - dime to nickel size." This was the first patient visit to the home program. The record evidenced the patient received services from the home training department, employee U was the primary nurse, and CAPD training began 7/2/12. The record evidenced the patient was diagnosed with MRSA on September 7, 2012. 8. On 9/28/12 at 10:30 AM, employee L confirmed the home program had two patients, # 8 and 9, who developed methicillin resistant staphylococcus aureus (MRSA) at their peritoneal access site. She said she did not review or investigate as to how or why the two patients may have contracted the infection and she did not look at the infection control practices of the staff and housekeeping to determine if the infections were from poor infection control practices and a contamination. 9. The facility's undated policy titled "Infection Control" stated, "To ensure the facility will provide and monitor a sanitary environment to minimize the transmission of infectious agents. within and between the facility and the public area. ... Infection control requirements			

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	apply to both the chronic dialysis facility in-center and the home dialysis program. ... Infection control in-services will be conducted annually and when there is a need."			

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V0637	494.110(a)(2)(ix) QAPI-INDICATOR-INF CONT-TREND/PLAN/ACT The program must include, but not be limited to, the following: (ix) Infection control; with respect to this component the facility must- (A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence; (B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and (C) Take actions to reduce future incidents. Based on administrative record, facility policy and clinical record review and interview, the facility failed to ensure a quality assessment and performance improvement (QAPI) program was in place that identified noncompliant infection control practices and current infections of all patients to prevent the cross contamination and minimize infection transmission to staff and patients with compromised immune systems and creating the potential to affect all of the facility's 116 current patients and all staff. The findings include: 1. The facility's QAPI meeting minutes dated June 2012 indicated the facility had 1 catheter infection in April and 3 catheter infections during the month of May. 2. The facility's QAPI meeting minutes	V0637	As noted in detail in V 627, the Governing Body of the Liberty Lafayette facility has directed the adoption of the FMCNA QAI Program to include policies/procedures, Minutes, audit templates and QAI Calendar. As noted above, the QAI Committee has been re-educated on all policies and steps have been instituted to identify and trend non-compliance as noted in infection tracking processes, inconsistencies in infection tracking data, staff members' infection control practice breaches and action plan follow up. The Clinical Manager is responsible to report a summary of trending and analysis of infections and infection control practice non-compliance monthly to the QAI and Medical Director.	10/08/2012

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	dated July 2012 indicated there were no infections of fistulas, grafts, or catheters. 3. The facility's QAPI meeting minutes dated August 21, 2012, stated, "In-center had 5 catheter infections, ... did an audit on the staff members and the audit was not very good. Reeducate staff about infection control. ... No infections in the home program. ... Action plan in place ... infections." A. A document titled "QAPI Action Plan" dated July 19, 2012, was attached to the QAPI minutes and stated, "Problem : Catheter Infections. Goal: To prevent any further infections. Action Plan: ... Rounds with housekeeping . ... Review P & P [policy and procedure] with staff and complete checklist with all DCP [direct care providers]. Perform weekly audits / disciplinary action to be taken for anyone not following P & P." B. The administrative documents titled "Infection And Exposure Control" were presented and reviewed. There were seven documents. 1) Two of these documents were not dated and there was no identifier for the auditor and the individual being		The Director of Operations is responsible to monitor the QAI data monthly to ensure the Clinical Manager is presenting all trending and documentation as required. The QAI Committee and Medical Director are responsible to analyze the data, determine a root cause analysis if trending identifies infections and infection control practices that are outside of target and ensure action plans are in place and resolution is occurring. The Governing Body is responsible to provide oversight to the QAI Committee to ensure the Committee is fulfilling its role in the identification, analysis, development of actions plans and monitoring improvement for all desired outcomes.	

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	evaluated. The tool did indicate 9 patient care technicians were observed and 7 of the nine did not complete hand hygiene when necessary and other non specific infection control breaks. 2) Three of these "tools" were dated 7/23/12 through 7/25/12 and did not reveal who completed the audit and who was evaluated. The tool revealed the auditor observed a break in infection control practices, but it was not clear what those breaks were. 3) Another tool was dated 7/23/12 and identified the breaks in infection control practices during patient care was hand hygiene. This tool did not identify the auditor or the individual evaluated. 4) Another tool was dated 7/24/12 and 7/26/12 and identified the auditor was employee I and indicated 3 unnamed staff were observed and problems with infection control practices was identified. 4. An undated administrative document titled "Meeting Agenda" stated, "Infection Control: result of infection control audit -			

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	poor." An attached sign in sheet indicated this meeting occurred on 7/26/12. 5. On 9/28/12 at 11:10 AM, employee M indicated there was an audit of the infection control practices of the staff in July 2012 and problems were identified. She said there was no documentation to evidence the problems and concerns had been addressed. 6. Clinical record # 8 evidenced the patient was a home dialysis patient and had visited the clinic routinely for clinic visits 1 - 2 times a month for the past 9 months, January through September 2012. A visit note dated 9/17/12, documented by employee U, a home program registered nurse, stated, "Pt [patient] here for nurse visit. [Employee M] to see and to complete care plan assessment. When exit site assessed, writer called into room. Pt. [patient] reported no problems with exit site, but is red and has small amount of drainage." The record evidenced a laboratory report dated 9/22/12 that stated, "Culture Wound ... MRSA." 7. Clinical record # 9 evidenced a visit note dated 6/11/12, documented by			

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	employee U, a home program registered nurse, that stated, "Pt [patient] here ... for flush. ... Exit site pink - dime to nickel size." This was the first patient visit to the home program. The record evidenced the patient received services from the home training department, employee U was the primary nurse, and CAPD training began 7/2/12. The record evidenced the patient was diagnosed with MRSA on September 7, 2012. 8. On 9/28/12 at 10:30 AM, employee L confirmed the home program had two patients, # 8 and 9, who developed methicillin resistant staphylococcus aureus (MRSA) at their peritoneal access site. She said she did not review or investigate as to how or why the two patients may have contracted the infection and she did not look at the infection control practices of the staff and housekeeping to determine if the infections were from poor infection control practices and a contamination. 9. The facility's undated policy titled "Infection Control" stated, "To ensure the facility will provide and monitor a sanitary environment to minimize the transmission of infectious agents. within and between the facility and the public			

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	area. ... Infection control requirements apply to both the chronic dialysis facility in-center and the home dialysis program. ... Infection control in-services will be conducted annually and when there is a need."			

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V0638	494.110(b) QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time. Based on administrative record, clinical record, and policy review and interview, the facility failed to ensure a quality assessment and performance improvement (QAPI) program was in place that systematically monitored infection control practices, resulting in noncompliance with infection control policies and procedures creating the potential to affect all the the facility's 116 current patients. The findings include: 1. The facility's QAPI meeting minutes dated June 2012 indicated the facility had 1 catheter infection in April and 3 catheter infections during the month of May. 2. The facility's QAPI meeting minutes dated July 2012 indicated there were no infections of fistulas, grafts, or catheters. 3. The facility's QAPI meeting minutes dated August 21, 2012, stated, "In-center had 5 catheter infections, ... did an audit on the staff members and the audit was	V0638	On October 8, 2012, the Regional Quality Manager scheduled a meeting with all participants of the QAI committee for the purpose of education on the QAI process. This education included but was not limited to the following: ·QAI Processes ·Infection control reporting, analysis and the identification of trends ·Instituting timely action plans with monthly follow up of action plans and interceding if data does not show resolution The Clinical Manager is responsible to review all infection control audits and infection tracking and analysis tools monthly. Reports will be analyzed and any identified as not meeting an outcome will have an action plan developed and followed monthly. The Clinical Manager is responsible to report a summary of findings monthly. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance	10/08/2012

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	not very good. Reeducate staff about infection control. ... No infections in the home program. ... Action plan in place ... infections." A. A document titled "QAPI Action Plan" dated July 19, 2012, was attached to the QAPI minutes and stated, "Problem : Catheter Infections. Goal: To prevent any further infections. Action Plan: ... Rounds with housekeeping . ... Review P & P [policy and procedure] with staff and complete checklist with all DCP [direct care providers]. Perform weekly audits / disciplinary action to be taken for anyone not following P & P." B. The administrative documents titled "Infection And Exposure Control" were presented and reviewed. There were seven documents. 1) Two of these documents were not dated and there was no identifier for the auditor and the individual being evaluated. The tool did indicate 9 patient care technicians were observed and 7 of the nine did not complete hand hygiene when necessary and other non specific infection control breaks. 2) Three of these "tools" were		will be monitored by the QAI committee.	

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	dated 7/23/12 through 7/25/12 and did not reveal who completed the audit and who was evaluated. The tool revealed the auditor observed a break in infection control practices, but it was not clear what those breaks were. 3) Another tool was dated 7/23/12 and identified the breaks in infection control practices during patient care was hand hygiene. This tool did not identify the auditor or the individual evaluated. 4) Another tool was dated 7/24/12 and 7/26/12 and identified the auditor was employee I and indicated 3 unnamed staff were observed and problems with infection control practices was identified. 4. An undated administrative document titled "Meeting Agenda" stated, "Infection Control: result of infection control audit - poor." An attached sign in sheet indicated this meeting occurred on 7/26/12. 5. On 9/28/12 at 11:10 AM, employee M indicated there was an audit of the infection control practices of the staff in July 2012 and problems were identified.			

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	She said there was no documentation to evidence the problems and concerns had been addressed. 6. Clinical record # 8 evidenced the patient was a home dialysis patient and had visited the clinic routinely for clinic visits 1 - 2 times a month for the past 9 months, January through September 2012. A visit note dated 9/17/12, documented by employee U, a home program registered nurse, stated, "Pt [patient] here for nurse visit. [Employee M] to see and to complete care plan assessment. When exit site assessed, writer called into room. Pt. [patient] reported no problems with exit site, but is red and has small amount of drainage." The record evidenced a laboratory report dated 9/22/12 that stated, "Culture Wound ... MRSA." 7. Clinical record # 9 evidenced a visit note dated 6/11/12, documented by employee U, a home program registered nurse, that stated, "Pt [patient] here ... for flush. ... Exit site pink - dime to nickel size." This was the first patient visit to the home program. The record evidenced the patient received services from the home training department, employee U was the primary nurse, and CAPD			

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	training began 7/2/12. The record evidenced the patient was diagnosed with MRSA on September 7, 2012. 8. On 9/28/12 at 10:30 AM, employee L confirmed the home program had two patients, # 8 and 9, who developed methicillin resistant staphylococcus aureus (MRSA) at their peritoneal access site. She said she did not review or investigate as to how or why the two patients may have contracted the infection and she did not look at the infection control practices of the staff and housekeeping to determine if the infections were from poor infection control practices and a contamination. 9. The facility's undated policy titled "Infection Control" stated, "To ensure the facility will provide and monitor a sanitary environment to minimize the transmission of infectious agents. within and between the facility and the public area. ... Infection control requirements apply to both the chronic dialysis facility in-center and the home dialysis program. ... Infection control in-services will be conducted annually and when there is a need."			

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V0640	494.110(c) QAPI-QAPI-IMMEDIATELY CORRECT ANY IJ ISSUES The facility must immediately correct any identified problems that threaten the health and safety of patients. Based on administrative record, clinical record, and facility policy review and interview, the facility failed to ensure a quality assessment and performance improvement (QAPI) program was in place to identify and correct noncompliant infection control practices and creating the potential to affect all of the facility's 116 current patients. The findings include: 1. The facility's QAPI meeting minutes dated June 2012 indicated the facility had 1 catheter infection in April and 3 catheter infections during the month of May. 2. The facility's QAPI meeting minutes dated July 2012 indicated there were no infections of fistulas, grafts, or catheters. 3. The facility's QAPI meeting minutes dated August 21, 2012, stated, "In-center had 5 catheter infections, ... did an audit on the staff members and the audit was not very good. Reeducate staff about infection control. ... No infections in the home program. ... Action plan in place ... infections."	V0640	As noted above in detail in V 627, 637 and 638 – that effective immediately, the facility has adopted the FMCNA Quality Improvement Program and all members of the QAI Committee have been trained. Documentation is available within the QAI Minutes. On October 8, 2012, the Regional Quality Manager scheduled a meeting with all participants of the QAI committee for the purpose of addressing the requirement that the facility must take immediate action when identified problems that threaten the health and safety of patients occur. Education further notes those types of “immediate threats” that warrant immediate action as defined in the Conditions for Coverage. The facility QAI Committee is currently analyzing the last 6 months of infection analysis and infection control practice noncompliance at the QAI Meeting on 11/20/12 to update the Minutes with the current status as evidenced by trends and log reports including re-evaluation of catheter	11/20/2012

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	A. A document titled "QAPI Action Plan" dated July 19, 2012, was attached to the QAPI minutes and stated, "Problem : Catheter Infections. Goal: To prevent any further infections. Action Plan: ... Rounds with housekeeping . ... Review P & P [policy and procedure] with staff and complete checklist with all DCP [direct care providers]. Perform weekly audits / disciplinary action to be taken for anyone not following P & P." B. The administrative documents titled "Infection And Exposure Control" were presented and reviewed. There were seven documents. 1) Two of these documents were not dated and there was no identifier for the auditor and the individual being evaluated. The tool did indicate 9 patient care technicians were observed and 7 of the nine did not complete hand hygiene when necessary and other non specific infection control breaks. 2) Three of these "tools" were dated 7/23/12 through 7/25/12 and did not reveal who completed the audit and who was evaluated. The tool revealed the		infections and tracking systems and home patients diagnosed with MRSA. The Governing Body will also perform an audit of the QAI minutes from 2012 to ensure that there are no other areas in need of improvement and to recognize any negative trends of any outcomes. If identified, the Governing Body will ensure that a root cause analysis of these trends is completed and an action plan developed.	

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	auditor observed a break in infection control practices, but it was not clear what those breaks were. 3) Another tool was dated 7/23/12 and identified the breaks in infection control practices during patient care was hand hygiene. This tool did not identify the auditor or the individual evaluated. 4) Another tool was dated 7/24/12 and 7/26/12 and identified the auditor was employee I and indicated 3 unnamed staff were observed and problems with infection control practices was identified. 4. An undated administrative document titled "Meeting Agenda" stated, "Infection Control: result of infection control audit - poor." An attached sign in sheet indicated this meeting occurred on 7/26/12. 5. On 9/28/12 at 11:10 AM, employee M indicated there was an audit of the infection control practices of the staff in July 2012 and problems were identified. She said there was no documentation to evidence the problems and concerns had been addressed.			

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	6. Clinical record # 8 evidenced the patient was a home dialysis patient and had visited the clinic routinely for clinic visits 1 - 2 times a month for the past 9 months, January through September 2012. A visit note dated 9/17/12, documented by employee U, a home program registered nurse, stated, "Pt [patient] here for nurse visit. [Employee M] to see and to complete care plan assessment. When exit site assessed, writer called into room. Pt. [patient] reported no problems with exit site, but is red and has small amount of drainage." The record evidenced a laboratory report dated 9/22/12 that stated, "Culture Wound ... MRSA." 7. Clinical record # 9 evidenced a visit note dated 6/11/12, documented by employee U, a home program registered nurse, that stated, "Pt [patient] here ... for flush. ... Exit site pink - dime to nickel size." This was the first patient visit to the home program. The record evidenced the patient received services from the home training department, employee U was the primary nurse, and CAPD training began 7/2/12. The record evidenced the patient was diagnosed with MRSA on September 7, 2012.			

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	8. On 9/28/12 at 10:30 AM, employee L confirmed the home program had two patients, # 8 and 9, who developed methicillin resistant staphylococcus aureus (MRSA) at their peritoneal access site. She said she did not review or investigate as to how or why the two patients may have contracted the infection and she did not look at the infection control practices of the staff and housekeeping to determine if the infections were from poor infection control practices and a contamination. 9. The facility's undated policy titled "Infection Control" stated, "To ensure the facility will provide and monitor a sanitary environment to minimize the transmission of infectious agents. within and between the facility and the public area. ... Infection control requirements apply to both the chronic dialysis facility in-center and the home dialysis program. ... Infection control in-services will be conducted annually and when there is a need."			

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V0715	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 interview, observation, and review of facility policy, medical records, medication documents, and personnel records, the medical director failed to ensure all policies and procedures related to infection control, safety, and patient care were followed with the potential to affect all the facility's patients. The findings include: 1. The medical director failed to ensure the facility followed its policy titled "Infection Control Measures" with an effective date of 7/21/2009 that stated, "Environmental Practices ... c. Sinks ... ii. Handwashing sinks will be dedicated only for hand washing purposes and should remain clean ... 4. Soiled Utility Room The soiled utility room is utilized for disposal and the rinsing of soiled equipment." (See V 114) 2. The medical director failed to ensure the facility followed it policy titled "Cleaning and Disinfection of Surfaces	V0715	The Director of Operations met with the Medical Director on 10/16/12 to review his requirements as defined in the Condition for Coverage to ensure that all policies and procedures relative to infection control, safety and patient care are adhered to by all individuals who treat patients in the facility. The Director of Operations also reviewed the Plan of Correction to be instituted to correct this issue. The Medical Director approved and directed the implementation of the plan. Specific plans related to handwashing sinks and the soiled utility room are addressed in V tag 114. Specific plans related to cleaning and disinfection of environmental surfaces and non-disposable equipment, proper mixing and use of 1:10 and 1:100 beach solutions and the requirement to utilize 1:10 bleach solution for visible blood spills are addressed in V 116, V 122, V 132 and V 401. Specific plans related to the GAC filters and chlorine testing are	10/16/2012

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	and Equipment" policy number "30.06", that states, "To provide direction regarding correct cleaning and disinfection of environmental surfaces and equipment to prevent transmission of dangerous pathogens. 1. Any manufacturer'"s guidance for sterilization or disinfectant of an item will be followed, as well as guidance from the chemical sterilant or disinfectant manufacturer, including appropriate dilution and contact time. 2. At the end of each dialysis treatment, a. All surfaces without, visible blood will be cleaned following the low level disinfection protocol using soap detergent or detergent germicide. b. For visible blood, the intermediate-level (1:10) disinfection protocol must be followed, which requires the area be immediately cleaned with a cloth soaked with tuberculocidal disinfection following the manufacturer's direction for dilution and contact time.... 6. At the end of each patient treatment, the staff will clean and disinfect the dialysis station....The staff will discard all fluids and clean and disinfect all surfaces of the containers associated with the prime waste (including containers attached to the machines) after each treatment. 7. After each treatment, the staff will clean and disinfect medical devices and equipment. Any shared items such as scissors, hemostats, clamps,		addressed in V 195 and V 196. Specific plans related to ensuring the facility has a safety plan to follow in the event of a disaster are addressed in V 409. Specific plans related to requirement to maintain current CPR certification, use of emergency equipment and medications, emergency supplies are addressed in V 410, V 411 and V 413. Specific plans related to requirement to assess patient immunization status in the CIA, and 90 day reassessment are addressed in V 506 and V 517. Specific plans related to documentation of patient/helper competence in performing home dialysis procedures and PD recordkeeping are addressed within V 586 and V 587 and specific plans related to requirement to develop and implement an aggressive infection control program as part of QAI including the management of infection control practice noncompliance and management of patients with diagnosis of active MRSA are addressed in V 627, V 637, V 638 and V 640. All plans as noted above have been reviewed and approved by the Medical Director. The Clinical Manager (CM) is responsible to present all data and monitoring/audit results as related to this Plan of Correction to the Medical Director at the QAI Meeting for oversight and review.	

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	stethoscopes, and blood pressure cuffs will be cleaned and disinfected between patient uses. If the item is visibly contaminated with blood, an intermediate-level disinfectant will be used.... 9. Dialysis machine disinfection will be documented, including testing for residual disinfectant." (See V 116, 122, 132, and 401) 3. The medical director failed to ensure the facility developed and implemented a policy in accordance with CDC guidelines for the cleaning of surfaces and equipment with visible blood. The policy titled "Procedure 01:03 ... Surface Cleaning in the hemodialysis setting" with no effective date stated, "Dialysis personnel will adhere to the following: Bleach solution (1:100) will be made every day, stored in a covered container, and labeled. Blood spills will be wiped immediately with 1:100 bleach solution." (See V 122) 4. The medical director failed to ensure the facility followed the policy titled "Granular Activated Carbon (GAC) Filters" that stated, "The granular activated carbon (GAC) filters ability to effectively remove total chlorine may be reduced if the reactive sites are masked by other substances as well as increases in pH and / or decreases in temperature.		The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented to the Medical Director during the monthly QAI Committee Meeting. The Medical Director as Chairperson of the QAI Committee is responsible to analyze the results and direct a root cause analysis with the development of a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI Committee.	

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	Due to these factors the GAC filter performance must be monitored regularly." (See V 195) 5. The medical director failed to ensure the facility followed its policy titled "RPC ULTRA - LOW Total Chlorine Test Strip Procedure" that stated, "Only trained personnel will perform the tests for ultra low total chlorine. Technician performing the test and the RN verifying the test are physically present during the time of testing. ... Supplies needed: ... timer with the ability to read ins seconds." (See V 196) 6. The medical director failed to ensure the facility followed it's policy titled "Disaster Plan / Emergency Preparedness" that stated, "The purpose of this policy is to ensure the facility has a safety plan to follow in the event of a disaster and / or emergency occurring in or around the facility. The plan will provide all employees (to meet OSHA requirements) and patients with information, education and drills so that appropriate actions may be implemented with calm and orderly precision. ... The facility will identify specific emergency situations that may occur within or around the facility: a) The facility will determine the types of emergency situations that may arise due to the nature of the dialysis patient, the			

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	location and the nature of the business, and the recommendations of the regulatory agencies responsible for the oversight of the facility. The facility will provide training and education regarding the types of emergency responses to those emergency situations to the staff and patients under the direction of the RN facility manager. The RN facility manager will schedule drills for the types of emergency situations listed. These drills will be randomized as to type and held minimally on an annual basis, documented and critiqued for appropriate response. " (See V 409) 7. The medical director failed to ensure the facility followed it's policy titled "Job Description and performance evaluation" that stated, "Skills required: Registered Nurse: ... Basic Cardiac Life Support (Course C)." (See V 410) 8. The medical director failed to ensure the staff were adequately and appropriately trained in emergency equipment and medication use of emergency medications with the potential to adversely affect all staff and patients. (See V 411) 9. The medical director failed to ensure the facility followed their policy titled "Emergency Preparedness," policy #60.02			

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	that states, "Non-expired emergency/evacuation supplies, including site dressings, saline, IV tubing, will be available to accommodate evacuated patients." (See V 413) 10. The medical director failed to ensure the facility followed their policy titled "Patient Assessment" that stated, "The comprehensive assessment ... will include: ... evaluation of current health status nd medical condition, including ... c morbid conditions, ... immunization history." (See V 506) 11. The medical director failed to ensure the facility followed their undated policy titled "Patient Assessment" that stated, "New patients (all admissions to the dialysis facility, including patients returning to dialysis from a failed transplant or changing modalities) ... within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care." (See V 517) 12. The medical director failed to ensure the facility followed their policy titled "Medical Records - Home PD" with a review date of 12/02/07 that stated, "All medical record documentation will include: ... Evidence that the patient / helper demonstrated competence in performing the home dialysis			

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	procedures." (See V 586) 13. The medical director failed to ensure the facility followed their policies titled "Peritoneal Dialysis Recordkeeping" with no effective date that stated, "Complete self-monitoring data and other information from self-care patients or their designated caregivers will be provided to the home training nurse to review at least every 2 months; and will be filed in patient's medical record" and titled "Medical Records - Home PD" with no effective date stated, "The facility is responsible to assure that records of dialysis treatments in the home setting are retrieved and reviewed by the appropriate and reviewed by the appropriate personnel at least every 2 months. Such review assists staff in monitoring home patients' status by determining if patients are following treatments and / or having problems with their dialysis at home." (See V 587) 14. The medical director failed to ensure the facility developed and implemented an aggressive infection infection control program as part of their improvement a quality assessment and performance improvement (QAPI) program which addressed the infection control problems identified in July 2012 and included a specific plan and resolution of the			

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	infection control practice noncompliance and the management of patients with diagnosis of active MRSA infections of their peritoneal access sites, resulting in the continued noncompliance with infection control policies and procedures and creating the potential to affect all of the facility's 116 current patients. (See V 627, 637, 638, and 640)			