

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152610	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 09/24/2012
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NAME OF PROVIDER OR SUPPLIER LIBERTY DIALYSIS LEBANON LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 2485 LEBANON ST LEBANON, IN 46052
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V0000	<p>This was a federal ESRD recertification survey.</p> <p>Survey Dates: 9/19/12 through 9/24/12</p> <p>Facility #: 007817</p> <p>Medicaid Vendor #: 200387680E</p> <p>Surveyor: Bridget Boston, RN, Public Health Nurse Surveyor</p> <p>Census by Service Type:</p> <p>Number of In-Center Hemodialysis Patients: 31 Number of Peritoneal Dialysis Patients: 2 Number of home hemodialysis patients: 1</p> <p>Total: 34</p> <p>Liberty Dialysis Lebanon LLC was found to be out of compliance with the Condition for Coverage 42 CFR 494.30: Infection Control.</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN October 2, 2012</p>	V0000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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V0110	<p>494.30 CFC-INFECTION CONTROL</p> <p>Based on observations, interview, and review of documents, policy and procedure, records, and personnel files, it was determined the facility failed to ensure soap and disposable towels and a waterless method to sanitize staff and patients hands was available in the home dialysis training room for 1 of 1 room observed and the potential to affect all of the home patients (See V 114), facility failed to ensure personal protective equipment was utilized appropriately in 2 of 3 patient care observations creating the potential to affect all of the facility's 34 current patients (See V 115), failed to ensure 3 of 3 Patient Care Technicians and 1 of 1 Registered Nurse observed disinfected equipment used on other patients prior to using the same equipment on another patient and before returning it to a clean area during 3 observation periods (See V 116), failed to ensure 1 of 1 home training room had appropriate and adequate disinfecting solution readily available and equipment was submerged in the disinfecting solution in 2 of 3 observations of the in-center creating the potential to spread infectious and communicable disease to facility staff and all 31 current in-center patients (See V 122), failed to ensure all susceptible patients had been offered the</p>	V0110	<p>The Governing Body acknowledges its responsibility to ensure that Liberty Dialysis Lebanon LLC 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 ensure soap and disposable towels and a waterless method to sanitize hands is available in the home dialysis training room, to ensure PPE is utilized appropriately, to ensure non-disposable equipment used on patients is disinfected prior to using on another patient, to ensure disinfection solution is readily available and equipment is submerged in the disinfection solution, to ensure all susceptible patients have been offered the Hepatitis B vaccine, to ensure infection control practices in the facility are evaluated and existing staff are reeducated with compliance of all staff monitored and to ensure medications available in the facility are current and not expired.</p> <p>The Governing Body, on October 8, 2012 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</p>	10/08/2012			

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	<p>vaccine against hepatitis B in 1 of 5 patient records reviewed creating the potential to affect the facility's 22 susceptible current patients (See 126), failed to ensure infection control practices in the facility were evaluated and existing staff were reeducated and an action plan was developed to monitor compliance of all staff to minimize infection transmission for 6 of 6 personnel files reviewed, creating the potential to affect all of the facility's 34 current patients and all staff (See V 132), failed to ensure medications available for use in the dialysis center were not expired for 1 of 1 facility with the potential for to affect all current patients as there was no other supply of the medications available in the facility (See V 143).</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to meet the requirements of the Condition for Coverage 42 CFR 494.30 Infection Control.</p>		<p>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.</p> <p>Effective immediately:</p> <ul style="list-style-type: none"> · 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 on October 8, 2012, 		

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			<p>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 provide a status report at each of the referenced Governing Body with a copy to the RVP if she is not in attendance. This additional oversight is to ensure the ongoing correction of deficiencies cited in the Statement of Deficiency as well as ensure the Governance of the Facility is presented current and complete data to enhance their governance oversight role</p> <ul style="list-style-type: none"> 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 115, V 116, V 122, V 126, V 132 and V 143 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	<p>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.</p> <p>Based on clinical record and policy review, observation, and staff interview, the facility failed to ensure soap and disposable towels and a waterless method to sanitize staff and patient's hands were available in the home dialysis training room for 1 of 1 room observed and the potential to affect all of the home patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> On 9/19/12 at 1:15 PM during a tour of the facility, the clinic manager, employee E, identified the room used for the home training program and for the home patients to be seen during clinic visits with the registered nurse, physician, social worker, and registered dietician. The room was observed without a supply of soap, disposable towels free of contamination, and an alcohol based hand sanitizer as a waterless option. There were no receptacles or holders for soap or towels. There was a short stack of folded brown paper towels, 8 in total. These towels had visible areas that had been previously moist and then dried. Patient record number 4 included a physician visit note dated 9/17/12 which 	V0114	<p>The Director of Operations ordered and installed a permanent paper towel holder which will keep towels free from contamination, along with placing soap and hand sanitizer in the home training room by 10/19/12.</p> <p>The Education Coordinator met with the Home Training Nurse on October 9, 2012 and review P/P FMS-CS-IC-II-155-090A "Hand Hygiene" emphasizing the requirement that there must be sufficient sinks available with water and soap to facilitate hand washing.</p> <p>The Home Program Manager will ensure that infection control audits are completed utilizing the QAI Infection Control audit tool daily when patients are present 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.</p> <p>The Home Program Manager will report a summary of findings monthly in QAI and compliance will be monitored by the QAI Committee.</p>	10/19/2012	

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	<p>indicated the patient was seen for a clinic visit 2 days prior in this training room.</p> <p>3. On 9/19/12 at 4:30 PM, employee B indicated the one room, though void of any training and education materials, was used for the home patients training and education.</p> <p>4. The undated policy titled "Infection Control Measure" stated, "Sinks. A sufficient number of sinks with warm water and soap will be available to facilitate hand washing. ... A sink will be available for patients to wash their access sites prior to treatment and their hands after treatment. Soap and a supply of paper towels protected from contamination will be available at each sink."</p>			

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V0115	<p>494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK</p> <p>Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. Based on observation, interview, and review of documents and facility policy, the facility failed to ensure personal protective equipment was utilized appropriately in 2 (1 and 2) of 3 patient care observations creating the potential to affect all of the facility's 34 current patients.</p> <p>The findings include:</p> <p>1. Observation on 9/19/12 from 10:50 AM through 1 PM</p> <p>A. At 10:50 AM employee G, on the in-center floor at station 9 preparing a dialysis machine for patient #6, was not wearing any PPE.</p> <p>B. At 12:30 PM, employee C was in station 7 with patient # 10 who had a central venous catheter (CVC). Employee</p>	V0115	<p>The Governing Body at its October 8, 2012 meeting determined that the use of masks with "face-shields" for eye protection is prohibited in this facility and that all staff will use face shields to provide full face protection. It was also decided that the use of snapped front gowns would be eliminated and that gowns that tie in the back would be used by all staff. New face shields and gowns will be available in the facility on October 15, 2012.</p> <p>Additionally, the Governing Body determined that all policies included within the Fresenius Bloodborne Pathogen Manual will be adopted effective October 8, 2012 – replacing existing policies within the facility. This is documented within the GB Minutes of this date.</p> <p>To ensure that all staff understands the correct application and the mandatory</p>	10/15/2012			

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	<p>C was observed to cleanse the catheter legs and change venous and arterial lines. She failed to don a clean mask prior to providing care.</p> <p>2. Observation on 9/20/12 from 9:35 AM through 11:40 AM:</p> <p>A. At 9:35 AM, employee L, a registered nurse, was observed to terminate dialysis treatment on patient #13 with a CVC in station 4. The employee pulled on, over her face and mouth, a combination face shield and mask which she had been wearing. After completing this task, she pulled her mask below her chin and went to station 3.</p> <p>B. At 9:48 AM, employee M was observed on the in-center floor, behind and around the dialysis machines in station 1, 2, and 3, while patients were being dialyzed. He was not wearing a gown.</p> <p>C. At 9:50 AM, employee C was observed to provide CVC care with patient #5 in station 7. Employee C failed to don a clean mask prior to the</p>		<p>wearing of Personal Protective Equipment (PPE), the Clinical Manager contacted the educational department and arranged for the formal reeducation of all staff to be completed no later than October 9, 2012. This reeducation is inclusive of but not limited to the following:</p> <ul style="list-style-type: none"> ·FMS-CS-IC-II-155-070A Dialysis Precautions ·Liberty Dialysis Hemodialysis Catheter Care Using Chloraprep and Alcavis 50 <input type="checkbox"/> FMS-CS-IC-11-155-080 Personal Protective Equipment <ul style="list-style-type: none"> o Gloves o Fluid Resistant Gowns o Face Shields o Masks (when worn are to cover the entire nose) <p>The educational agenda and attendance sheet document the training, and participation, and is available for review at the facility. Staff compliance is further monitored by the Education Coordinators, Director of Operations, Operation Managers and Clinical Manager as follows:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Observing staff's adherence to properly wear/secure required PPE <input type="checkbox"/> Observing staff compliance to remove all PPE prior to exiting the treatment area <input type="checkbox"/> Immediate intervention, consisting of reeducation up to disciplinary action, to address and correct identified noncompliance 		

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	<p>task. She wore the same face mask she had been wearing all morning, pulling the mask from below her chin onto and covering her mouth.</p> <p>D. At 10:40 AM, employee L entered station 8 and obtained reading from the dialysis machine #2. A patient was dialyzing at the time. Her gown was open in the front from the waist down; unsnapped.</p> <p>E. At 11:05 AM, employee C was observed to provide catheter care and initiate hemodialysis in station 1 on patient #11. While employee C provided care, her protective gown was not snapped completely in the front, open from waist down. When she reached across her field while providing catheter care, her gown brushed across the field contaminating the field. She did not don a clean mask prior to providing CVC care; she reapplied the same disposable mask she had worn previously.</p> <p>3. On 9/19/12 at 5 PM, employee E confirmed the staff were provided disposable mask / shield combination and the directions on the box indicate the</p>		<p>with the appropriate staff member</p> <p>In order to monitor staff adherence to the correct application of personal protective equipment (PPE), the Director of Operations incorporated the observation of the facility's PPE requirements in the Plan of Correction Monitoring Tool. As such, the following has been implemented:</p> <ul style="list-style-type: none"> <input type="checkbox"/> On October 1, 2012 the Regional Quality Manager presented the developed Plan of Correction monitoring tool to the Education Coordinator and Facility Management team. <input type="checkbox"/> Beginning 10/2/12, the Education Coordinators or Clinical Manager/Home Program Manager will complete the tool daily during each patient shift on each employee including the home therapies staff whenever they are seeing patients <input type="checkbox"/> 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. <input type="checkbox"/> The Clinical Manager or Director of Operations will review the tool and administer corrective action as needed. <p>The Clinical Manager will review</p>		

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	<p>mask is disposable and only good for one hour.</p> <p>4. The undated policy titled "Infection Control Measures" states, "To ensure the facility will provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the facility and any public areas. ... Personal protective equipment (PPE): (gloves, gowns, ... masks). All personal protective equipment will be readily available to staff and consistently monitored ... Gloves, gowns, ... and masks will be worn when there is a potential for contamination with blood or other potentially infectious material. ... At those times a cover garment which provides an impervious barrier to fluids must be worn. ... The garment may be open in the back or front, but the cover garment must be closed in the front during use for patient care. The protective garment should fully cover the arms and torso from the neck area to the thigh / knee area."</p> <p>5. The directions for the Henry Schein combination mask and eye shield used in the dialysis center states, "These masks are for single use only/ disposable masks. Re-use or extended use, beyond one hour, may lead to infection or cross contamination."</p>		<p>the copies of the completed rounding tool, any identified noncompliance and the applied interventions with the Director of Operations and Medical Director weekly.</p> <p>Additionally, the Director of Operations and Clinical Manager met with Employees # C,G,L,M and E reviewing their actions which resulted in citations and providing education to the issues.</p> <p>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.</p> <p>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.</p> <p>The Clinical Manager is responsible and the QAI Committee monitors to ensure on going compliance.</p>		

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V0116	<p>494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT</p> <p>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.</p> <p>-- 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.</p> <p>-- 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.</p> <p>Based on observation, staff interview, and review of policy and procedures, the facility failed to ensure 3 of 3 Patient Care Technicians (PCT) (employees C, G, and J) and 1 of 1 Registered Nurse (RN) (employee L) observed disinfected equipment used on other patients prior to using the same equipment on another patient and before returning it to a clean area during 3 observation periods creating the potential to spread infection causing agents among facility staff and all 31 current in-center patients</p> <p>The findings include:</p> <p>1. During observation on the in-center unit on September 19, 2012, from 10:50 AM through 1 PM.</p>	V0116	<p>The Governing Body on October 8, 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.</p> <p>All staff attended a mandatory in-service conducted by the clinic educator on 10/9/12 reviewing the following policies:</p> <ul style="list-style-type: none"> · 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 	10/09/2012	

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	<p>A. Observed employee C, a patient care technician, in station 7 write on a paper treatment record which was attached to a clip board and was lying on top of the dialysis machine. After she documented on the paper, she lifted the front of her open gown and placed her pen in her right pocket. She removed the contaminated paper from the clip board and took it to a computer terminal, entered information at the computer, then returned the paper document back to the clipboard lying on the dialysis machine.</p> <p>Employee C indicated she removes the paper treatment record from the clip boards every hour and takes them to one of two computer terminals. One terminal was located between station 5 and 6 and the other was inside the nurses station. She indicated she tried to do this every hour throughout the treatment day to keep the electronic medical record up to date with information from the paper treatment record.</p> <p>2. Observation of the in center on September 20, 2012, observation from 9:35 AM through 11:40 AM:</p> <p>A. At 9:35 AM, employee L, a registered nurse, was observed to remove her gloves in station 4. Without completing hand</p>		<ul style="list-style-type: none"> · 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 <p>Emphasis was placed on proper disinfection of contaminated medical records, pens, clip boards, thermometer, wearing gloves and practicing hand hygiene, use of tape, wearing appropriate gowns and cleanliness in the medication area.</p> <p>Paper treatment sheets and pens will be kept on the nurses station counters until 2 additional computer terminals can be installed. Staff will perform proper hand hygiene before and after using the pens kept at the nurses station with the paper treatment sheets. Proper disinfection will be used before returning non-disposable items to a clean area as described in policy FMS-CS-IC-II-155-070.</p> <p>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 daily until the facility is</p>		

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	<p>hygiene, she pulled her mask and shield down under her chin, picked up the tympanic thermometer from the counter of the nurses station, walked to station 7, took the patient's temperature, and returned the thermometer to the nurse station counter without decontaminating the instrument.</p> <p>B. At 9:45 AM, employee J was observed to obtain a roll of tape from the central supply located in the middle of the in center. She took the roll of tape into station 6, tore the tape, placed it onto the chair side tray table, then returned the roll of tape back to the central supply.</p> <p>C. At 10:25 AM, employee L was observed to take the tympanic thermometer to the patient in station 9. The employee took the patient's temperature then returned the thermometer to the counter without decontaminating it. She then touched the patient's legs and documented on the paper treatment record attached to the clipboard lying on top of the dialysis machine. She placed the pen she had used in her pocket, underneath her open front gown. She did not decontaminate the thermometer or the pen.</p> <p>D. At 10:40 AM, employee L walked to dialysis machine #2 in station 8, obtained</p>		<p>resurveyed then weekly. Frequency of ongoing monitoring will be determined by the QAI Committee based on results of monitoring and resolution of the issues.</p> <p>Staff compliance is further monitored by the Education Coordinators, Director of Operations, Operation Managers and Clinical Manager as follows:</p> <ul style="list-style-type: none"> ·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 <p>Compliance with these policies will be maintained by the Clinical Manager on an ongoing basis.</p> <p>Additionally, the Director of Operations and Clinical Manager met with Employees # C,G,J and L reviewing their actions which resulted in citations and providing education to the issues.</p> <p>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</p>		

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	<p>a reading, and obtained one clean glove which she donned on her right hand. She retrieved a pen from her pocket from under her open front gown. She held her pen in her left hand, then placed it in her right hand, and documented on the paper treatment record on the clipboard lying on top of the dialysis machine. Then she placed her pen back into her pocket under her open front gown. She did not decontaminate her pen.</p> <p>E. At 11:15 AM, employee L walked to station 1, patient # 11, donned a pair of gloves, administered intravenous medications, and removed a pen from her pocket from under her open front gown. She picked up the clip board that was lying on the top of the dialysis machine and documented on the paper treatment record while wearing her gloves. She then removed her gloves, walked away from the station, and placed the pen back in her pocket under her gown. Employee H informed employee L and C the top of the dialysis machine and the clipboard were all contaminated and informed employee L her pen was also contaminated and could not be taken from station to station. Employee L indicated she was not aware and said, "Well then every dialysis machine needs a pen."</p> <p>3. Observation of the in center on</p>		responsible to provide oversight and ensure resolution is occurring.				

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	<p>September 21, 2012, from 10:20 AM through 11:50 AM:</p> <p>A. At 10:20 AM, employee J donned gloves, obtained a roll of tape from the supply in the center of the in center, and carried it into station 2. She tore pieces of tape, placed them on the the edge of the tray table, and returned the tape to the bulk supply.</p> <p>B. At 10:30 AM, employee L was observed in station 8. She removed a pen from her pocket on the left side under her open front gown. She used the pen to document on the paper treatment record located on the clip board on top of the dialysis machine. She returned the pen to her pocket under her open front gown. She obtained the tympanic thermometer from the counter, walked to station number 2, assessed the patient's temperature, and then returned the thermometer to the desk without decontaminating.</p> <p>C. At 11:00 AM, observed employee L at an area of the in center identified and labeled "medication area." She removed a pen from her pocket and placed it on the counter as she prepared IV medications.</p> <p>D. At 11:30 AM, employee L walked to station 6, obtained the pen from her</p>			

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	<p>pocket from under her open front gown, and document information from the dialysis machine onto a paper treatment record on a clip board. She left the station and returned to the computer terminal behind the nurses' station. Her gown remained open throughout this time and her pen was not decontaminated.</p> <p>E. At 11:46 AM, employee L walked from a common area supply area in front of nurses station, donned a pair of gloves, held her pen in her hand, walked to station 8 with patient # 9, and touched the face of the dialysis machine. She then removed her gloves, placed her pen in her pocket under her gown, and went to station # 7. With bare hands, she touched the patient and pulled back the patient's covers. She completed hand hygiene when she finished.</p> <p>4. The undated policy titled "Cleaning and Disinfection of Surfaces and Equipment" stated, "After each treatment, the staff will clean and disinfect medical devices and equipment. Any shared items such as ... hemostats, clamps, ... will be cleaned and disinfected between patient use."</p>						

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V0122	<p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing-</p> <p>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]</p> <p>(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.</p> <p>Based on observation, staff interview, and policy and procedure review, the facility failed to ensure 1 of 1 home training room had appropriate and adequate disinfecting solution readily available and equipment was submerged in the disinfecting solution in 2 of 3 observations of the in-center creating the potential to spread infectious and communicable disease to facility staff and all 31 current in-center patients.</p> <p>The findings include:</p> <p>1. On 9/19/12 at 4:30 PM, the home training room was observed without disinfectants or cleaning supplies readily available for use during patient training. Employee B indicated she would leave the home training room and go to the in-center unit to obtain a bleach solution for cleaning of supplies and training room equipment after a home patient visits.</p>	V0122	<p>On October 10, 2012, 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.</p> <p>·Effective immediately, the Clinical Manager has added the daily assignment of bleach mixing as part of the facility's patient assignment process</p> <p>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:</p> <p>·FMS Blood Borne Pathogen Manual specifically ·Cleaning and Disinfection FMS-CS-IC-II-155-110A – ensuring that clamps are totally submersed in bleach solution</p>	10/10/2012			

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	<p>2. On 9/19/12 at 12 PM, a covered container labeled "dirty clamps / 1:100 bleach" was observed beside the dirty sink. Inside the container was clamps and hemostats and a clear solution that did not cover the pile of clamps.</p> <p>3. On 9/20/12 at 11:40 AM, a container beside the dirty sink labeled "dirty clamps 1:100 bleach" was observed containing a heaping pile of hemostats and clamps. The heap was not submerged in the bleach solution. On the top of this heap was a pediatric size blood pressure cuff.</p> <p>4. On 9/20/12 at 11:40 AM, employee C indicated the container observed was the only container for soaking the clamps and hemostats and the items were to soak in the 1:100 bleach solution. At the end of the day, the items were rinsed and placed on a chux to air dry.</p> <p>4. The undated policy titled "Cleaning and Disinfection of Surfaces and Equipment" stated, "After each treatment, the staff will clean and disinfect medical devices and equipment. Any shared items such as ... hemostats,clamps, ... will be cleaned and disinfected between patient use."</p>		<ul style="list-style-type: none"> ·Bleach Mixing FMS-CS-IC-II-155-115-C ·Documentation requirements emphasizing immediate documentation by the preparer. ·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 <p>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.</p> <p>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.</p> <p>The Clinical Manager's action will be structured to reinforce by further education following through as necessary with the application of progressive</p>		

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			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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V0126	<p>494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF Hepatitis B Vaccination</p> <p>Vaccinate all susceptible patients and staff members against hepatitis B. Based on administrative document, patient record, and facility policy review and interview, the facility failed to ensure all susceptible patients had been offered the vaccine against hepatitis B in 1 (# 1) of 5 patient records reviewed creating the potential to affect the facility's 22 susceptible current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The facility's hepatitis status report evidenced patient number 1 was susceptible with an antibody value of less than 10 on 8/7/12. The record evidenced the patient requested to receive the hepatitis vaccine series and signed the consent form 8/7/12. The record failed to evidence the patient was monitored for hepatitis B antigens and antibodies since 8/7/12 through 9/21/12 or that the patient received the requested vaccine. 2. On 9/20/2012 at 4:29 PM, employee B indicated the documentation of a titer > 10 written on the patients consent form was incorrect and the patient was not monitored since 8/7/12 nor did the patient begin the series as requested. 	V0126	<p>As a result of the citations from the Sept 19 – Sept 24, 2012 CMS Recertification survey and to ensure that the facility fully complies with the Centers of Disease Control and Prevention guidelines to decrease the transmission of infection within the dialysis facility in regards to the care and services of the Hepatitis B positive patient, the following corrective actions have been implemented by the Governing Body and facility management team:</p> <ul style="list-style-type: none"> On 10/9/12, the Operations Manager presented the preliminary findings of the survey to all facility staff. Reinforced during this meeting was the requirement of all staff to fully comply with all aspects of the facility Infection Control Polices inclusive of identifying susceptible patients, obtaining physician orders and vaccinating all susceptible patients and staff members against hepatitis B <p>To further ensure compliance and to prevent reoccurrence, on 10/9/12, the facility's Education Coordinator presented the Bloodborne Pathogen Infection Control Manual education to all</p>	10/19/2012	

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	<p>3. On September 21, 2012, at 1:35 PM, employee B indicated patient #1, now a home patient, was not monitored since 8/7/12 and was susceptible to hepatitis B. The patient did not receive any of the vaccine series as of 9/21/12.</p> <p>4. The undated policy titled "Infection Control" stated, "Screening and record keeping: Patients: All new patients entering the program will have Hepatitis B screening with results available to their first treatment. ... All patients with a negative Hepatitis B antibodies will be offered a Hepatitis B vaccine as part of their admission criteria. ... If patients request the vaccine, it will be given at any time."</p>		<p>the staff emphasizing:</p> <ul style="list-style-type: none"> · Reeducation and reinforcement of FMS-CS-IC-11-155-142A Policy "Patient Testing and Vaccination for Hepatitis B "with emphasis on: Routine testing of all patients, prompt review of results and ensuring that patients are managed appropriately based on their results inclusive of, but not limited to: <ul style="list-style-type: none"> o All new/transferred patients o Any existing patients <p>A copy of the education provided is maintained available at the facility for review.</p> <p>On 10/19/12, all existing patients Hepatitis B antigens and antibodies were reviewed. Any patient found to be susceptible including patient # 1, will be presented to their attending physician, orders will be obtained and the patient will be offered the Hepatitis B vaccine. The acceptance or refusal of the vaccine will be documented on the "Consent/Declination" form and stored as part of their medical record. It will also be tracked on the Vaccination tracking tool as a part of the QAI program.</p> <p>To ensure that each patient is offered the vaccine upon admission and receives the vaccination in accordance to</p>		

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			<p>prescribed orders, the Clinical Manager has initiated the following:</p> <ul style="list-style-type: none"> ·Reviews patient hepatitis status prior to admission ·Assigns a nurse to initiate patient assessment prior to the first treatment and as part of this assessment the following occurs: <ul style="list-style-type: none"> ·Confirmation of patient's hepatitis status ·Obtaining an order for the Hepatitis B vaccine from the patient's attending physician for any patient's identified as susceptible ·Patient education on the hepatitis virus ·Patient education on the benefit of vaccination to hepatitis virus ·Obtains the patient consent/declination indicated by patient signature on the appropriate form ·Administer vaccine series as ordered <p>The Clinical Manager reviews the new patient admission paper work inclusive of required consents for completion and patient preference weekly. The Clinical Manager is responsible to update the Hepatitis Tracking Tool accordingly no less than 1 week after patient admission.</p> <p>Each month, as part of the monthly QAI process, the Clinical Manager will present the following to the QAI Committee:</p>	

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			<ul style="list-style-type: none"> ·A summary of patients susceptible to Hepatitis B ·A summary of patients currently receiving Hepatitis B vaccination series ·A summary of any patients who have missed a dose or the vaccination has not been initiated as ordered ·Any patients that have specific, documented reasons for not receiving scheduled doses of Hepatitis B vaccine. <p>The QAI Committee will assess for an opportunity for improvement. If an opportunity for improvement is identified, the QAI Committee will initiate a formal action plan to be followed through to a resolution.</p> <p>The committee may 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</p> <p>The Clinical Manager is responsible and the QAI Committee monitors for compliance</p>	

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V0132	<p>494.30(a)(1)(i) IC-TRAINING & EDUCATION Infection Control Training and Education</p> <p>Infection control practices for hemodialysis units: intensive efforts must be made to educate new staff members and reeducate existing staff members regarding these practices.</p> <p>Based on administrative document, personnel record, and facility policy review and interview, the facility failed to ensure infection control practices in the facility were evaluated, existing staff were reeducated, and an action plan was developed to monitor compliance of all staff to minimize infection transmission for 6 of 6 personnel files reviewed creating the potential to affect all of the facility's 34 current patients and all staff. (B, C, G, J, K, and L)</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The facility's QAPI meeting minutes dated 4/20/12, 5/25/12, 6/29/12, 7/12/12, and 8/31/12 failed to evidence observation and audits of infection control practices of the staff. 2. On 9/19/12 at 4:34 PM, employee E indicated she had no evidenced the staff were audited for infection control procedures and processes as part of the QAPI. She provided a one page document and indicated she had no other 	V0132	<p>The Clinical 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. Training will be completed by 10/9/12 and an in-service attendance sheet will be available in the facility for review.</p> <p>On October 3, 2012, the Education Coordinators completed individual skills and competency checks on all patient care staff. 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.</p> <p>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</p>	10/09/2012			

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	<p>documentation the staff were observed individually and audited for compliance to infection control policies and procedures.</p> <p>3. On 9/19/12 at 4:41 PM, employee E indicated she had not completed individual evaluations of the skill and competency of the patient care technicians and nurses as part of an infection control monitoring. She confirmed the most recent documentation for employees C, G, J, and L was dated 12/1/09 and employee files B and K failed to evidence monitoring or observation of their infection control practices.</p> <p>4. The undated policy titled "Infection Control Measures" stated, "Infection control and adverse events monitoring, assessment, and improvement will be part of the facility's QAPI program."</p>		<p>implemented:</p> <p>¿ On October 1, 2012 the Regional Quality Manager presented the developed Plan of Correction monitoring tool to the Education Coordinator and Facility Management team.</p> <p>¿ Beginning 10/2/12, the Education Coordinators or Clinical Manager/Home Program Manager will complete the tool during each patient shift on each employee including the home therapies staff whenever they are seeing patients</p> <p>¿ 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.</p> <p>¿ The Clinical Manager or Director of Operations will review the tool and administer corrective action as needed.</p> <p>The Clinical Manager reviews the copies of the completed rounding tool, identified 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</p>		

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			<p>Committee based on results of monitoring and resolution of the issues. The report is summarized and reviewed, during the monthly QAI meeting.</p> <p>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.</p> <p>The Clinical Manager is responsible and the QAI Committee monitors to ensure on going compliance.</p>		

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V0143	<p>494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS [The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and Based on interview and observation, the facility failed to ensure medications available for use in the dialysis center were not expired for 1 of 1 facility with the potential for to affect all current patients as there was no other supply of the drugs available in the facility.</p> <p>The findings include:</p> <ol style="list-style-type: none"> On 9/19/12 at 11:25 AM, the medication cabinet was observed and 2 medications were found to be expired. <ul style="list-style-type: none"> A. Sodium citrate 4%, lot # 120119@21, expired June 2012 and 9 of the 10 vials in the original package remained. B. Fortaz ceftaidine 1 gram vials, lot # 11964, expired 7/17/12. Ten of the original 10 packages remained. On 9/19/12 at 11:30 AM, employee E, provided a clipboard with one page list of medications and the inventory of the medications dated May 2012. The 	V0143	<p>Effective immediately as of the date of the survey, all expired medications were discarded.</p> <p>On October 10, 2012 – the Operations Manager met with the Clinical Manager to emphasize her requirement to ensure the facility maintained the appropriate supply of current un-expired medications. It was determined that the Charge Nurse would be responsible to monitor medication expiration dates and this was added to the staff schedule to ensure compliance. The Clinical Manager and the unit secretary are responsible to the monthly counting of the inventory and ordering the appropriate medications based on that monthly count.</p> <p>On 10/10/12, the Operations Manager had a staff in-service to review the “Medication Policy” with emphasis placed on checking for expiration dates monthly.</p> <p>The Clinical Manager and Operations Manager created a list of all of the facility’s medications along with expiration dates. This</p>	10/10/2012			

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	supplies had not been inventoried since May 2012. The medications that were found to be expired on 9/19/12 were noted on the May 2012 inventory and with the same count, indicating none of the medication had been administered once expired. The potential for the expired medication to be administered if ordered was great as there was not another supply of the medication available within the facility.		<p>was introduced at the staff in-service and will be completed by the Charge Nurse the last day of each month.</p> <p>The Clinical Manager is responsible for ensuring compliance by directly observing the medications and the checklist on the first day of each month. Any issues of non-compliance will be addressed immediately with the Charge Nurse by the Clinical Manager.</p> <p>The Clinical Manager is responsible to present the monthly check list completed by the Charge Nurse along with the audit by the Clinical Manager along with the current inventory management process to the QAI Committee on a monthly basis. Frequency of ongoing monitoring will be determined by the QAI Committee based on results of monitoring and resolution of the issues.</p> <p>The Clinical Manager will report a summary of findings monthly in QAI and the QAI Committee will provide oversight to ensure the current supply of medications are not expired and the facility has an adequate supply in inventory.</p>		

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V0191	<p>494.40(a) SOFTENERS: TESTING HARDNESS/LOG 6.2.4 Softeners: Testing hardness/log Users should ensure that test accuracy and sensitivity are sufficient to satisfy the total hardness monitoring requirements of the reverse osmosis machine manufacturer. Total hardness of the water exiting the water softener should be measured at the end of each treatment day.</p> <p>Water hardness test results should be recorded in a water softener log. Based on administrative document review, staff interview, and policy and procedure review, the facility failed to ensure the water hardness test was completed at the end of the treatment day and recorded for 7 of the last 7 months of water treatment logs reviewed with the potential to affect all the facility's incenter patients.</p> <p>The findings include:</p> <p>1. Administrative document titled "Lebanon Water Room Checklist" line 15 states, "Post Treatment Water Hardness Test." There was not an area in which to document the time of day this post treatment hardness test was complete.</p> <p>A. On 9/19/12 at 12 PM, the facility document "Lebanon Water Room Checklist" dated September 19, 2012, was reviewed. The post treatment value was</p>	V0191	<p>On 10/1/12, the Director of Operations met with the Technical Operations Manager to discuss the identified technical deficiency.</p> <p>On October 8, 2012, the Governing Body met and decided to replace the policies directly related to issues noted within the survey, are being adopted effective October 8, 2012. This is documented within the GB Minutes of this date.</p> <p>The Director of Operations and Technical Operations Manager will arrange and schedule staff in-services to educate all direct patient care staff on the following policy "Water Treatment Equipment" 153-020-022 and the water softener log (WS-1) which provides for the documentation of the time of the post treatment water hardness testing documentation. As part of the training a return demonstration of all staff will be done by the</p>	10/14/2012	

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	<p>documented though the facility was still providing dialysis treatment.</p> <p>B. A review of the administrative documents titled "Lebanon Water Room Checklist" dated March 1, 2012, through September 19, 2012, with treatment days Monday through Saturday, failed to evidence the total water hardness was determined at the end of the treatment day.</p> <p>2. On 9/19/12 at 12:08 PM, employee G indicated the hardness test was only determined at the beginning of each treatment day and was not evaluated at the end of the treatment day.</p> <p>3. On 9/19/12 at 4:30 PM, employee C indicated the facility had not been checking the total water hardness at the end of the treatment day for approximately 9 months.</p> <p>4. On 09/24/2012 at 2:24 PM, employee E indicated she was not aware the staff were not checking the total water hardness at the end of the treatment day.</p> <p>5. The undated policy titled "Water Softener and Brine Tank" stated, "The water softener will be monitored for total hardness at the end of each operating day. Test results will be documented on the</p>		<p>Technical Program Manager using the IFU and a water hardness skills checklist. Training will be completed by 10/14/12 and an in-service attendance sheet will be available in the facility for review.</p> <p>Ongoing, this skills checklist will be added to the QAI Calendar to ensure annual competency occurs.</p> <p>The Technical Program Manager or their designee will assure that the cited deficiency does not reoccur by directly observing a staff member perform a water hardness test and document the staff member's proficiency utilizing the water hardness skills checklist daily until the facility is resurveyed. The frequency of ongoing observation of the skills check 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 water hardness testing until competency is demonstrated.</p> <p>The Clinical Manager is responsible to report a summary of findings monthly in QAI including review of the log and</p>				

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	water quality documentation log and initialed by the staff member performing the test."		compliance will be monitored by the QAI Committee.		

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V0195	<p>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).</p> <p>Based on interview and review of policy, 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.</p> <p>The findings include:</p> <ol style="list-style-type: none"> On 9/24/2012 at 1:02 PM, employee M indicated he had not determined the empty bed contact time (EBCT) and was not aware of this documentation need. He indicated the patient care technicians complete the chloramines checks and said, "Nothing has changed, the carbon tanks were rebed in March 2012. Therefore, there should not be a need." On 9/24/2012 at 2:26 PM, employee E 	V0195	<p>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.</p> <p>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 as noted in V 191 including employees M, E and H, relating to GAC monitoring and maintenance. Emphasis was placed on calculating EBCT monthly and documenting 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</p>	10/12/2012	

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	<p>indicated she did not know how to determine the EBCT and would need to call the area technical manager for guidance.</p> <p>3. The undated policy 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."</p> <p>4. On 9/24/12 at 3 PM, employee H indicated the policy did not specify a frequency and the standard was to monitor the EBCT monthly. She indicated the EBCT was determined to be 6.0 minutes per tank at this day and time.</p>		<p>occurs.</p> <p>The Technical Program Manager (TPM) will assure that the cited deficiency does not reoccur by auditing the ER-1 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.</p> <p>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.</p>		

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V0196	<p>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.</p> <p>Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet.</p> <p>Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N.N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAM] 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 documents and policy, the facility failed to ensure chlorine testing had been completed in accordance with facility policy in 1 of 1 water test observed creating the potential to affect all of the facility's 34 current patients.</p>	V0196	<p>On 10/4/12, the Technical Operations Manager met with the Technical Program Manager to discuss the identified technical deficiency.</p> <p>The Technical Operations Manager and Technical Program</p>	10/14/2012			

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	<p>The findings include:</p> <ol style="list-style-type: none"> 1. The policy dated 7/8/10 titled "Total Chlorine Testing" stated, "Test Frequency - Total chlorine testing will be performed daily prior to the start of the first patient shift and again every 4 hours thereafter. The water treatment system must run for minimum of 15 minutes, prior to performing the test." 2. The undated policy found in the water log binder, titled "RPC Ultra - Low Total Chlorine test Strip Procedure" stated, "Technician performing the test and the RN verifying the test are physically present during the time of the testing. ... R.O. is placed in force run for 15 minutes. Record time RO placed in force run mode on the total chlorine log sheet. Wait 15 minutes prior to testing for total chlorine. ... Technician performing the test and the RN verifying the test are physically present during the time of the testing. Collect a fresh 100 milliliter sample of water." 3. The directions for the "E-Z Chek Sensitive Total Chlorine Test Strips and Ultra - Low Total Chlorine Test Strips" stated, "Collect a fresh 100 milliliters sample of water in a clean dry, plastic sample cup. ... Remove one test strip 		<p>Manager will arrange and schedule staff in-services to educate all direct patient care staff on all recently adopted Fresenius Medical Care water polices 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 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 10/14/12 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.</p> <p>The Technical Program Manager or his designee will assure that the cited deficiency does not reoccur by directly observing a staff member 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</p>		

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	<p>from its foil package and dip it in the sample for 20 seconds. ... While dipping the strip, move it back and forth at a constant gentle rate of approximately two, 1 - 2 wide strokes (one forward - one backward) per second. Remove the strip and shake once, briskly, to remove excess water. Wait 20 seconds for the test strip to develop. While waiting, fold the white plastic handle of the test strip under the reagent area aperture so that it provides a consistent viewing background. ... After the 20 second wait period, immediately compare the strip color chart to determine the total chlorine level in the sample."</p> <p>4. On 9/19/12 at 12:45 PM, employee E indicated the water tests are not scheduled to a particular person and stated, "They just get done" and asked employee C to complete. Employee E looked at the log and said, "It is late." Surveyor went to the water room with employee C who pointed to the reverse osmosis machine and stated, "This is supposed to be running for 15 minutes." She indicated she could look at the water level and know it was running because of the water level. The reverse osmosis was not "on" [producing product water] at the time we entered the water room. Employee C opened a valve which allowed product water to drain from the holding tank which caused the reverse osmosis to turn on automatically.</p>		<p>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.</p> <p>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.</p>		

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	<p>She then went to the 1st post carbon tap and allowed the water flow; she let the water flow for 18 seconds, and then collected 50 - 60 cc of product water in a standard 100 specimen cup. Employee C indicated she was to collect approximately 30 milliliters. She was unable to read the quantity in the sample cup and indicated she could not determine the volume she collected. The cup was etched. She indicated it did not matter how much water was in the cup as long as the indicator on the chlorine test strip was in the water submerged, that it was okay (sufficient). She then obtained an indicator strip, brand "E-Z Chek Sensitive Total Chlorine Test Strips and Ultra - Low Total Chlorine Test Strips," and submerged it in the water sample and then carried the cup to the in-center floor. She indicated the patient care technicians always carry the sample to the floor because the nurse cannot leave the floor to read the test strip.</p> <p>A. At 12:49 PM, per clock on the in-center wall above stations 5 and 6, employee C returned to the in-center floor with the test strip. She read the strip and completed documentation on the "Total Chlorine Log Sheet," then handed the test strip and the log to employee L for verification. Employee L looked at the strip and cosigned the chlorine test log.</p>			
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	<p>B. The water log and documentation for 9/19/12 was reviewed. Employee C documented on the water log she turned the reverse osmosis on at 12:30 PM and completed the chlorine test timely at 12:45 PM. The documentation failed to evidence an accurate representation of the actions which occurred and the time of the test. The documentation evidenced the reverse osmosis (R. O.) was "on" and producing product water for 15 minutes prior to the test being conducted; the documentation was not accurate. The R. O. was not "on" for 15 minutes prior to the test being conducted; therefore, the entire water test for total chlorine was invalid and more than 4 hours had passed since the previous chlorine test.</p> <p>5. The product procedure titled "RPC Ultra - Low Total Chlorine test Strip Procedure" stated, "The technician performing the test and the RN verifying the test are physically present during the time of the testing" was reviewed with employee L who stated, "Well, that does not happen."</p>				

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V0239	<p>494.40(a) BICARB CONC DISTRIB-WKLY DISINFECT/DWELL/CONC 5.5.4 Bicarbonate concentrate distribution systems: weekly disinfection/dwell times/conc Bicarbonate concentrate delivery systems should be disinfected on a regular basis to ensure that the dialysate routinely achieves the level of bacteriological purity [required by these regulations].</p> <p>For piped distribution systems, the entire system, including patient station ports, should be purged of bicarbonate concentrate before disinfection. Each patient station port should be opened and flushed with disinfectant and then rinsed; otherwise, it would be a "dead leg" in the system.</p> <p>Appropriate dwell times and concentrations should be used as recommended by the manufacturer of the concentrate system. If this information is not available, bleach may be used at a dilution of 1:100 and proprietary disinfectants at the concentration recommended by the manufacturer for disinfecting piping systems.</p> <p>6.5 Concentrate distribution: The interval between disinfection should not exceed 1 week. If the manufacturer does not supply disinfection procedures, the user must develop and validate a disinfection protocol.</p> <p>Based on observation and interview, the facility failed to ensure chlorine test strips used by the technical staff to determine the adequate parts per million of bleach during disinfection of the bicarb system and equipment were not expired for 1 of 1</p>	V0239	<p>Effective immediately at the date of the survey, all expired reagents and solutions were discarded.</p> <p>As noted in V 143, the Clinical Manager and Operations Manager added all testing</p>	10/10/2012			

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	<p>vial of test strips present in the water room with the potential to affect all the facility's patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> On 9/24/2012 at 1:30 PM, employee M indicated he verified the parts per million of bleach concentration with test strips and produced one vial labeled "Easy Check Potency Chlorine Test Strips" product code K100-0112. The vial labeled "Easy Check Potency Chlorine Test Strips" product code K100-0112 indicated the vial originally contained 100 test strips. The vial, lot # 021060B, expired on 6/2012. The lid was opened and dated "9/17/12" and contained the initials of employee M. Employee M indicated he had no other supply available. The count on 9/24/12 was 96 strips. The disinfection logs were reviewed and evidenced the bicarbonate mixer was disinfected with bleach on 9/17/12 and no other disinfection occurred after 9/17/12. 		<p>reagents and solutions to the list of the facility's medications along with expiration dates. This was introduced at the staff in-service on 10/10/12 and will be completed by the Charge Nurse the last day of each month as defined in the processes noted above in V 143.</p> <p>The Clinical Manager is responsible for ensuring compliance by directly observing the reagents and solutions and the checklist on the first day of each month. Any issues of non-compliance will be addressed immediately with the Charge Nurse by the Clinical Manager.</p> <p>The Clinical Manager is responsible to present the monthly check list completed by the Charge Nurse along with the audit by the Clinical Manager along with the current inventory management process including reagents and solutions to the QAI Committee on a monthly basis. Frequency of ongoing monitoring will be determined by the QAI Committee based on results of monitoring and resolution of the issues.</p> <p>The Clinical Manager will report a summary of findings monthly in QAI and the QAI Committee will provide oversight to ensure the current supply of reagents and solutions are not expired and the facility has an</p>				

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			adequate supply in inventory.	

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V0401	<p>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 and patient and staff interview, the facility failed to ensure a comfortable treatment environment for 1 of 4 days of observation with the potential to affect all the patients in the facility.</p> <p>The findings include:</p> <ol style="list-style-type: none"> On 9/19/12 at 11:15 AM, the in-center treatment room temperature was notably cool. Two wall thermostats read 68 degrees Fahrenheit. At 11:15 AM, 8 of 9 patients on dialysis were covered with a blanket or some type of covering. At 11:15 AM, patient # 3 in station 6 was observed covered with 2 blankets. The patient stated, "I always use 2 blankets here." At 11:30 AM, employee E confirmed the thermostat was turned down to 68 degrees in the in-center and stated, "They [patient care technicians] do that [reduce the room temperature] during turnover 	V0401	<p>The Governing Body met on October 8, 2012 and determined the temperature in the facility will be maintained at 72 degrees. Additionally, the Governing Body reinforced the responsibility of the Clinical Manager to ensure that the facility maintains this temperature to ensure for patient comfort. This is documented within the GB Minutes of this date.</p> <p>On October 1, 2012, the Operations Manager, Clinical Manager and Technical Operations Manager reviewed the treatment room environment to ensure environmental factors were not contributing to cold areas within the facility.</p> <p>The facility will have a lock box installed over the thermostat on the treatment floor with the key to be placed with the Charge Nurse by 10/19/12.</p> <p>The Clinical Manager instituted a temperature log on 10/12/12 to be completed daily. To monitor for compliance that the log is completed and any out of range temperatures are addressed, the</p>	10/19/2012			

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	and I go behind them and turn it back up to 70 degrees [Fahrenheit]. "		<p>Clinical Manager will perform an audit daily until the facility is resurveyed. The frequency of ongoing observation of the room temperature will be determined by the QAI Committee upon review of the audit results. Any noted non-compliance through staff adjusting the thermostat will be addressed immediately with the personnel involved including corrective action as appropriate</p> <p>This log includes patient responses to the treatment room temperature in order to maintain a comfortable temperature within the facility. A patient focused survey will be conducted on 10/12/12 and then again 1 week later to assess patient satisfaction to the temperature of the treatment floor.</p> <p>The Clinical Manager will report a summary of findings monthly in QAI with compliance monitored by the QAI Committee.</p>		

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V0404	<p>494.60(c)(1) PE-PT CARE ENVIRONMENT-SUFFICIENT SPACE The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff.</p> <p>Based on interview and observation, the facility failed to ensure adequate space was available in the home training and education room for all the patient training and education supplies required for the home training and dialysis, assessment tools, to prevent cross contamination, to provide a privacy screen when the patient requests, for the patient's helper, staff, and any of the other disciplines (the social worker, dietician, or physician) to visit during during clinic visits, and for the staff to provide emergent care for 1 of 1 home program training room with the potential to affect all home patients.</p> <p>The findings include:</p> <p>1. On 9/19/12 at 1:15 PM, during a tour of the facility, the clinical manager indicated the facility shared a space under the same roof with a physician group named Sigma Specialty. She identified the hallway as the line which divides the space except for one room which she identified as the home training and</p>	V0404	<p>Effective immediately, the facility has installed scales within the training room. The room has been stocked with training and educational materials which will be maintained by the facility and kept available to facility home dialysis patients.</p> <p>The Home Program Manager will report a summary of findings monthly in QAI and compliance will be monitored by the QAI Committee.</p>	10/12/2012	

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	<p>education room. This room opens into the hallway which divides the space and is shared by the staff of the physician group. There was no boundary between the physician offices and the home program space. The one room designated as the home program training room was small and nearly vacant. It had one dialysis chair, 2 stools, limited supplies, no soap, no disposable towels, no waterless hand sanitizer to cleanse hands, 1/2 box of latex free - nitrile gloves. There is no space for standard physician office scales. There were no training materials or tools in the space.</p> <p>2. On 9/19/12 at 4:30 PM, employee B indicated the one room, though void of any training and education materials, was used for the home patients training and education.</p> <p>3. On 9/24/12 at 3 PM, employee B indicated the home program staff was using the scales from the physician office space they share. She indicated the home patients enter through the entrance door and waiting room identified as the Sigma Specialty physician group. She said the home program brings the home patients through the left entrance of the physician office and uses the scales from the physician office that are also used by the</p>				

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	physician office patients. Employee B indicated the scales do not belong to the facility, nor do they maintain these scales. She indicated the scales are owned and maintained by the physician group.			

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V0408	<p>494.60(d) PE-EMERGENCY PREPAREDNESS-PROCEDURES The dialysis facility must implement processes and procedures to manage medical and non medical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. Based on interview and review of administrative and personnel files, the facility failed to develop and implement processes and procedures to manage medical and non medical emergencies that are likely to threaten the health and safety of patients, staff, and visitors, for 1 of 1 facility reviewed with the potential to affect all staff, visitors, and patients.</p> <p>The findings include:</p> <p>1. On 9/24/12 at 3:55 PM, employee B indicated she had worked for the facility for more than one year and had never participated in any emergency training or been part of any emergency development. She also indicated if she had a patient in the home training room and experienced an emergency, she was unable to describe the facility specific emergency plans and could not explain what was the responsibility of the nurses in the event of</p>	V0408	<p>On October 8, 2012, the Governing Body met and determined to adopt the FMCNA Fire Policies as well as the Facility Specific Fire Safety Plan. This is documented within the GB Minutes of this date. The Operations Manager met with the facility's staff on October 10, 2012 to review their requirements as stated in the Conditions for Coverage and defined in policy and procedure FMS-CS-IC-II-130-013A/C "Fire Drill Policy, to ensure that every staff member is oriented and educated on fire preparedness. On 10/19/12, the Education Coordinator provided an in-service to all staff members reviewing the Lebanon – Facility Specific Fire Safety Plan. Fire/Emergency Drill Observation documentation and attendance sheet are available at the facility. Fire drills were held on 10/24/12 and 10/25/12, to include activation of the fire alarm and staff members' specific roles.</p>	10/25/2012			

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	<p>an emergency. She stated, "You will have to ask employee E."</p> <p>2. On 9/24/12 at 4:17 PM, employee E indicated the only emergency preparedness completed is by a hospital staff who comes and pulls the fire alarm. This occurs every 2 - 3 months. She indicated there was no other information.</p> <p>3. The "Fire Drill" documentation was reviewed and the documents were not complete. The documents failed to evidence all staff had participated over the last 12 months.</p> <p>4. The personnel files of employee B, C, G, J, and K failed to evidence any emergency training specific to this facility since 12/1/09.</p> <p>5. On 9/24/12 at 4:20 PM, employee B reviewed personnel files B, C, G, J, and K and confirmed there was no emergency training and preparedness contained within the files and could not found to be elsewhere.</p> <p>6. The undated policy titled "Administrative Manual Policies and Procedures" stated, "Each employee will have a personnel file maintained ... This file will contain but is not limited to ... documentation of continuing education, ...</p>		<p>Documentation of the drills is available within the facility. Ongoing, fire drills will be held per the QAI quarterly audit tool. As part of the admission process, each new patient will also be given this education. Quarterly, each patient will participate in the facility's fire 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 fire drill, which will be 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 Fire Drill Observation tracking of all patients and staff quarterly to ensure that all patients and staff participated in the facility's fire 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 preparedness within their first month on dialysis. The Clinical Manager is responsible to review the fire drills identifying any opportunities for improvement and ensuring that all staff members are aware of their</p>				

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	documentation of performance evaluations, incidents and counseling. Documentation of annual competency testing."		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 fire drill 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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V0409	<p>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:</p> <p>(i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of-</p> <p>(A) What to do;</p> <p>(B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;</p> <p>(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</p> <p>(D) How to disconnect themselves from the dialysis machine if an emergency occurs.</p> <p>Based on interview and review of administrative and personnel files, the facility failed to provide annual emergency training specific to this facility for 5 of 5 personnel file reviewed (B, C, G, J, and K) with the potential to affect all staff, visitors, and patients.</p> <p>The findings include:</p> <p>1. On 9/24/12 at 3:55 PM, employee B indicated she had worked for the facility</p>	V0409	<p>On October 8, 2012, the Governing Body met and determined to replace the current Liberty Lebanon 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.</p> <p>The Operations Manager met with the facility's staff on 10/10/12 to review their requirements as stated in the Conditions for</p>	10/25/2012			

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	<p>for more than one year and had never participated in any emergency training or been part of any emergency development. She also indicated if she had a patient in the home training room and experienced an emergency, she was unable to describe the facility specific emergency plans and could not explain what was the responsibility of the nurses in the event of an emergency. She stated, "You will have to ask employee E."</p> <p>2. On 9/24/12 at 4:17 PM, employee E indicated the only emergency preparedness completed is by a hospital staff who comes and pulls the fire alarm. This occurs every 2 - 3 months. She indicated there was no other information.</p> <p>3. The "Fire Drill" documentation was reviewed and the documents were not complete. The documents failed to evidence all staff had participated over the last 12 months.</p> <p>4. The personnel files of employee B, C, G, J, and K failed to evidence any emergency training specific to this facility since 12/1/09.</p> <p>5. On 9/24/12 at 4:20 PM, employee B reviewed personnel files B, C, G, J, and K and confirmed there was no emergency training and preparedness contained</p>		<p>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</p> <p>On 10/19/12, the Operations Manager provided an in-service to all staff members reviewing the Lebanon – Facility Specific Disaster Plan. Disaster Drill Observation documentation and attendance sheet are available at the facility. Disaster drills were held on 10/24/12 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.</p> <p>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</p>		

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	<p>within the files and could not found to be elsewhere.</p> <p>6. The undated policy titled "Administrative Manual Policies and Procedures" stated, "Each employee will have a personnel file maintained ... This file will contain but is not limited to ... documentation of continuing education, ... documentation of performance evaluations, incidents and counseling. Documentation of annual competency testing."</p>		<p>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.</p> <p>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.</p> <p>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.</p> <p>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</p>		

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			<p>action plans if needed.</p> <p>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.</p>		

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V0506	<p>494.80(a)(3) PA-IMMUNIZATION/MEDICATION HISTORY The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>Immunization history, and medication history. Based on interview and review of clinical records and policy, the facility failed to ensure all patients' comprehensive assessment included the patient's immunization history for 1 of 5 clinical records of current patients reviewed with the potential to affect all current patients, staff, and visitors. (1)</p> <p>The findings include:</p> <p>1. Clinical record #1 included a comprehensive assessment dated 8/31/12 which failed to assess quarterly the patients tuberculosis exposure status and the patient's susceptibility to hepatitis B, with an antibody value of less than 10 on 8/7/12. The patient had requested to receive the hepatitis B vaccine 8/7/12.</p> <p>2. On 9/20/2012 at 4:29 PM, employee B indicated the documentation of a titer > 10 written on the patients consent form was incorrect and the patient was not monitored since 8/7/12. The patient did not begin the series as requested.</p>	V0506	<p>The Governing Body met on October 8, 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 of this date when determined.</p> <p>The Operations Manager met with the facility's Interdisciplinary Team on 10/10/12 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.</p> <p>The nursing staff was educated on 10/10/12 by the Operations Manager on the recently adopted</p>	10/26/2012	

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	3. The undated policy titled "Infection Control" stated, "Screening and record keeping: Patients: All new patients entering the program will have Hepatitis B screening with results available to their first treatment. ... All patients with a negative Hepatitis B antibodies will be offered a Hepatitis B vaccine as part of their admission criteria. ... If patients request the vaccine, it will be given at any time."		<p>policies, 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 both TB with an annual Assessment and susceptibility to Hepatitis B.</p> <p>The Clinical Manager and Home Program Manager completed 100% review of all patients' Comprehensive Assessments by 10/19/12 to ensure that all Assessments include a medication and immunization review that is complete and current. Any patient's Assessment found to be missing an immunization history including patients # 1 will be presented to the IDT for completion by 10/26/12 including obtaining patient testing as necessary.</p> <p>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.</p> <p>The Clinical Manager and Home Program Manager is responsible to report a summary of findings monthly utilizing the tracking tool as noted above to include the</p>	

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			<p>number of Assessments due focusing on the immunization history, those completed and those missed to the QAI. Any patient missing any component of the Assessment will be scheduled for completion the following month and corrective action will be taken as appropriate.</p> <p>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.</p> <p>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.</p>		

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V0627	<p>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.</p> <p>Based on administrative 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 regards to their hepatitis B status resulting in the continued noncompliance with infection control policies and procedures and the mismanagement of hepatitis B susceptible patients creating the potential to affect all of the facility's 34 current patients.</p> <p>The findings include:</p> <p>1. The facility's QAPI meeting minutes dated 4/20/12 indicated the facility census of hemodialysis patients in March 2012 was 29 and, of those patients, 24 did not have a hepatitis B antibody > 10 mIU / mL. A total of 11 patients had completed the hepatitis B vaccination series.</p>	V0627	<p>On October 8, 2012, the Governing Body determined to replace the current Liberty Lebanon QAI Process with the adoption of the FMCNA QAI Program including the policies, templates, Minutes and audits.</p> <p>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:</p> <ul style="list-style-type: none"> · 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 <ul style="list-style-type: none"> o Vaccination tracking tool analysis o Identification and resolution of infection control practice 	10/26/2012	

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	<p>2. The facility's QAPI meeting minutes dated 5/25/12 indicated the patient census for April 2012 was 30 patients and 25 of those patients did not have a hepatitis B antibody > 10 mIU / mL. Eleven patients had completed the hepatitis B vaccine series.</p> <p>3. The facility's QAPI meeting minutes dated 6/29/12 indicated the patient census for May 2012 was 31 patients and 27 of those patients did not have a hepatitis B antibody > 10 mIU / mL. Eleven patients had completed the Hepatitis B vaccine series.</p> <p>4. The facility's QAPI meeting minutes dated 7/12/12 indicated the patient census for June 2012 was 32 patients and 24 of those patients did not have a hepatitis B antibody > 10 mIU / mL. Eleven patients had completed the Hepatitis B vaccine series.</p> <p>5. The facility's QAPI meeting minutes dated 8/31/12 indicated the patient census for July 2012 was 31 patients and 25 of those patients did not have a hepatitis B antibody > 10 mIU / mL. Twelve patients had completed the hepatitis B vaccination series.</p> <p>6. The Target for all state, "Goal:100% of</p>		<p>noncompliance</p> <ul style="list-style-type: none"> o Management of patients with regards to their Hepatitis B status through creating a project on evaluating hepatitis status's on all patients <p>The QAI Committee will analyze the last 3 months of vaccination analysis, infection control practice noncompliance and patients' hepatitis susceptibility at the QAI Meeting on October 26, 2012 to update the Minutes with the current status as evidenced by trends and log reports.</p> <p>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.</p> <p>The Clinical Manager is responsible to report a summary of trending and analysis of vaccinations, infection control practice non-compliance and patients' hepatitis B status tracking monthly to the QAI and Medical Director.</p> <p>The Director of Operations is responsible to monitor the QAI data monthly to ensure the Clinical Manager is presenting all</p>				

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	<p>eligible patients are vaccinated. The goal remained the same every month. The meeting minutes failed to identify how the facility intended to reach their goal of 100% vaccination and what new interventions were in place.</p> <p>The QAPI meeting minutes reviewed failed to evidence any observations and audits of infection control practices of the staff.</p> <p>7. On 9/19/12 at 4:34 PM, employee E indicated said she had no evidenced the staff were audited for infection control procedures and processes as part of the QAPI. She provided a one page document and said she had no evidence that the staff were observed and audited for compliance to infection control policies and procedures.</p> <p>8. On 9/19/12 at 4:41 PM, employee E indicated she had not completed individual evaluations of the skill and competency of the patient care technicians and nurses as part of a infection control monitoring. She confirmed the most recent documentation for employee C, G, and J was dated 12/1/09.</p>		<p>trending and documentation as required.</p> <p>The QAI Committee and Medical Director are responsible to analyze the data, determine a root cause analysis if trending identifies immunization, infection control practice and patient's Hepatitis B susceptibility rates that are outside of target and ensure action plans are in place and resolution is occurring.</p> <p>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.</p>		

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	9. The undated policy titled "Infection Control Measures" stated, "Infection control and adverse events monitoring, assessment, and improvement will be part of the facilities QAPI program."			

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V0637	<p>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-</p> <p>(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.</p> <p>Based on administrative record and facility policy 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 developed recommendations and action plans to minimize infection transmission creating the potential to affect all of the facility's 34 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The facility's QAPI meeting minutes dated 4/20/12, 5/25/12, 6/29/12, 7/12/12, and 8/31/12 failed to evidence observation and audits of infection control practices of the staff. 2. On 9/19/12 at 4:34 PM, employee E indicated said she had no evidenced the staff were audited for infection control 	V0637	<p>As noted in detail in V 627, the Governing Body of the Liberty Lebanon facility has directed the adoption of the FMCNA QAI Program to include policies/procedures, Minutes, audit templates and QAI Calendar.</p> <p>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 immunization processes, staff members' infection control practice breaches and patients' Hepatitis B susceptibility.</p> <p>The Clinical Manager is responsible to report a summary of trending and analysis of vaccinations, infection control practice non-compliance and patients' hepatitis B status tracking monthly to the QAI and Medical Director.</p>	10/26/2012	

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	<p>procedures and processes as part of the QAPI. She provided a one page document and indicated she had no other documentation the staff were observed individually and audited for compliance to infection control policies and procedures.</p> <p>3. On 9/19/12 at 4:41 PM, employee E indicated she had not completed individual evaluations of the skills and competency of the patient care technicians and nurses as part of an infection control monitoring. She confirmed the most recent documentation for employee C, G, and J was dated 12/1/09.</p> <p>4. The undated policy titled "Infection Control Measures" stated, "Infection control and adverse events monitoring, assessment, and improvement will be part of the facilities QAPI program."</p>		<p>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.</p> <p>The QAI Committee and Medical Director are responsible to analyze the data, determine a root cause analysis if trending identifies immunization, infection control practice and patient's Hepatitis B susceptibility rates that are outside of target and ensure action plans are in place and resolution is occurring.</p> <p>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.</p>	

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V0715	<p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; Based on policy review and observation, and interview, the medical director failed to ensure facility staff had documented accurately the care provided in accordance with the facility's patient monitoring policy in 6 of 14 post treatment records reviewed (#s 3, 5, 6, 7, 8, and 9) dated 9/19/12 creating the potential to affect all of the facility's 31 current in-center patients.</p> <p>The findings include:</p> <p>1. The undated policy titled "EMR HD Treatment Documentation" stated, "To ensure the integrity of the electronic record, the documentation should accurately reflect the care given at the time of service. ... Pre - HD [hemodialysis] ... Physical assessment performed by - RN pre-treatment. ... Document any abnormal physical assessments. ... Completed by - the staff that filled in the final information."</p> <p>2. On 9/19/12 at 10:50 AM, employee E</p>	V0715	<p>The Director of Operations met with the Medical Director on 10/8/12 to review her requirements as defined in the Condition for Coverage and Staff Bylaws to ensure that all policies and procedures relative to patient admission, patient care, infection control and patient safety are adhered to by all individuals who treat patients in the facility emphasizing the requirement for a pre treatment assessment to be performed and accurately documented within 1 hour of the treatment beginning and the timely and accurate documentation of medication administration. 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 as noted below.</p> <p>The Director of Operations met with all nursing personnel including the Clinical Manager on October 10, 2012 to review the requirement that all documentation must be signed</p>	10/26/2012			

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	<p>was on duty and the only registered nurse on the premises. At 12:34 PM, employee L arrival onto the in-center dialysis unit.</p> <p>The administrative document of the staff's time accountability and payroll hours evidenced employee L arrived for work at 12:18 PM on 9/19/12.</p> <p>3. The post treatment record dated 9/19/12 for patient #3 evidenced the patient began dialysis treatment at 9:58 AM. The record failed to evidence the registered nurse on duty completed the pre- HD assessment within one hour of the beginning of treatment. The record evidenced employee L, a registered nurse, documented the pre - HD assessment was completed at 10 AM by employee E.</p> <p>4. The post treatment record dated 9/19/12 for patient #5 evidenced the patient began dialysis treatment at 10:47 AM. The record failed to evidence the registered nurse on duty completed the pre- HD assessment within one hour of the beginning of treatment. The record evidenced employee L completed and documented the pre - HD assessment at 10:50 AM. The post treatment record evidenced the medication calcitrol was administered to the patient at 11 AM by employee L, prior to her arrival at work.</p>		<p>only by the RN performing the task, that a pretreatment assessment must be performed and documented within 1 hour of the treatment beginning by the nurse that performs the assessment. Medication administration and documentation was also reviewed during the meeting. Any breach in documentation principles and/or requirements will be addressed with corrective action up to and including termination.</p> <p>The Operations Manager or designee will audit 100% of all patients' dialysis flow sheets daily to ensure that the pre-treatment assessment has been completed and documented within 1 hour of the treatment beginning by the nurse that performed the assessment and that medication administered is documented by the nurse administering the medication. The daily audits will continue until the facility is resurveyed then weekly. The frequency of ongoing audits will be determined by the QAI Committee upon review of the audits and resolution of the issue. Any evidence of non-compliance will be addressed immediately including corrective action up to and including termination.</p> <p>The Clinical Manager (CM) is responsible to present all data and monitoring/audit results as</p>				

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	<p>5. The post treatment record dated 9/19/12 for patient # 6 evidenced the patient began dialysis treatment at 11:06 AM. The record evidenced employee L documented she completed an assessment of the patient at 11:10 AM and completed the dialysis machine settings, prior to her arrival at work.</p> <p>6. The post treatment record dated 9/19/12 for patient # 7 evidenced the patient began dialysis treatment at 10:22 AM. The record failed to evidence the registered nurse on duty completed the pre- HD assessment within one hour of the beginning of treatment. The record evidenced employee L documented completion of the pre - HD assessment and dialysis machine settings at 10:25 AM. The record evidenced employee L documented administration of a medication Heparin at 10:25 AM 1 hour and 53 minutes prior to her arrival to work.</p> <p>7. The post treatment record dated 9/19/12 for patient # 8 evidenced the patient began dialysis treatment at 10:24 AM. The record failed to evidence the registered nurse on duty completed the pre- HD assessment within one hour of the beginning of treatment. The record evidenced employee L documented completion of the pre - HD assessment</p>		<p>related to this Plan of Correction to the Medical Director at the QAI Meeting for oversight and review.</p> <p>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.</p> <p>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</p>				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152610		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 09/24/2012	
NAME OF PROVIDER OR SUPPLIER LIBERTY DIALYSIS LEBANON LLC				STREET ADDRESS, CITY, STATE, ZIP CODE 2485 LEBANON ST LEBANON, IN 46052			
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	<p>and dialysis machine settings at 10:25 AM. The record evidenced employee L documented administration of the medications Heparin at 10:25 AM 1 hour and 53 minutes prior to her arrival to work, calcitrol 0.25 mcg orally, epogen 3000 units via intravenous, and clonidine 0.1 milligram were documented as administered at 11 AM, one hour and eighteen minutes prior to her arrival to work.</p> <p>8. The post treatment record dated 9/19/12 for patient # 9 evidenced the patient began dialysis treatment at 10:45 AM. The record failed to evidence the registered nurse on duty completed the pre- HD assessment within one hour of the beginning of treatment. The record evidenced employee L documented completion of the pre - HD assessment and dialysis machine settings at 10:45 AM. The record evidenced also employee L documented administration of the medication Heparin intravenously at 10:45 AM, one hour and thirty three minutes prior to her arrival to work.</p> <p>9. On 9/24/12 at 3:24 PM, employee E indicated employee L signed for assessments and medications she had not completed or administered on 9/19/12. Employee E indicated she got behind and employee L documented for her.</p>						

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