STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152552	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING	(X3) DATE SURVEY COMPLETED 08/11/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FRESENIUS MEDICAL CARE HENDRICKS COUNTY	1594 E MAIN ST STE A DANVILLE, IN 46122

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V000000	This was a (CORE) federal ESRD recertification survey. Survey Dates: August 4, 5, 6, 7, 8, and 11, 2014 Facility #: 010185 Medicaid Vendor #: 200181260A Surveyor: Bridget Boston, RN, Public Health Nurse Surveyor Census: 63 In-center Hemodialysis - 57 which includes Nocturnal - 7 Home Peritoneal dialysis - 6 Home Hemodialysis - 0 FMC Hendricks County was found to be out of compliance with the Condition for Coverage 42 CFR 494.30: Infection Control. Quality Review: Joyce Elder, MSN, BSN, RN August 20, 2014	V000000		

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

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

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V000110	494.30 CFC-INFECTION CONTROL Based on observation, policy and procedure review, and interview, it was determined the facility failed to ensure staff followed infection control precautions to minimize the transmission of infectious agents for 2 of 3 days of observations (See V 112), failed to ensure staff members followed the Centers for Disease Control recommendations and facility infection control policies during the initiation of dialysis treatments in 1 of 1 observation of access of arteriovenous fistula (AVF) for initiation of dialysis and in 2 of 2 observations during the termination of dialysis with a AVF, and 1 of 1 observation of the collection of a blood culture sample creating the potential to affect all dialysis patients (See V 113), failed to ensure 2 of 4 Patient Care Technicians observed kept clean areas clearly separated from contaminated areas creating the potential to spread infectious and communicable disease to all 57 in-center patients of the facility (See V 117) and failed to ensure 1 of 1 employees observed treating a patient with a central venous catheter provided care in compliance with central venous catheter policy and assessed the access site on a patient with a femoral catheter with the potential to affect all patients	V000110	As a result of the citations from the August 11, 2014, survey and as part of the developed plan of correction, the Director of Operations over saw the completion of the following actions. · Implemented an intensive monitoring process, reeducated staff and reinforced the mandatory requirement of direct patient care staff follow the infection control precautions to minimize the risk of infection transmission Please refer to V-112 ·Implemented an intensive monitoring process, reeducated staff and reinforced the mandatory requirement of direct patient care staff to comply with all aspects of the facility's infection control policies including accessing the AVF and drawing blood cultures. Please refer to V-113 ·Implemented an intensive monitoring process, reeducated staff and reinforced the mandatory requirement of separation of clean and contaminated areas and reorganized the clean and contaminated areas to facilitate compliance Please refer to V-117 ·Implemented an intensive monitoring process, reeducated staff and reinforced the mandatory requirement of the facility's Central Venous Catheters policies and	08/27/2014

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	with catheters (See V 147). 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.		procedures. Please refer to V 147 Documentation of the education, monitoring process, staff and patient assignments document the implemented corrective actions and are available at the facility for review Monitoring of the staff for compliance has occurred and will continue to occur by the Clinical Manager or assigned Nurse as follows: ·Direct observation of the staff's adherence to infection control policies and procedures. ·Immediate intervention, consisting of reeducation up to disciplinary action, to address and correct identified noncompliance with the appropriate staff member. The Clinical Manager documents staff compliance on the developed plan of correction monitoring tool. This tool was implemented on 8/13/2014 and was completed during each patient shift with decreased frequency as determined by the Governing Body. Any identified staff non-compliance will have an immediate intervention by the Clinical Manager/Designee providing oversight. The noncompliance and intervention will be documented on the plan of correction monitoring tool or in the employees personnel file if warranted. In the event that a staff member is found to continually not follow the facility procedures for infection control, the Clinical Manager will be	

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			notified and is responsible to address the findings with the identified staff member. The Clinical Manager's action will be structured to reinforce by further education following through as necessary with the application of progressive disciplinary action. The Clinical Manager will summarize the findings and report to the QAI Committee monthly and to the Governing Body weekly who will determine further audit frequency by decreasing the frequency incrementally. Once compliance has been established the monitoring will revert to the QAI infection control audit tool. The Clinical Manager is responsible and the QAI Committee and the Governing Body monitor for ongoing compliance	
V000112	494.30(a) IC-CDC MMWR 2001 The facility must demonstrate that it follows standard infection control precautions by implementing- (1)(i) The recommendations (with the exception of screening for hepatitis C), found in "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS			

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	Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. The recommendation found under section header "HBV-Infected Patients", found on pages 27 and 28 of RR05 ("Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients"), concerning isolation rooms, must be complied with by February 9, 2009.			
	Based on observation, policy and procedure review, and interview, the facility failed to ensure staff followed infection control precautions to minimize the transmission of infectious agents for 2 of 3 days of observations. (Employees D, F, G, and K) The findings include: 1. The facility's April 2013 "Infection Control Overview" states, "All infection control policies are consistent with recommendation of the Centers for Disease Control (CDC). All infection control policies will adhere to CMS and OSHA rules and regulation . . . Mandatory Components of Program:	V000112	A Governing Body meeting was held on 8/27/2014 via conference call. The Director of Operations reviewed the Statement of Deficiencies and discussed the condition level deficiency for Infection Control and each of the standard level deficiencies. All parties verbalized understanding. The Clinical Manager discussed the actions that were implemented immediately to correct the Infection Control and standard level deficiencies as described in the paragraphs below. The Clinical Manager discussed the new process for disinfection and handling the Patient Communication Binders, as well as the preparation of take off supplies no earlier than 15 minutes prior to termination of the treatment, the new procedures ware approved and adopted by the	09/03/2014

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	Adherence to standard and dialysis precautions . . . Infection control training and education, including maintenance of training records . . . Infection Control Policies: . . . Hand Hygiene, Dialysis unit precautions (including the use of personal protective equipment) . . . Rinsing, cleaning, disinfection, preparation, and storage of reused items conforming to CMS requirement for use." 2. The agency policy titled "Hand Hygiene" with an effective date of March 20, 2013, stated, "The purpose of this policy is to prevent transmission of pathogenic microorganisms to patients and staff through cross contamination ... Hands will be ... decontaminated using alcohol based hand rub or by washing hands with antimicrobial soap and water before and after direct contact with patients, entering and leaving the treatment area ... immediately after removing gloves ... after contact with inanimate objects near the patient , when moving from a contaminated body site to a clean body site of the same patient." 3. The facility's "Assessment and Preparation of Internal Access for Needle Placement" revision date 9/25/13 states, "Ask your patient to wash access area with liquid soap for one minute, rinsing well. Dry with clean paper towel."		Governing Body for implementation after staff training. On 8/27/2014, 8/28/2014 and 8/29/2014, the Clinical Manager conducted formal staff meetings during which the Statement of Deficiencies was reviewed and serious nature of the condition level deficiency was explained. The Regional Quality Manager assisted the Clinical Manager in the presentation and re-education of the staff on the policies and procedures listed below as related to the citations with emphasis on their role with infection prevention and control and the responsibility of every employee to ensure patient safety During the survey, the Clinical Manager met with the staff individually on 8/4/2014, 8/5/2014 and 8/7/2014 and reviewed the Dialysis Precautions Policy, FMS-CS-IC-II-15-070A with emphasis on the definitions of clean and dirty areas and the need for clear separation between clean and dirty areas including: avoiding contamination of clean supplies by placing a clean barrier on the overbed table upon which to set the clean supplies; avoiding contamination of patient's belongings, including the ECF Communication Binder, by ensuring that all are removed from the table during initiation and termination of	

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	4. The CDC Morbidity and Mortality Weekly Report (MMWR) October 25, 2002, Volume 51 No. RR-16 "Guideline for Hand Hygiene in Health-Care Setting" states, "Recommendations: Indications for handwashing and hand antisepsis . . . Decontaminate hands before having direct contact with patients . . . Decontaminate hands after contact with a patient's intact skin . . . Decontaminate hands if moving from a contaminated body site to a clean body site during patient care. Decontaminate hands after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient. Decontaminate hands after removing gloves." 5. Facility policy titled "Collection of blood specimens for Blood Culture" revision date of September 25, 2013, states, "8. Put on ... clean gloves. ... Use aseptic technique to insert the butterfly assembly into the disinfected arterial bloodline port or CVC." 6. Facility policy titled "Dialysis Precautions" revision date of January 2012 states, "Clean area: An Area designated for clean and unused equipment, supplies, ... Dirty area: ... this is a potential for contamination with		treatment, as well as during any intervention required during the treatment; utilizing a trash can to put dirty items such as tape and gauze which do not require disposal in the infectious waste. At the end of 8/5/14, the Clinical Manager placed trash cans between each patient station. A process change was implemented that supplies used for termination of treatment will not be included in the "on kit" but will be prepared at the clean supply cart and brought to the patient station no earlier than 15 minutes prior to termination of treatment. The CM met one on one with employees E, D, G, on 8-4 and 8-6 and reviewed her expectations that they would adhere to the infection control policies. During the period of 8/5/2014 through 8/8/2014, the Education Coordinators completed Annual Skills Checklists on all day shift staff to ensure competency. Annual Skills Checklists will be completed on nocturnal staff by 9/03/2014. Competency skills checklist are available in the employee files for review. On 8/25/2014, the Clinical Manager and Director of Operations met with the day shift nurses to conduct a root cause analysis, obtain input and	

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	blood or body fluids and areas where contaminated or used supplies, ... equipment, blood supplies or biohazard containers are stored or handled. ... Clean areas should be clearly separated from dirty areas where used supplies, equipment or blood samples are handled." 7. On 8/4/14 at 1:25 PM, employee D, patient care technician (PCT), was observed performing discontinuation of dialysis and post dialysis access care with patient 9. A wood laminate bedside table was present beside and overtop of the patient's bed. The PCT obtained new supplies to discontinue dialysis that included 2 X 2 gauze and placed it directly onto the patient's bedside table, without a barrier, prior to the removal of the needles from the patients fistula. The PCT removed each needle and used the gauze supply directly from the bedside table and secured it to the patient's access. 8. On 8/4/14 at 2:20 PM, observed employee F, PCT, with patient 8 (access was a femoral catheter) in station 14. The bedside table contained 2 emesis basins, one holding fluid, soiled gloves and a facial mask. The PCT obtained a box with supplies to draw blood cultures, placed the box on top of the gloves and		identify process changes to achieve sustainable, ongoing compliance with infection control policies and procedures. The Clinical Manager also reviewed the responsibility and expectation that the nurses to monitor the actions of all staff on the floor to ensure compliance with policy and procedure and bring any concerns to the immediate attention of the Clinical Manager. As a result of this meeting, the Clinical Manager revised the format of the Daily Patient Schedule to include patient antibody status and notation of patient station numbers, addition of PCT assignment for patient monitoring to increase accountability, sign off area for completion of side jobs and review of the patient on/off times for each section to ensure intervals between patients are appropriate. In addition, each Patient Care Technician will be assigned to complete an infection control or Flash Tour audit daily, observing all staff beginning 8/31/2014 to further increase the focus on infection control and adherence to policies and procedures. On 8/27/2014, the Clinical Manager communicated with the ECF regarding a patient whose communication paperwork was in a paper folder. The Clinical Manager notified the ECF that the facility would place the communication documentation in a vinyl binder that	

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	mask which were on the bedside table, and between the two emesis basins. She donned gloves, picked up the emesis basin containing fluid, moved it to a corner of the bedside table. Without changing gloves, she opened the box and began removing the contents, placed the Blood Culture Adapter to the sample bottle, and then began to remove the blood lines to collect the blood sample. The PCT failed to complete hand hygiene and don clean gloves after contact with the emesis basin. At 2:45 PM, employee F indicated she should have completed hand hygiene after contact with the soiled items. 9. On 8/4/14 at 1:10 PM, employee F, PCT, was in station # 12 terminating dialysis treatment with patient #11 whose access was a central venous catheter. The PCT obtained supplies for the termination and placed them on the wood laminate bedside table without a barrier underneath. The PCT terminated the dialysis treatment. After she cleansed the hubs of each catheter limb with an alcohol wipe, she tossed the contaminated gauze on the top of the bedside table amongst the clean supplies and all the personal items the patient had brought to the in-center and placed on the bedside table and the one piece of		could be disinfected rather than using the paper folder. Again on 8/27/2014, 8/28/2014 and 8/29/2014, the Clinical Manager conducted formal staff meetings during which the Statement of Deficiencies was reviewed and serious nature of the condition level deficiency was explained. The Regional Quality Manager assisted the Clinical Manager in the presentation and re-education of the staff on the policies and procedures listed below as related to the citations with emphasis on their role with infection prevention and control and the responsibility of every employee to ensure patient safety. ·Dialysis Precautions, FMS-CS-IC-II-155-070A ·Hand Hygiene, FMS-CS-IC-II-155-090A ·Assessment and Preparation of Internal Access for Needle Placement, FMS-CS-IC-I-115-006C ·Collection of Specimens for Blood Culture Procedure, FMS-CS-IC-II-135-014C ·CDC Morbidity and Mortality Weekly Review (MMWR), April 27, 2001, Vol. 50, No. RR-5, Recommendations for Preventing Transmission of Infection Among Chronic Hemodialysis Patients ·CDC Morbidity and Mortality Weekly Review (MMWR), October 25, 2002, Vol. 51, No. RR-16,	

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	educational material the dialysis staff had delivered to each patient that day. 10. On 8/4/14 at 1:44 PM, employee G, PCT, was observed in station # 19 terminating dialysis treatment with patient #12 (access was a central venous catheter). The PCT obtained supplies for the termination and placed them on the wood laminate bedside table without a barrier underneath; there was a barrier brought to the station which remained folded and unused to maintain either a clean or soiled area. On top of the folded barrier were gloves, 4 X 4 gauze, and two syringes with a clear liquid. The PCT terminated the dialysis treatment. After she cleansed the hubs of each catheter limb with an alcohol wipe, she tossed each contaminated gauze on to the clean gloves, syringes, and gauze. She did not dispose of the contaminated items; she used the gloves, instilled the heparin into each lumen, applied the gauze, and wrapped the limbs prior to the patient leaving the facility. A. Observed at 1:52 PM, the patient left the station and soiled masks, gloves, and soiled gauze remained on the bedside table. Patient's communication binder, which traveled between the facility and the residential facility in which the patient resided, was also on the		Guidelines for Hand Hygiene in Health-Care Setting ·Initiation of Treatment Using a Central Venous Catheter and Optiflux® Single Use Ebeam Dialyzer Policy, FMS-CS-IC-I-105-002A ·Termination of Treatment Using a Graft or Fistula and Optiflux® Hollow Fiber Dialyzer Procedure, FMS-CS-IC-I-105-029C ·Changing the Catheter Dressing, FMS-CS-IC-I-105-032A ·Termination of Treatment Using a Central Venous Catheter and Optiflux® Hollow Fiber Dialyzer, FMS-CS-IC-I-105-028C The Clinical Manager also educated the staff regarding disinfection and handling of the communication binder that is sent with patients who reside in an ECF. The disinfected binders will be placed at the nurses' station or cart at the scale after disinfection. The binder will be returned to the patient and placed in their bag upon discharge post treatment back to the ECF. The policies and procedures listed above were printed and placed in a binder for all staff to review and initial each procedure by 8/27/2014. The Clinical Manager or designee will complete the Infection Control audits daily starting 8/13/2014 and continuing until the condition level	

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	bedside table. B. At 2 PM, employee K was observed to carry the communication binder from the station to the nurses station and return to the station. She donned a glove, touched the dialysis machine, and removed the glove and tossed it onto the pile of rubbish on the bedside table and walked away. 11. At 1:48 PM, employee F, PCT, was observed in station # 17 terminating dialysis treatment with patient #1 whose access was a fistula. The PCT obtained unwrapped gauze and gloves for the termination and placed them on educational material the staff had distributed, which was on a wood laminate bedside table along with the patient's glasses used for reading and personal cell phone. The PCT removed the tape from the first access, removed the first needle, applied the piece of 2 X 2 gauze and indiscriminately tossed the soiled tape onto the bedside table among the remaining clean gauze and personal items on the beside table. The patient, with gloved right hand, held pressure on the access and the insertion site began to bleed. The PCT applied new gauze and tossed the soiled gauze on to the bedside table. When the bleeding was controlled, the PCT removed her gloves, tossed them		deficiency is lifted. After the condition level deficiency is lifted, weekly infection control audits will be conducted on each of the five patient shifts for a period of four weeks at which time the QAI Committee and Governing Body will determine if the facility can return to the monthly auditing schedule. The Clinical Manager will present the results to the QAI Committee monthly and weekly to the Governing Body who will determine further audit frequency by decreasing the frequency incrementally. Once compliance has been established the monitoring will revert to the QAI infection control audit tool. The Director of Operations is responsible to ensure all documentation required as part of the QAI process is presented, current, analyzed, trended, and a root cause analysis completed as appropriate, with the subsequent development of action plans. The QAI Committee is responsible to analyze the results and determine a root causes analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI Committee and Governing Body. The Clinical Manager is responsible and the QAI Committee and the Governing Body monitor for ongoing compliance	

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	onto the bedside table, and left the station. At 2 PM, the PCT returned to the station, removed the second needle, utilized the 2 X 2 gauze from the bedside table, removed her gloves, and tossed them onto the bedside table. Trash was observed to fall off the bedside table. The patient held the access with gloved right hand, resting right elbow on table among the soiled gloves and tape, educational material, and the patient's cell phone and glasses. At 2:07 PM, observed patient pick up personal cell phone, glasses, and educational material and left the unit. The staff failed to decontaminate the patient's personal items once contaminated and failed to replace the educational material. 12. On 8/4/14 at 2:45 PM, employee F was observed in station # 14 terminating the dialysis treatment with patient # 8. After the PCT cleansed each of the hubs with an alcohol pad, she threw them onto the bedside table where there was no barrier and no delineation between the dirty and clean area of the table top. The barrier which was under the patients lines during dialysis treatment was crumbled up on the bedside table and against the blood specimen mailing box which remained.			

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	13. Employee F, a patient care technician (PCT), was observed to initiate the dialysis treatment for patient number 13 on 8/6/14 at 10:10 AM. The PCT washed the patient's access and palpated the access site and then inserted each needle into the patient's AVF. Employee F failed to change her gloves and cleanse her hands after washing the patient's access and locating and palpating the access site with her gloved finger in preparation for cannulation of the sites. 14. On 8/4/14 at 5:05 PM, employee A indicated the staff were to maintain separation between clean and soiled areas.			
V000113	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station. Based on observation, facility policy review, and interview, the facility failed to ensure staff members followed the Centers for Disease Control (CDC) recommendations and facility infection control policies during the initiation of	V000113	The Clinical Manager met with Employee F and D, on 8/4/2014 and 8/6/2014, and reviewed the Hand Hygiene Policy, FMS-CS-IC-II-155-090A, with emphasis on performing hand hygiene after glove removal,	08/31/2014

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	dialysis treatments in 1 of 1 observation of access of arteriovenous fistula (AVF) for initiation of dialysis (employee F) and in 2 of 2 observations during the termination of dialysis with a arteriovenous fistula (AVF) (employees D and F), and 1 of 1 observation (employee F) of the collection of a blood culture sample creating the potential to affect all dialysis patients. The findings include: 1. The facility's April 2013 "Infection Control Overview" policy number FMS-CS-IC-II-155-060A states, "All infection control policies are consistent with recommendation of the Centers for Disease Control (CDC). All infection control policies will adhere to CMS and OSHA rules and regulation . . . Mandatory Components of Program: Adherence to standard and dialysis precautions . . . Infection control training and education, including maintenance of training records . . . Infection Control Policies: . . . Hand Hygiene, Dialysis unit precautions (including the use of personal protective equipment) . . . Rinsing, cleaning, disinfection, preparation, and storage of reused items conforming to CMS requirement for use." A. The agency policy titled "Hand		changing gloves after touching dirty items, before beginning clean tasks. On 8/27/2014, 8/87/2014 and 8/29/2014, the Clinical Manager conducted formal staff meetings during which the Statement of Deficiencies was reviewed and serious nature of the condition level deficiency was explained. The Regional Quality Manager assisted the Clinical Manager in the presentation and re-education of the staff on the policies and procedures listed below as related to the citations with emphasis on their role with infection prevention and control and the responsibility of every employee to ensure patient safety. ·Dialysis Precautions, FMS-CS-IC-II-155-070A ·Hand Hygiene, FMS-CS-IC-II-155-090A ·Assessment and Preparation of Internal Access for Needle Placement, FMS-CS-IC-I-115-006C ·Collection of Specimens for Blood Culture Procedure, FMS-CS-IC-II-135-014C ·CDC Morbidity and Mortality Weekly Review (MMWR), April 27, 2001, Vol. 50, No. RR-5, Recommendations for Preventing Transmission of Infection Among Chronic Hemodialysis Patients ·CDC Morbidity and Mortality Weekly Review (MMWR), October 25, 2002, Vol. 51, No. RR-16,	

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	Hygiene" with an effective date of March 20, 2013, stated, "The purpose of this policy is to prevent transmission of pathogenic microorganisms to patients and staff through cross contamination ... Hands will be ... decontaminated using alcohol based hand rub or by washing hands with antimicrobial soap and water before and after direct contact with patients, entering and leaving the treatment area ... immediately after removing gloves ... after contact with inanimate objects near the patient , when moving from a contaminated body site to a clean body site of the same patient." B. The CDC Morbidity and Mortality Weekly Report (MMWR) October 25, 2002, Volume 51 No. RR-16 "Guideline for Hand Hygiene in Health-Care Setting" states, "Recommendations: Indications for handwashing and hand antisepsis . . . Decontaminate hands before having direct contact with patients . . . Decontaminate hands after contact with a patient's intact skin . . . Decontaminate hands if moving from a contaminated body site to a clean body site during patient care. Decontaminate hands after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient. Decontaminate hands after removing gloves."		Guidelines for Hand Hygiene in Health-Care Setting ·Initiation of Treatment Using a Central Venous Catheter and Optiflux® Single Use Ebeam Dialyzer Policy, FMS-CS-IC-I-105-002A ·Termination of Treatment Using a Graft or Fistula and Optiflux® Hollow Fiber Dialyzer Procedure, FMS-CS-IC-I-105-029C ·Changing the Catheter Dressing, FMS-CS-IC-I-105-032A ·Termination of Treatment Using a Central Venous Catheter and Optiflux® Hollow Fiber Dialyzer, FMS-CS-IC-I-105-028C Each Patient Care Technician will be assigned to complete an infection control or Flash Tour audit daily, observing all staff beginning 8/31/2014 to further increase the focus on infection control and adherence to policies and procedures. The Clinical Manager or designee will complete the Infection Control audits daily starting 8/13/2014 and continuing until the condition level deficiency is lifted. After the condition level deficiency is lifted, weekly infection control audits will be conducted on each of the five patient shifts for a period of four weeks at which time the QAI Committee and Governing Body will determine if the facility can return to the monthly auditing schedule. The Clinical Manager will present	

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	C. The facility's "Assessment and Preparation of Internal Access for Needle Placement" revision date 9/25/13 procedure number FMS-CS-IC-I-115-006C states, "Ask your patient to wash access area with liquid soap for one minute, rinsing well. Dry with clean paper towel." D. Facility policy titled "Collection of blood specimens for Blood Culture" revision date of September 25, 2013 states, "8. Put on ... clean gloves. ... Use aseptic technique to insert the butterfly assembly into the disinfected arterial bloodline port or CVC." 2. Employee F, a patient care technician (PCT), was observed to initiate the dialysis treatment for patient number 13 on 8/6/14 at 10:10 AM. The PCT washed the patient's access and palpated the access site and then inserted each needle into the patient's AVF. Employee F failed to change her gloves and cleanse her hands after washing the patient's access and locating and palpating the access site with her gloved finger in preparation for cannulation of the sites. 3. On 8/4/14 at 1:25 PM, employee D, PCT, was observed performing discontinuation of dialysis and post		the results to the QAI Committee monthly and weekly to the Governing Body who will determine further audit frequency by decreasing the frequency incrementally. Once compliance has been established the monitoring will revert to the QAI infection control audit tool. The Director of Operations is responsible to ensure all documentation required as part of the QAI process is presented, current, analyzed, trended, and a root cause analysis completed as appropriate, with the subsequent development of action plans. The QAI Committee is responsible to analyze the results and determine a root causes analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI Committee and Governing Body. The Clinical Manager is responsible	

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	dialysis access care with patient 9. A wood laminate bedside table was present beside and overtop of the patients bed. The PCT obtained new supplies to discontinue dialysis that included 2 X 2 gauze and placed it directly onto the patient's bedside table, without a barrier, prior to the removal of the needles from the patient's fistula. The PCT removed each needle and used the gauze supply directly from the bedside table and secured it to the patient's access. 4. On 8/4/14 at 2:20 PM, observed employee F with patient 8, whose access was a femoral catheter, in station 14. The bedside table contained 2 emesis basins, one holding fluid, soiled gloves, and a facial mask. The PCT obtained a box with supplies to draw blood cultures, placed the box on top of the gloves and mask which were on the bedside table and between the two emesis basins. She donned gloves, picked up the emesis basin containing fluid, amd moved it to a corner of the bedside table. Without changing gloves, she opened the box and began removing the contents, placed the Blood Culture Adapter to the sample bottle, and then began to remove the blood lines to collect the blood sample. The PCT failed to complete hand hygiene and don clean gloves after contact with the emesis basin.			

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	At 2:45 PM, employee F indicated she should have completed hand hygiene after contact with the soiled items.			
V000117	494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled. When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station. Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients. Based on facility policy review, observation, and staff interview, the facility failed to ensure 2 of 4 Patient Care Technicians (PCT) (employee F and	V000117	The Clinical Manager met with staff individually on 8/4/2014, 8/5/2014 and 8/7/2014 and reviewed the Dialysis Precautions Policy, FMS-CS-IC-II-15-070A with emphasis	08/31/2014

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	G) observed kept clean areas clearly separated from contaminated areas creating the potential to spread infectious and communicable disease to all 57 in-center patients of the facility. The findings include: 1. Facility policy titled "Dialysis Precautions" revision date of January 2012 states, "Clean area: An Area designated for clean and unused equipment, supplies, ... Dirty area: ... this is a potential for contamination with blood or body fluids and areas where contaminated or used supplies, ... equipment, blood supplies or biohazard containers are stored or handled. ... Clean areas should be clearly separated from dirty areas where used supplies, equipment or blood samples are handled." 2. Facility policy titled "Collection of blood specimens for Blood Culture" revision date of September 25, 2013 states, "8. Put on ... clean gloves. ... Use aseptic technique to insert the butterfly assembly into the disinfected arterial bloodline port or CVC." 3. On 8/4/14 at 1:10 PM, employee F, PCT, was in station # 12 terminating dialysis treatment with patient #11 whose		on the definitions of clean and dirty areas and the need for clear separation between clean and dirty areas including: avoiding contamination of clean supplies by placing a clean barrier on the overbed table upon which to set the clean supplies; avoiding contamination of patient's belongings, including the ECF Communication Binder, by ensuring that all are removed from the table during initiation and termination of treatment, as well as during any intervention required during the treatment; utilizing a trash can to put dirty items such as tape and gauze which do not require disposal in the infectious waste. A process change was implemented that supplies used for termination of treatment will not be included in the "on kit" but will be prepared at the clean supply cart and brought to the patient station no earlier than 15 minutes prior to termination of treatment. On 8/27/2014, 8/28/2014 and 8/29/2014, the Clinical Manager conducted formal staff meetings during which the Statement of Deficiencies was reviewed and serious nature of the condition level deficiency was explained. The Regional Quality Manager assisted the Clinical Manager in the presentation and re-education of the staff on the policies and	

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	access was a central venous catheter. The PCT obtained supplies for the termination and placed them on the wood laminate bedside table without a barrier underneath. The PCT terminated the dialysis treatment. After she cleansed the hubs of each catheter limb with an alcohol wipe, she tossed the contaminated wipe and gauze on the top of the bedside table among the clean supplies, all the personal items the patient had brought to the in-center and placed on the bedside table, and the one piece of educational material the dialysis staff had delivered to each patient that day. 4. On 8/4/14 at 1:44 PM, employee G, PCT, was observed in station # 19 terminating dialysis treatment with patient #12 whose access was a central venous catheter. The PCT obtained supplies for the termination and placed them on the wood laminate bedside table without a barrier underneath; there was a barrier brought to the station which remained folded and not used to maintain either a clean or soiled area. On top of the folded barrier were gloves, 4 X 4 gauze, and two syringes with heparin. The PCT terminated the dialysis treatment, After she cleansed the hubs of each catheter limb with an alcohol wipe, she tossed the contaminated wipe and gauze on the top of the gloves, syringes,		procedures listed below as related to the citations with emphasis on their role with infection prevention and control and the responsibility of every employee to ensure patient safety. ·Dialysis Precautions, FMS-CS-IC-II-155-070A ·Hand Hygiene, FMS-CS-IC-II-155-090A ·Assessment and Preparation of Internal Access for Needle Placement, FMS-CS-IC-I-115-006C ·Collection of Specimens for Blood Culture Procedure, FMS-CS-IC-II-135-014C ·CDC Morbidity and Mortality Weekly Review (MMWR), April 27, 2001, Vol. 50, No. RR-5, Recommendations for Preventing Transmission of Infection Among Chronic Hemodialysis Patients ·CDC Morbidity and Mortality Weekly Review (MMWR), October 25, 2002, Vol. 51, No. RR-16, Guidelines for Hand Hygiene in Health-Care Setting ·Initiation of Treatment Using a Central Venous Catheter and Optiflux® Single Use Ebeam Dialyzer Policy, FMS-CS-IC-I-105-002A ·Termination of Treatment Using a Graft or Fistula and Optiflux® Hollow Fiber Dialyzer Procedure, FMS-CS-IC-I-105-029C ·Changing the Catheter Dressing, FMS-CS-IC-I-105-032A ·Termination of Treatment Using a Central Venous Catheter and	

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	and gauze. She did not dispose of the contaminated items; she used the gloves, instilled the heparin into each lumen, applied the gauze, and wrapped the limbs prior to the patient leaving the facility. A. At 1:52 PM, the patient was no longer in the station. Soiled masks, gloves, and the 2 X 2 gauze remained on the bedside table. Patient's communication binder, which travels between the facility and the residential facility in which the patient resides, was also on the bedside table. B. At 2 PM, employee K was observed to carry the communication binder from the station to the nurses station and return to the station. She donned a gloves, touched the dialysis machine, removed the glove, and tossed into the pile of rubbish on the bedside table. 5. At 1:48 PM, employee F, PCT, was observed in station # 17 terminating dialysis treatment with patient #1 whose access was a fistula. The PCT obtained supplies for the termination and placed them on the wood laminate bedside table without a barrier underneath; a barrier was present which remained rolled and not utilized as a barrier for either a clean area nor soiled items. Gauze and gloves		Optiflux® Hollow Fiber Dialyzer, FMS-CS-IC-I-105-028C The policies and procedures listed above were printed and placed in a binder for all staff to review and initial each procedure by 8/27/2014. The Clinical Manager or designee will complete the Infection Control audits daily starting 8/13/2014 and continuing until the condition level deficiency is lifted. After the condition level deficiency is lifted, weekly infection control audits will be conducted on each of the five patient shifts for a period of four weeks at which time the QAI Committee and Governing Body will determine if the facility can return to the monthly auditing schedule. The Clinical Manager will present the results to the QAI Committee monthly and weekly to the Governing Body who will determine further audit frequency by decreasing the frequency incrementally. Once compliance has been established the monitoring will revert to the QAI infection control audit tool. The CM is responsible.	

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	were placed onto of the educational material, among the patient's glasses used for reading and personal cell phone. The PCT removed the tape from the first access, removed the first needle, applied the 2 X 2 gauze, and indiscriminately tossed the soiled tape onto the bedside table among the remaining gauze and personal items on the beside table. The patient, with gloved right hand, held pressure on the access which began to bleed. The PCT applied new gauze and tossed the soiled gauze on the bedside table. When the bleeding was controlled, the PCT removed her gloves, tossed them onto the bedside table, and left the station. At 2 PM, the PCT returned to the station, removed the second needle, utilized the 2 X 2 gauze from the bedside table, removed her gloves, and tossed them onto the bedside table. Trash was observed to begin to fall off the bedside table. The patient held access with gloved right hand, resting right elbow on table. Soiled gloves and tape were placed on the bedside table among the educational material and patient's cell phone. At 2:07 PM, observed patient pick up personal cell phone and educational material and leave unit. The staff failed to decontaminate the patient's personal items once contaminated and			

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	failed to replace the educational material. 6. On 8/4/14 at 2:20 PM, observed employee F with patient 8, whose access was a femoral catheter, in station 14. The bedside table contained 2 emesis basis, one holding fluid, soiled gloves, and a facial mask. The PCT obtained a box with supplies to draw blood cultures and placed the box on top of the gloves and mask which were on the bedside table and between the two emesis basins. She donned gloves, picked up the emesis basin containing fluid and moved it to a corner of the bedside table. Without changing gloves, she opened the box and began removing the contents, placed the Blood Culture Adapter to the sample bottle, and then began to remove the blood lines to collect the blood sample. At 2:45 PM, employee F was observed in station # 14 terminating dialysis treatment with patient # 8. After the PCT cleansed each of the hubs with an alcohol pad, she threw them onto the bedside table where there was no barrier and no delineation between the dirty and clean area of the table top. The barrier which was underneath of the patient's lines during dialysis treatment was crumbled up on the bedside table and against the blood specimen mailing box			

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	which remained. 7. On 8/4/14 at 5:05 PM, employee A indicated the staff were to maintain separation between clean and soiled areas.			
V000147	494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE Recommendations for Placement of Intravascular Catheters in Adults and Children I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters. II. Surveillance A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site. Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.			

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	VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections]. Based on policy review, observation, and interview, the facility failed to ensure 1 of 1 employees (E) observed treating a patient with a central venous catheter (CVC) provided care in compliance with central venous catheter policy and assessed the access site on a patient with a femoral catheter with the potential to affect all patients with catheters. The findings include: 1. Facility policy titled "Initiation of Treatment Using a Central Venous Catheter" revision date April 4, 2012, stated, "The catheter exit site must be examined for signs and symptoms of infection, dislodgement of catheter or other problems, and the exit site care and dressing replacement must be completed prior to accessing the bloodstream." 2. On 8/8/13 at 9:50 AM, employee E, a patient care technician, was observed to initiate dialysis on patient # 1 at station #17. The dressing with visible blood was observed on the right chest area and the patient indicated a CVC was placed on 8/7/14. Employee E did not assess the	V000147	The Clinical Manager met with staff individually on 8/4/2014, 8/5/2014 and 8/7/2014 and reviewed the Initiation of Treatment Using a Central Venous Catheter and Optiflux® Single Use Ebeam Dialyzer Policy, FMS-CS-IC-I-105-002A and the FMS-CS-IC-I-105-032A Changing the Catheter Dressing policy, with emphasis on the requirement to examine the exit site for signs and symptoms of infection and dislodgment of the catheter or other problems before initiating treatment and to report any abnormal findings to the RN On 8/27/2014, 8/28/2014 and 8/29/2014, the Clinical Manager conducted formal staff meetings during which the Statement of Deficiencies was reviewed and serious nature of the condition level deficiency was explained. The Regional Quality Manager assisted the Clinical Manager in the presentation and re-education of the staff on the policies and procedures listed below as related to the citations with emphasis on their role with infection prevention and control and the responsibility of every employee to ensure patient safety.	08/31/2014

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	patient's exit site prior to the initiation of treatment nor did the employee notify or obtain consult with the register nurse to begin treatment without an assessment of the new CVC access. Employee E indicated, when asked, the patient informed her the physician did not want the dressing removed and, therefore, it was not changed and the site assessed. A. At 10 AM, employee L, a registered nurse, indicated she was not aware the patient had received a catheter. B. At 2:30 PM, employee L indicated the physician was contacted for orders and the CVC access was assessed and she changed the patient's dressing. 3. On 8/8/14 at 10:25 AM, employee E was observed to initiate dialysis on patient # 8. The patient's access was a femoral catheter and was covered with a dressing. The employee asked the patient if the staff changed the dressing or did the patient. The patient indicated they change their own dressing and then the employee placed the dressing supplies in the patient's travel bag. Then the employee was observed to initiate dialysis without an assessment of the patient's access. On 8/8/14 at 12:10 PM, employee A		The Clinical Manager or designee will complete the POC audit tool which includes the appropriate dressing changes for CVC access and the evaluation of the exit site before initiating treatment, daily until the condition is lifted. After the condition level deficiency is lifted, weekly POC audits will be conducted on each of the five patient shifts for a period of four weeks at which time the QAI Committee and Governing Body will determine if the facility can return to the monthly auditing schedule. The Clinical Manager will present the results to the QAI Committee monthly and weekly to the Governing Body who will determine further audit frequency by decreasing the frequency incrementally. Once compliance has been established the monitoring will revert to the QAI infection control audit tool. The CM is responsible.	

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	indicated clinical record 8 did not contain a physician order to omit the examination of the access.			
V000543	494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; Based on clinical record and facility policy review and interview, the facility failed to ensure patients' blood pressures were checked every 30 minutes in 3 of 5 in-center hemodialysis post treatment records reviewed (# 3, 4, and 5). The findings include: 1. The facility's "Patient Monitoring During Patient Treatment" dated July 4, 2012, states, "Vital signs will be monitored at the initiation of dialysis and every 30 minutes." 2. On 8/7/14 at 12:21 PM, employee A indicated the facility policy is to assess the patient's blood pressure and check the patient every 30 minutes and there is	V000543	The Clinical Manager met with the staff on August 27, 28, & 29, to review the SOD from the re-certification survey that was completed on August 11, 2014. Included in this meeting was the re-education on policy FMS-CS-IC-I-110-133A Monitoring During Patient Treatment Policy with emphasis on but not limited to ·Vital Signs and Mental Status: o Vitals signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently as needed o Observe for changes in the patient's respiration's, heart rate and blood pressure o Verify and react to unusual findings such as atypical blood pressure readings o Monitor for trends such as hypotension and bradycardia	09/04/2014

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	difficulty primarily at turnover of one patient shift to another. 3. Review of clinical record number 3 included twelve post hemodialysis treatment flow sheets dated 7/7/14 through 8/4/14. Eight of the twelve post treatment flow sheets failed to evidence the patient's vital signs were checked at least every 30 minutes. A. The treatment flow sheet dated 7/9/14 evidenced the patient's blood pressure was assessed at 8:22 AM and not again until 9:03 AM and not assessed again until 10:01 AM, a period of 41 minutes and 58 minutes between checks respectively. B. The treatment flow sheet dated 7/14/14 evidenced the patient's blood pressure was assessed at 8:25 AM and not again until 9:06 AM, assessed at 10:04 AM and not again until 11:02 AM, a period of 41 minutes and 58 minutes between checks respectively. C. The treatment flow sheet dated 7/18/14 evidenced the patient's blood pressure was assessed at 8:29 AM and not again until 9:11 AM, assessed at 10:04 AM and not again until 10:49 AM, a period of 42 minutes and 45 minutes between checks respectively.		o Respond to changes in vital signs as indicated by the patient's symptoms, nursing judgment or as ordered by the physician o Check for any changes in mental status or level of consciousness. ·Notifications: ·Unusual observations, findings and the inability to reach prescribed orders must be promptly reported to the charge nurse/team leader ·Notify the physician as determined by the clinical judgment of the charge nurse/team leader ·Documentation ·Documentation of patient monitoring will be completed on the treatment record ·Appropriate interventions in response to changes in vital signs, treatment parameters or machine adjustments shall be documented in the treatment record Documentation of staff education is available at the facility for review. The Clinical Manager and or designee will audit the flow sheets weekly to determine compliance to the above items. The audit will be comprised of 10% of the patient census and be done weekly using a POC audit tool to track compliance. In the event that a staff member is found to not follow the facility policy the Clinical Manager will be notified and is responsible to address the findings with the identified staff member. The Clinical Manager's	

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	D. The treatment flow sheet dated 7/23/14 evidenced the patient's blood pressure was assessed at 8:27 AM and not again until 9:06 AM, a period of 39 minutes between checks. E. The treatment flow sheet dated 7/25/14 evidenced the patient's blood pressure was assessed at 8:20 AM and not again until 9:14 AM, a period of 56 minutes between checks. F. The treatment flow sheet dated 7/28/14, evidenced the patient's blood pressure was assessed at 8:22 AM and not again until 9:02 AM, a period of 40 minutes between checks, and not assessed again until 10:05 AM, a period of 1 hour and 3 minutes. G. The treatment flow sheet dated 8/1/14 evidenced the patient's blood pressure was assessed at 8:25 AM and not again until 9:02 AM, a period of 37 minutes between checks. H. The treatment flow sheet dated 8/4/14 evidenced the patient's blood pressure was assessed at 8:23 AM and not again until 9:10 AM, a period of 47 minutes between checks. 3. Review of clinical record number 4		action will be structured to reinforce by further education following through as necessary with the application of progressive disciplinary action. The Clinical Manager will review the status of the implemented plan daily and summarize the status of staff compliance to monitor the patients no less than every 30 minutes, reporting daily to the Governing Body until full resolution of the identified issues occurs. The Governing Body will review status of the implemented corrective action and when so determined, decrease the frequency of the report incrementally. Additionally the summaries are compiled and reported to the QAI committee at is monthly meeting. Upon determination of compliance by the Governing Body, the monitoring will revert to the QAI infection control audit schedule. The Clinical Manager is responsible to ensure implementation of the corrective actions and the Director of Operations will monitor for ongoing compliance through Governing Body oversight and the QAI process.	

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	included thirteen post hemodialysis treatment flow sheets dated 7/7/14 through 8/6/14. Four of the thirteen post treatment flow sheets failed to evidence the patient's vital signs were checked at least every 30 minutes. A. The treatment flow sheet dated 7/9/14 evidenced the patient's blood pressure was assessed at 9:10 AM and not again until 10:01 AM, assessed at 12:01 PM and not assessed again until 12:42 PM, a period of 51 minutes and 41 minutes between checks respectively. B. The treatment flow sheet dated 7/25/14 evidenced the patient's blood pressure was assessed at 10:33 AM and not again until 11:37 AM, assessed at 10:04 AM and not again until 11:02 AM, a period of 41 minutes and 58 minutes between checks respectively. C. The treatment flow sheet dated 8/1/14 evidenced the patient's blood pressure was assessed at 9:16 AM and not again until 10:03 AM, assessed at 12:02 PM and not again until 12:42 PM, a period of 47 minutes and 40 minutes between checks respectively. D. The treatment flow sheet dated 8/4/14 evidenced the patient's blood pressure was assessed at 9:14 AM and			

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	not again until 10:07 AM, a period of 53 minutes between checks. 4. Review of clinical record number 5 included eleven post hemodialysis treatment flow sheets dated 7/3/14 through 7/31/14. Five of the eleven post treatment flow sheets failed to evidence the patient's vital signs were checked at least every 30 minutes. A. The treatment flow sheet dated 7/3/14 evidenced the patient's blood pressure was assessed at 6:38 AM and not again until 7:32 AM, assessed at 8:07 AM and not assessed again until 9:09 AM, a period of 54 minutes and 1 hour and 2 minutes between checks respectively. B. The treatment flow sheet dated 7/10/14 evidenced the patient's blood pressure was assessed at 7:31 AM and not again until 8:11 AM, a period of 40 minutes between checks. C. The treatment flow sheet dated 7/15/14 evidenced the patient's blood pressure was assessed at 5:14 AM and not again until 6:06 AM, assessed at 8:02 AM and not again until 9:02 AM, a period of 52 minutes and 60 minutes between checks respectively.			

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	D. The treatment flow sheet dated 7/26/14 evidenced the patient's blood pressure was assessed at 5:04 AM and not again until 6:02 AM, a period of 52 minutes between checks. E. The treatment flow sheet dated 7/29/14 evidenced the patient's blood pressure was assessed at 5:02 AM and not again until 6:04 AM, a period of 62 minutes between checks.			
V000585	494.100(a)(3) H-TRAIN CONTENT INCLUDES ER PREP HOME PTS The training must- (3) Be conducted for each home dialysis patient and address the specific needs of the patient, in the following areas: (i) The nature and management of ESRD. (ii) The full range of techniques associated with the treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care. (iii) How to detect, report, and manage potential dialysis complications, including water treatment problems. (iv) Availability of support resources and how to access and use resources. (v) How to self-monitor health status and record and report health status information.			

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	(vi) How to handle medical and non-medical emergencies. (vii) Infection control precautions. (viii) Proper waste storage and disposal procedures. Based on clinical record review and interview, the facility failed to ensure training was conducted and documented to the specific needs of the patient for 1 of 1 clinical record reviewed of a patient that resided in an extended care facility (ECF) and who received their peritoneal dialysis treatments from the extended care staff. (Patient 6) Findings include: 1. Clinical record # 6, start of care 5/23/14, evidenced the patient resided in an ECF and the facility staff were completing the patient's peritoneal dialysis daily beginning June 13, 2014, through August 11, 2014, date of survey exit. The clinical record failed to evidence all of the staff of the ECF that were providing the peritoneal exchanges for this patient were trained to the specific dialysis treatment and specific needs of this patient. 2. On August 4, 2014, at 3 PM, employee J indicated patient 6 resided in an ECF Brownsburg Health Care Center and the patient received peritoneal	V000585	A new Facility Skilled Nursing Home Contract was signed 8/8/2014 and submitted to the Governing body for review. On 8/19/2014, the Home Therapies RN met with administration and ADON at the Nursing Home and provided education on the requirement that only staff that have completed the Fresenius Home Training education, exam and skills check off, may complete the dialysis treatment. On 8/19/2014, the Nursing home staff completed Fresenius home training education, exam and Skills Check Off. In addition, the Home Therapies RN trained the staff on the use of revised monthly Home records documentation which includes staff initials and signatures. The Home Therapy RN will review the patient records monthly to assure only trained staff are performing dialysis tasks. The Home Therapy Program Manager is responsible.	08/19/2014

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	dialysis per the ECF staff. 3. On August 5, 2014, at 2 PM, during a visit to the ECF in which patient 6 resided, the ECF unit manager indicated no training of the ECF staff had occurred since the patient was admitted to the ECF in August 2013. 4. On August 5, 2014, at 2:30 PM, employee J indicated the dialysis facility did not have evidence that the staff of the ECF, Brownsburg Health Care Center, were trained by the dialysis staff to the specific dialysis needs of this patient. 5. On August 6, 2014, at 1 PM, employee I indicated she did not train or assess the nursing home staff upon the patient's admission to this ESRD. She indicated her first visit to the nursing home was 7/11/14 and during the visit she observed the unit manager performing a peritoneal dialysis exchange with the patient.			
V000586	494.100(b)(1) H-PT/CAREGIVER DEMO COMPREHEND TRAINING The dialysis facility must - (1) Document in the medical record that the			

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	patient, the caregiver, or both received and demonstrated adequate comprehension of the training; Based on clinical record review and interview, the facility failed to ensure documentation evidenced that the caregivers of the extended care facility (ECF) who performed the peritoneal dialysis received training and demonstrated adequate comprehension of the training for 1 of 1 clinical records reviewed of patients that resided in an extended care facility. (Patient 6) Findings include: 1. Clinical record # 6, start of care 5/23/14, evidenced the patient resided in an ECF and the facility staff were completing the patient's peritoneal dialysis daily beginning June 13, 2014, through August 11, 2014, date of survey exit. The clinical record failed to evidence all of the staff of the ECF that were providing the peritoneal exchanges for this patient were trained to the specific dialysis treatment and specific needs of this patient. 2. On August 4, 2014, at 3 PM, employee J indicated patient 6 resided in an ECF Brownsburg Health Care Center and the patient received peritoneal	V000586	A new Facility Skilled Nursing Home Contract was signed 8/8/2014 and submitted to the Governing body for review. On 8/19/2014, the Home Therapies RN met with administration and ADON at the Nursing Home and provided education on the requirement that only staff that have completed the Fresenius Home Training education, exam and skills check off, may complete the dialysis treatment. On 8/19/2014, the Nursing home staff completed Fresenius home training education, exam and Skills Check Off. In addition, the Home Therapies RN trained the staff on the use of revised monthly Home records documentation which includes staff initials and signatures. The Home Therapy RN will review the patient records monthly to assure only trained staff are performing dialysis tasks. The Home Therapy Program Manager is responsible	08/19/2014

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	dialysis per the ECF staff. 3. On August 5, 2014, at 2 PM, during a visit to the ECF in which patient 6 resided, the ECF unit manager indicated no training of the ECF staff had occurred since the patient was admitted to the ECF in August 2013. 4. On August 5, 2014, at 2:30 PM, employee J indicated the dialysis facility did not have evidence that the staff of the ECF, Brownsburg Health Care Center, were trained by the dialysis staff to the specific dialysis needs of this patient. 5. On August 6, 2014, at 1 PM, employee I indicated she did not train or assess the nursing home staff upon the patient's admission to this ESRD. She indicated her first visit to the nursing home was 7/11/14 and during the visit she observed the unit manager performing a peritoneal dialysis exchange with the patient.			
V000628	494.110(a)(2) QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and			

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	facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves. Based on quality assurance performance improvement (QAPI) minutes, document, and facility policy review and interview, the facility failed to ensure its QAPI program included monitoring of fluid and blood pressure management in 6 (February through July 2014) of 6 months reviewed. The findings include: 1. The facility's QAPI meeting minutes, dated 2/25/14, 3/25/14, 4/23/14, 5/28/14, 6/25/14, and 7/25/14, failed to evidence the facility had monitored fluid and blood pressure management by the review and evaluation of the percentage of intradialytic weight loss, blood pressure variances pre and post dialysis, and intradialytic symptoms of depletion. 2. The clinic manager, indicated on 8/11/14 at 3 PM the facility's QAPI does not address monitored fluid and blood pressure management by the review and evaluation of the percentage of intradialytic weight loss, blood pressure variances pre and post dialysis, and intradialytic symptoms of depletion.	V000628	On or before 9/3/2014, the Director of Operations will provide an in-service to the QAI committee members and reaffirm the programs requirement to monitor, measure, analyze, and tract quality indicators and improve care in the facility. This education is also inclusive of the need to monitor, track, and trend fluid and blood pressure and fluid management. The focus of the education was on the analysis and trending of intradialytic weight loss, blood pressure variances and symptoms of intradialytic depletion. As a result of this in-service meeting, the QAI committee has taken the following actions: · Reviewed the survey from August 11, 2014 along with Monthly Quality Status Report and eCube Clinical Reports · Determined that all pertinent reports as noted above will be reviewed monthly with a specific focus on blood pressure and fluid management, and evaluated for trends in causes · Determined that the QAI documentation will evidence any recognized trends in causes or contributing factors in blood pressure variances and excessive intradialytice weight loss or symptoms of depletion · In the event a trend or	09/04/2014

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	3. The facility's September 25, 2013, document "Quality Assessment and Performance Improvement" states, "The Quality Assessment Performance Improvement (QAI) Program encompasses all aspects of patient care, including in-center, home hemodialysis, home peritoneal dialysis and self care, as well as support services to provide that care . . . Elements to be reviewed in the QAI meeting include: Patient Care Outcomes."		contributing factor is identified the facility will take immediate action to implement and monitor performance improvement action plans To ensure compliance, on or before 9/4/2014, the Governing Body will commit to review the QAI program on a quarterly basis to ensure: · Tracking, trending and analyzing of collected fluid and blood pressure management data · Any trends or contributing factors identified have performance improvement action plan in place To ensure the QAI committee prioritizes improvement and as part of the developed plan of correction, the Governing Body has determined to review QAI activities monthly until full resolution of the implemented corrective processes is verified and quarterly thereafter. The Clinical Manager is responsible and the QAI committee monitors for compliance.	
V000715	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			

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	nonphysician providers; Based on clinical record and facility policy review and interview, the medical director failed to ensure physician orders were obtained for the care to be provided by the home program registered nurse (RN) prior to the initiation of care in 1 (# 7) of 2 records reviewed of patients receiving home peritoneal dialysis support and failed to ensure all personnel had adhered to facility policies and procedures relative to in-center hemodialysis patient care to ensure patients' blood pressures were checked every 30 minutes in 3 of 5 in-center hemodialysis post treatment records reviewed (# 3, 4, and 5). The findings include: Related to peritoneal Dialysis: 1. The facility's policy titled "Physician Order Documentation" dated June 19, 2013, stated, "Nurse Practice Acts require nurses to carry out treatment care, ... procedures, and other treatments , based on physician orders. ... Providing service without physician orders is a violation of nurse practice acts. ... All medical orders must be written in the paper record or entered in the electronic medical order. "	V000715	On August 27, 2014 the Medical Director (MD) met with the Director of Operations (DO) and the Clinical Manager (CM) to review the DO and CM responsibilities related to employee Blood Pressure, Heart Rate, and treatment data are monitored every 30 minutes and more frequently as needed. The Medical Director also emphasized his expectation that the DO and CM will assure the staff is held accountable to follow all approved policies and procedures as trained. Also on August 27, 2014, the Governing body including the Medical Director, DO, and CM reviewed the Medical Directors requirements specific to Part 494 Conditions for Coverage, the Fresenius Professional Bylaws and the Fresenius Medical Director Agreement as well as the citations received specific to the Medical Director. The Home Therapy Program manager met with her staff and reviewed the Policy “Physician Order Documentation” with emphasis on the requirement to perform procedures based on a physician order. Catheter flushes will be performed with an order to do so. Compliance to this policy will be validated through the QAI medical record audit which is required monthly for all new patients. The Clinical Manager met with the staff on August 27, 28, & 29, to	09/04/2014

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	2. Clinical record number 7 evidenced the patient had a peritoneal catheter placed on 7/9/14 and received care in the facility by employee I on 7/16/14, 7/24/14, and 8/2/14. The record failed to evidence physician orders for the care to be provided by the dialysis facility home program staff. 3. On August 11, 2014, at 3:34 PM, employee J indicated the record did not contain physician orders prior to the care provided. Related to hemodialysis monitoring: 1. The facility's "Patient Monitoring During Patient Treatment" dated July 4, 2012, states, "Vital signs will be monitored at the initiation of dialysis and every 30 minutes." 2. On 8/7/14 at 12:21 PM, employee A indicated the facility policy is to assess the patient's blood pressure and check the patient every 30 minutes and there is difficulty primarily at turnover of one patient shift to another. 3. Review of clinical record number 3 included twelve post hemodialysis treatment flow sheets dated 7/7/14 through 8/4/14. Eight of the twelve post		review the SOD from the re-certification survey that was completed on August 11, 2014. Included in this meeting was the re-education on policy FMS-CS-IC-I-110-133A Monitoring During Patient Treatment Policy with emphasis on but not limited to ·Vital Signs and Mental Status: o Vitals signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently as needed o Observe for changes in the patient's respiration's, heart rate and blood pressure o Verify and react to unusual findings such as atypical blood pressure readings o Monitor for trends such as hypotension and bradycardia o Respond to changes in vital signs as indicated by the patient's symptoms, nursing judgment or as ordered by the physician o Check for any changes in mental status or level of consciousness. ·Notifications: ·Unusual observations, findings and the inability to reach prescribed orders must be promptly reported to the charge nurse/team leader ·Notify the physician as determined by the clinical judgment of the charge nurse/team leader ·Documentation ·Documentation of patient monitoring will be completed on the treatment record ·Appropriate interventions in	

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	treatment flow sheets failed to evidence the patient's vital signs were checked at least every 30 minutes. A. The treatment flow sheet dated 7/9/14 evidenced the patient's blood pressure was assessed at 8:22 AM and not again until 9:03 AM and not assessed again until 10:01 AM, a period of 41 minutes and 58 minutes between checks respectively. B. The treatment flow sheet dated 7/14/14 evidenced the patient's blood pressure was assessed at 8:25 AM and not again until 9:06 AM, assessed at 10:04 AM and not again until 11:02 AM, a period of 41 minutes and 58 minutes between checks respectively. C. The treatment flow sheet dated 7/18/14 evidenced the patient's blood pressure was assessed at 8:29 AM and not again until 9:11 AM, assessed at 10:04 AM and not again until 10:49 AM, a period of 42 minutes and 45 minutes between checks respectively. D. The treatment flow sheet dated 7/23/14 evidenced the patient's blood pressure was assessed at 8:27 AM and not again until 9:06 AM, a period of 39 minutes between checks.		response to changes in vital signs, treatment parameters or machine adjustments shall be documented in the treatment record Documentation of staff education is available at the facility for review. The Clinical Manager and or designee will audit the flow sheets weekly to determine compliance to the above items. The audit will be comprised of 10% of the patient census and be done weekly using a POC audit tool to track compliance. In the event that a staff member is found to not follow the facility policy the Clinical Manager will be notified and is responsible to address the findings with the identified staff member. The Clinical Manager's action will be structured to reinforce by further education following through as necessary with the application of progressive disciplinary action. The Clinical Manager will review the status of the implemented plan daily and summarize the status of staff compliance to monitor the patients no less than every 30 minutes, reporting weekly to the Governing Body until full resolution of the identified issues occurs. The Governing Body will review status of the implemented corrective action and when so determined, decrease the frequency	

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	E. The treatment flow sheet dated 7/25/14 evidenced the patient's blood pressure was assessed at 8:20 AM and not again until 9:14 AM, a period of 56 minutes between checks. F. The treatment flow sheet dated 7/28/14, evidenced the patient's blood pressure was assessed at 8:22 AM and not again until 9:02 AM, a period of 40 minutes between checks, and not assessed again until 10:05 AM, a period of 1 hour and 3 minutes. G. The treatment flow sheet dated 8/1/14 evidenced the patient's blood pressure was assessed at 8:25 AM and not again until 9:02 AM, a period of 37 minutes between checks. H. The treatment flow sheet dated 8/4/14 evidenced the patient's blood pressure was assessed at 8:23 AM and not again until 9:10 AM, a period of 47 minutes between checks. 3. Review of clinical record number 4 included thirteen post hemodialysis treatment flow sheets dated 7/7/14 through 8/6/14. Four of the thirteen post treatment flow sheets failed to evidence the patient's vital signs were checked at least every 30 minutes.		of the report incrementally. Additionally the summaries are compiled and reported to the QAI committee at is monthly meeting. Upon determination of compliance by the Governing Body, the monitoring will revert to the QAI infection control audit schedule. The Clinical Manager is responsible to ensure implementation of the corrective actions and the Director of Operations will monitor for ongoing compliance through Governing Body oversight and the QAI process.	

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	A. The treatment flow sheet dated 7/9/14 evidenced the patient's blood pressure was assessed at 9:10 AM and not again until 10:01 AM, assessed at 12:01 PM and not assessed again until 12:42 PM, a period of 51 minutes and 41 minutes between checks respectively. B. The treatment flow sheet dated 7/25/14 evidenced the patient's blood pressure was assessed at 10:33 AM and not again until 11:37 AM, assessed at 10:04 AM and not again until 11:02 AM, a period of 41 minutes and 58 minutes between checks respectively. C. The treatment flow sheet dated 8/1/14 evidenced the patient's blood pressure was assessed at 9:16 AM and not again until 10:03 AM, assessed at 12:02 PM and not again until 12:42 PM, a period of 47 minutes and 40 minutes between checks respectively. D. The treatment flow sheet dated 8/4/14 evidenced the patient's blood pressure was assessed at 9:14 AM and not again until 10:07 AM, a period of 53 minutes between checks. 4. Review of clinical record number 5 included eleven post hemodialysis treatment flow sheets dated 7/3/14 through 7/31/14. Five of the eleven post			

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	treatment flow sheets failed to evidence the patient's vital signs were checked at least every 30 minutes. A. The treatment flow sheet dated 7/3/14 evidenced the patient's blood pressure was assessed at 6:38 AM and not again until 7:32 AM, assessed at 8:07 AM and not assessed again until 9:09 AM, a period of 54 minutes and 1 hour and 2 minutes between checks respectively. B. The treatment flow sheet dated 7/10/14 evidenced the patient's blood pressure was assessed at 7:31 AM and not again until 8:11 AM, a period of 40 minutes between checks. C. The treatment flow sheet dated 7/15/14 evidenced the patient's blood pressure was assessed at 5:14 AM and not again until 6:06 AM, assessed at 8:02 AM and not again until 9:02 AM, a period of 52 minutes and 60 minutes between checks respectively. D. The treatment flow sheet dated 7/26/14 evidenced the patient's blood pressure was assessed at 5:04 AM and not again until 6:02 AM, a period of 52 minutes between checks. E. The treatment flow sheet dated			

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	7/29/14 evidenced the patient's blood pressure was assessed at 5:02 AM and not again until 6:04 AM, a period of 62 minutes between checks.			