

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152502	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 01/28/2015
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS EAST	STREET ADDRESS, CITY, STATE, ZIP CODE 6635 E 21ST ST STE 400 INDIANAPOLIS, IN 46219
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V000000	<p>This was a Federal ESRD complaint investigation survey.</p> <p>Complaint #: IN00154287; Substantiated, Federal deficiencies related to the allegations are cited. Unrelated deficiencies are also cited.</p> <p>Survey Date: 1-28-15</p> <p>Facility #: 005149</p> <p>Surveyor: Vicki Harmon, RN, PHNS</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN February 2, 2015</p>	V000000		
V000113	<p>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.</p> <p>Based on observation, interview, and review of facility policy, the facility failed to ensure staff had changed gloves and cleansed hands appropriately in 3 (#s 1, 6, and 7) of 11 infection control observations completed creating the potential to affect all of the facility's 137 current patients.</p>	V000113	<p>The Governing Body for the facility met on 2/10/15 to review the Statement of deficiencies and developed the plan of Correction. The Director of Operations reviewed the following policies ""Infection Control Overview" policy number FMS-CS-IC-II-155-060A, "Hand Hygiene Policy"</p>	02/28/2015

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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	<p>The findings include:</p> <ol style="list-style-type: none"> Employee DD, a patient care technician (PCT), was observed to discontinue the dialysis treatment on patient number 1, with an arteriovenous fistula, on 1-28-15 at 12:55 PM. The PCT was observed to touch the computer keyboard and use the mouse to enter data at the dialysis station. The PCT was then observed to don clean gloves without cleansing her hands. Employee EE, a PCT, was observed to discontinue the dialysis treatment on patient number 2, with a central venous catheter (CVC), on 1-28-15 at 10:20 AM. The PCT was observed to touch the machine and tubing to reinfuse the extracorporeal circuit. The PCT failed to change gloves and cleanse hands prior to disinfecting the CVC connections and disconnecting the blood lines. Employee D, a PCT, was observed to discontinue the dialysis treatment on patient number 3, with a CVC, on 1-28-15 at 11:00 AM. The PCT was observed to fill 2 syringes with normal saline from the bag hanging on the machine and touch the machine and tubing. The PCT failed to change gloves and cleanse hands prior to disinfecting 		<p>FMS-CS-IC-II-155-090A and "Cleaning and Disinfection" policy number FMS-CS-IC-II-155-110A with the Clinical Manager on 2/10/15 emphasizing his responsibility to ensure all staff members are educated on the policies, competency is assessed and staff understands the requirement to follow policies and procedures as written. All current staff will participate in a mandatory in-service by the clinic manager regarding Infection Control Practices the week of 2/13/15 specifically focusing on the policies listed above. In addition, the staff will be educated on their responsibility to ensure that all staff wears disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. The importance of hand sanitation before and after glove change will be reinforced. The "Infection Control Information Acknowledgment" form will be placed in each staff members personnel/education file.</p> <p>The Clinical Manager or designee will ensure that infection control audits utilizing the QAI Infection Control audit tool are done weekly for 4 weeks, monthly for 3 months, and then as determined by the QAI calendar. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager who is responsible to</p>		

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	<p>the CVC connections and disconnecting the blood lines.</p> <p>4. The above-stated observations were presented to the Clinic Manager and the Director of Operations on 1-28-15 at 2:50 PM. The manager and the director indicated the staff had not followed facility policies and procedures.</p> <p>5. The facility's 1-4-12 "Infection Control Overview" policy number FMS-CS-IC-II-155-060A states, "All infection control policies for patient care are consistent with recommendation of the Centers for Disease Control (CDC)."</p> <p>The Centers for Disease Control "Standards Precautions" states, "IV. Standard Precautions . . . IV.A. Hand Hygiene. IV.A.1. During the delivery of healthcare, avoid unnecessary touching of surfaces in close proximity to the patient to prevent both contamination of clean hands from environmental surfaces and transmission of pathogens from contaminated hands to surfaces . . . Perform hand hygiene: IV.A.3.a. Before having direct contact with patients. IV.A.3.b. After contact with blood, body fluids or excretions, mucous membranes, nonintact skin, or wound dressings. IV.A.3.c. After contact with a patient's intact skin (e.g., when taking a pulse or</p>		<p>address the issue with each employee including corrective action as appropriate</p> <p>The Clinical Manager is responsible to evaluate and present the audit findings in the monthly QAI meeting/minutes. The QAI Committee is responsible to review, analyze and trend all monitoring results to ensure resolution is both occurring and is sustained.</p>	

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	<p>blood pressure or lifting a patient). IV.3.d. If hands will be moving from a contaminated-body site to a clean-body site during patient care. IV.A.3.e. After contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient. IV.A.3.f. After removing gloves . . . IV.F.5. Include multi-use electronic equipment in policies and procedures for preventing contamination and for cleaning and disinfection, especially those items that are used by patients, those used during delivery of patient care, and mobile devices that are moved in and out of patient rooms frequently . . . IV.B. Personal protective equipment (PPE) . . . IV.B.2. Gloves. IV.B.2.a. Wear gloves when it can be reasonably anticipated that contact with blood or potentially infectious materials, mucous membranes, nonintact skin, or potentially contaminated intact skin . . . could occur."</p> <p>6. The facility's 3-20-13 "Hand Hygiene" policy number FMS-CS-IC-II-155-090A states, "Hand will be . . . Decontaminated using alcohol based hand rub or by washing hands with antimicrobial soap and water . . . Immediately after removing gloves . . . After contact with inanimate objects near the patient. When moving from a contaminated body site to</p>						

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V000116	<p>a clean body site of the same patient."</p> <p>7. The facility's 1-6-14 "Termination of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer." procedure states, "While closely monitoring the catheter site, return blood through the arterial line either by gravity, or by applying gentle pressure to the saline bag . . . Follow the steps below to disinfect the catheter and to disconnect the patient from the extracorporeal system: . . . Obtain the patient's sitting blood pressure (with legs down) prior to disconnecting the patient . . . Discard the gloves and perform hand hygiene. Don clean gloves . . . Disconnect the arterial bloodline from the catheter limb . . . Repeat . . . for the venous end of the catheter limb."</p> <p>8. The facility's 3-20-13 "Cleaning and Disinfection" policy number FMS-CS-IC-II-155-110A states, "Hand hygiene is imperative after contact with the Chairside computer devices and before contact with the patient."</p> <p>494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT Items taken into the dialysis station should</p>				

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	<p>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, interview, and review of facility policy, the facility failed to ensure equipment had been cleaned and disinfected before being returned to a common area in 6 (#s 1, 2, 3, 4, 5, and 6) of 6 use of non-disposable equipment observations completed creating the potential to affect all of the facility's 137 current patients.</p> <p>The findings include:</p> <p>1. Employee DD, a patient care technician (PCT), was observed to use a tympanic thermometer on patient number 1 on 1-28-15 at 12:55 PM after the dialysis treatment had been completed. The PCT used the thermometer and replaced it on the countertop between stations 17 and 18. The PCT was not observed to clean and disinfect the thermometer after use.</p>	V000116	<p>The Director of Operations met with the Clinical Manager on 2/10/15 and emphasized his responsibility to ensure all staff members are educated on the policy "Cleaning and Disinfection" FMS-CS-IC-II-155-123A and the requirement that staff follow policy and procedure as written.</p> <p>All current staff will be in-serviced by the Clinical Manager on disinfection and Infection Control Practices the week of 2/13/15, specifically focusing on the following policies:</p> <ul style="list-style-type: none"> • "Cleaning and Disinfection" FMS-CS-IC-II-155-123A <p>In addition, the staff will be educated on their responsibility to ensure all equipment including Phoenix Meters and Tympanic Thermometers must be considered potentially blood</p>	02/28/2015

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	<p>2. Employee J, a PCT, was observed to use a phoenix meter to check the dialysis machine's pH and conductivity at station number 12 on 1-28-15 at 9:20 AM. The PCT was not observed to clean and disinfect the meter prior to replacing it in a clean area.</p> <p>3. Employee S, a PCT, was observed to use a phoenix meter to check the dialysis machine pH and conductivity at station number 3 on 1-28-15 at 9:30 AM. The PCT was not observed to clean and disinfect the meter prior to replacing it in a clean area.</p> <p>The PCT was observed to use a tympanic thermometer on patient number 5 on 1-28-15 at 9:30 AM. The PCT was not observed to clean and disinfect the thermometer prior to replacing it onto the countertop at station number 5.</p> <p>4. Employee DD, a PCT, was observed to use a phoenix meter to check the dialysis machine's pH and conductivity at station number 24 on 1-28-15 at 12:40 PM. The PCT was not observed to clean and disinfect the meter prior to replacing it in a clean area.</p> <p>5. Employee D, a PCT, was observed to use a thermometer on patient number 3 at</p>		<p>contaminated, and should be separated, handled with caution and either disinfected or discarded.</p> <p>The Clinical Manager or designee will ensure that infection control audits utilizing the QAI Infection Control audit tool are done weekly for 4 weeks, monthly for 3 months, and then as determined by the QAI calendar. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager who is responsible to address the issue with each employee including corrective action as appropriate</p> <p>The Clinical Manager is responsible to evaluate and present audit findings in the monthly QAI meeting minutes. The QAI Committee is responsible to review, analyze and trend all monitoring results to ensure resolution is both occurring and is sustained.</p>	

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V000122	<p>the end of the dialysis treatment on 1-28-15 at 11:25 AM. The PCT was not observed to clean and disinfect the thermometer prior to replacing it onto the countertop at the station.</p> <p>6. The above-stated observations were presented to the Clinic Manager and the Director of Operations on 1-28-15 at 2:50 PM. The manager and the director indicated the staff had not followed facility policies and procedures.</p> <p>7. The facility's 3-20-13 "Cleaning and Disinfection" policy number FMS-CS-IC-II-155-110A states, "After use, all equipment and supplies must be considered as potentially blood contaminated, and should be separated, handled with caution and either disinfected or discarded."</p> <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- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. Based on observation, interview, and</p>	V000122	The Director of Operations met	02/28/2015
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	<p>review of facility policy, the facility failed to ensure dialysis machines and equipment had been thoroughly cleaned and disinfected after use in 2 (#s 1 and 2) of 2 cleaning and disinfection of the dialysis station observations completed creating the potential to affect all of the facility's 137 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Employee J, a patient care technician (PCT), was observed to clean and disinfect the dialysis machine at station number 11 on 1-28-15 at 9:55 AM. The PCT was not observed to empty the prime waste bucket or clean the top of the machine. Employee D, a PCT, was observed to clean and disinfect the dialysis machine and chair at station number 24 on 1-28-15 at 11:25 AM. The PCT was observed to use the same cloth as was used to clean the machine to clean the dialysis chair. The PCT was not observed to clean the blood pressure cuff. The PCT was not observed to clean the front of the dialysis chair arms, especially where patients place their hands. The PCT was not observed to clean the computer keyboard or the countertop behind the dialysis station. 		<p>with the Clinical Manager on 2/10/15 and emphasizing his responsibility to ensure all staff members are educated on the policy FMS-CS-IC-II-155-110A and FMS-CS-IC-II-155-122A and the requirement that staff follow policy and procedure as written.</p> <p>All current staff will be in-serviced by the Clinical Manager on disinfection and Infection Control Practices the week of 2/13/15, specifically focusing on the following policies: ·FMS-CS-IC-II-155-110A "Cleaning and Disinfection Policy ·FMS-CS-IC-II-155-122A "Cleaning and Disinfection of the Blood Pressure Cuff" In addition, the staff will be educated on their responsibility to ensure all equipment in the patient care station; including all sections of the dialysis machine, prime waste bucket, chair arms, computer, and counter top are properly disinfected per P&P. All areas must be considered potentially blood contaminated, and should be separated, handled with caution and either disinfected or discarded. The "Infection Control Information Acknowledgment" form will be placed in each staff members personnel/education file. The Clinical Manager or designee will ensure that infection control audits utilizing the QAI Infection Control audit tool are done weekly for 4 weeks, monthly for 3</p>		

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	<p>The PCT was observed to remove, empty, and clean the prime waste bucket after cleaning the dialysis machine. The PCT was not observed to change her gloves or cleanse her hands after emptying the prime waste bucket.</p> <p>3. The above-stated observations were presented to the Clinic Manager and the Director of Operations on 1-28-15 at 2:50 PM. The manager and the director indicated the staff had not followed facility policies and procedures.</p> <p>4. The facility's 1-4-12 "Cleaning and Disinfection of the Blood Pressure Cuff" policy number FMS-CS-IC-II-155-122A states, "Blood pressure cuffs will be disinfected with a 1:100 dilution of a hypochlorite solution at the completion of each patient treatment."</p> <p>5. The facility's 3-20-13 "Cleaning and Disinfection" policy number FMS-CS-IC-II-155-110A states, "After use, all equipment and supplies must be considered as potentially blood contaminated, and should be separated, handled with caution and either disinfected or discarded . . . All work surfaces shall be cleaned and disinfected with 1:100 bleach solution after completion of procedures . . . Externally disinfect the dialysis machine with 1:100</p>		<p>months, and then as determined by the QAI calendar. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager who is responsible to address the issue with each employee including corrective action as appropriate</p> <p>The Clinical Manager is responsible to evaluate and present the audit findings in the monthly QAI meeting/minutes. The QAI Committee is responsible to review, analyze and trend all monitoring results to ensure resolution is both occurring and is sustained.</p>	

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V000147	<p>bleach solution after each dialysis treatment . . . Discard all fluid and clean and disinfect all containers associated with the prime waste (including buckets attached to the machines.) . . .</p> <p>Non-disposable items such as blood pressure cuffs, IV poles, TVs, TV remotes, portable phones, etc. . . . should be disinfected with 1:100 bleach solution after each treatment."</p> <p>494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE Recommendations for Placement of Intravascular Catheters in Adults and Children</p> <p>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.</p> <p>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.</p> <p>Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery</p>			

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	<p>Catheters in Adult and Pediatric Patients.</p> <p>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].</p> <p>Based on observation, interview, and review of facility policy, the facility failed to ensure staff had discontinued dialysis treatments using a central venous catheter (CVC) in accordance with facility policy for one of one observation of discontinuation of dialysis in patients with a CVC creating the potential to affect all of the facility's patients with CVCs.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Employee EE, a patient care technician (PCT), was observed to discontinue the dialysis treatment on patient number 2 with a CVC on 1-28-15 at 10:20 AM. The PCT was not observed to place a clean field under the CVC ports prior to starting. Employee D, a PCT, was observed to discontinue the dialysis treatment on patient number 3 with a CVC on 1-28-15 at 11:00 AM. The PCT was not observed to place a clean field under the CVC ports prior to starting. 	V000147	<p>The Director of Operations reviewed the following policy FMS-CS-IC-I-105-032A "Changing the Catheter Dressing" Policy and "Termination of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer" procedure with the Clinical Manager on 2/10/15 emphasizing his responsibility to ensure all staff members are educated on the policies and follow policy and procedure as written.</p> <p>All current staff will be in serviced by the Clinic Manager on Infection Control Practices the week of 2/13/15 specifically focusing on the policy listed above. In addition, the staff will be educated on their responsibility to ensure that aseptic technique is maintained when providing catheter care dressing changes with placement of a clean under pad prior to discontinuation of treatment, and the importance of preventing cross contamination. The "Infection Control Information Acknowledgment" form will be placed in each staff members personnel/education file.</p> <p>The Clinical Manager or designee</p>	02/28/2015

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V000401	<p>3. The above-stated observations were presented to the Clinic Manager and the Director of Operations on 1-28-15 at 2:50 PM. The manager and the director indicated the staff had not followed facility policies and procedures.</p> <p>4. The facility's 1-6-14 "Termination of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer" procedure states, "Ensure that a clean under pad is below the catheter limbs to protect the work area and clothing."</p> <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, interview, and review of facility policy, the facility failed to ensure a safe and clean treatment environment had been maintained in 2</p>	V000401	<p>will ensure that infection control audits utilizing the QAI Infection Control audit tool are done weekly for 4 weeks, monthly for 3 months, and then as determined by the QAI calendar. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager who is responsible to address the issue with each employee including corrective action as appropriate. The specific area of focus during the monitoring will be proper aseptic technique is observed during Central Venous Catheter dressing changes</p> <p>The Clinical Manager is responsible to evaluate and present the audit findings in the monthly QAI meeting/minutes. The QAI Committee is responsible to review, analyze and trend all monitoring results to ensure resolution is both occurring and is sustained.</p> <p>The Director of Operations met with the Clinical Manager on 2/10/15 and reviewed policy number FMS-CS-IC-II-155-116A "Housekeeping" emphasizing his</p>	02/28/2015

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	<p>(#s 1 and 2) of 2 treatment area observations creating the potential to affect all of the facility's 137 current patients.</p> <p>The findings include:</p> <p>1. On 1-28-15 at 9:20 AM, the following was observed:</p> <p style="padding-left: 40px;">A. A 1/2" by 3" piece of white paper was observed on the floor at station number 4.</p> <p style="padding-left: 40px;">B. A 1/2" by 1" white piece of paper was observed on the floor at station number 8.</p> <p style="padding-left: 40px;">D. Two pieces of white paper, 1/2" by 1" were observed on the floor at station number 9.</p> <p style="padding-left: 40px;">E. A capped needle and a 1" by 3" piece of paper were observed on the floor at station number 24.</p> <p style="padding-left: 40px;">F. A 1/2" by 1" piece of paper was observed on the floor at station number 23.</p> <p style="padding-left: 40px;">G. A face shield, used by the nurses and patient care technicians, was observed on the floor at station number 22.</p>		<p>responsibility to ensure all staff members are educated on the policies, competency is assessed and staffs are required to follow policy and procedure as written.</p> <p>Staff will be reeducated by CM the week of 2/13/15 on the policy listed above, with an emphasis placed on the following responsibilities:</p> <ul style="list-style-type: none"> ·Ensuring a safe and clean treatment environment ·All areas must be kept clean and organized, including but not limited to the treatment area, water/supply room and offices." <p>The Clinical Manager or designee will ensure housekeeping audits are performed daily utilizing the QAI Infection Control audit tool for two weeks then weekly for 4 weeks, monthly for 3 months, and then as determined by the QAI calendar. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager who is responsible to address the issue with each employee including corrective action as appropriate</p> <p>The Clinical Manager is responsible to evaluate and present the audit findings in the monthly QAI meeting/minutes. The QAI Committee is responsible to review, analyze and trend all monitoring results to ensure resolution is both</p>				

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	<p>H. A 1/2" by 1/2" piece of white paper was observed on the floor at stations numbered 20 and 21. A 1" by 2" piece of cellophane was also observed on the floor at station number 20.</p> <p>I. A 1/2" by 1" piece of white paper and a white plastic cap were observed on the floor at station number 16.</p> <p>J. A 1/2" by 1" piece of blue disposable glove and a plastic water bottle were observed on the floor at station number 15.</p> <p>K. A white 4 x 4 piece of gauze was observed on the floor at station number 14.</p> <p>2. On 1-28-15 at 11:30 AM, the following was observed:</p> <p>A. The trash can at station 13 was completely full and close to overflowing onto the floor.</p> <p>B. Three pieces of 1/2" by 2" pieces of paper were observed on the floor at station number 14.</p> <p>C. A blue disposable glove and a 1/2" by 4" piece of white paper was observed on the floor next to the trash can at</p>		occurring and is sustained.	

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	<p>station number 15.</p> <p>D. A moderate amount of clean fluid was observed on the floor at station number 16.</p> <p>E. A chewing gum wrapper was observed on the floor at station number 19.</p> <p>F. A piece of clear plastic approximately 1" long was observed on the floor at station number 21.</p> <p>G. Three labels were observed on the floor at station number 22 under the foot rest of the dialysis chair.</p> <p>H. A drop of blood, approximately 2 millimeters in diameter, was observed on the floor at station number 1.</p> <p>I. A 1/2" by 2" piece of white paper was observed on the floor at station number 4.</p> <p>J. A blood pressure cuff was observed on the floor at station number 6.</p> <p>K. A blue disposable glove was observed on the floor at station number 10.</p> <p>L. A drinking straw was observed on</p>			

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V000550	<p>the floor at station number 12.</p> <p>3. Patient number 6 stated, on 1-28-15 at 11:40 AM, "It could be cleaner in here. I see stuff on the floor a lot of the time."</p> <p>4. The above-stated observations were presented to the Clinic Manager and the Director of Operations on 1-28-15 at 2:50 PM. The manager and the director indicated the staff had not followed facility policies and procedures.</p> <p>5. The facility's 3-20-13 "Housekeeping" policy number FMS-CS-IC-II-155-116A policy states, "All areas must be kept clean and organized, including but not limited to the treatment area, water/supply room and offices."</p> <p>494.90(a)(5) POC-VASCULAR ACCESS-MONITOR/REFERRALS The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. Based on observation, interview, and review of facility policy, the facility failed to ensure staff had provided</p>	V000550	The Director of Operations met with the Clinical Manager on 2/10/15 emphasizing his responsibility to ensure all staff	02/28/2015

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	<p>arteriovenous fistula (AVF)/graft (AVG) care in accordance with facility policy in 3 (#s 1, 2, and 3) of 3 AVF/AVG observations completed creating the potential to affect all of the facility's patients with AVFs or AVGs.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Employee D, a patient care technician (PCT), was observed to initiate the dialysis treatment on patient number 4, with an AVF, on 1-28-15 at 10:40 AM. The PCT was not observed to evaluate the access and locate/palpate the cannulation site prior to inserting the needles. Employee S, a PCT, was observed to initiate the dialysis treatment on patient number 5, with an AVG, on 1-28-15 at 11:15 AM. The PCT was not observed to evaluate the access and locate/palpate the cannulation site prior to inserting the needles. Employee FF, a PCT, was observed to provide care to patient number 1 after the dialysis treatment had ended and the needles had been removed. The PCT was not observed to remove the gauze from the needle insertion sites and replace with clean gauze after the bleeding had stopped. The PCT was observed to place 		<p>members are educated on the policy FMS-CS-IC-I-115-013C "Post Treatment Fistula Needle Removal" and "Post Treatment Fistula Needle Removal" procedure and the requirement that staff follow policy and procedure as written.</p> <p>The Clinical Manager will educate and review with all staff the following policy at a mandatory staff in-service the week of 2/3/15 with emphasis on changing dressing after hemostasis has been achieved and access evaluation and assessment.</p> <ul style="list-style-type: none"> FMS-CS-IC-I-115-013C "Post Treatment Fistula Needle Removal" "Post Treatment Fistula Needle Removal" procedure <p>The Clinical Manager or designee will ensure that infection control audits utilizing the QAI Infection Control audit tool are done weekly for 4 weeks, monthly for 3 months, and then as determined by the QAI calendar. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager who is responsible to address the issue with each employee including corrective action as appropriate</p> <p>The Clinical Manager is responsible to evaluate and</p>	

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V000637	<p>additional tape on the gauze already in place.</p> <p>4. The above-stated observations were presented to the Clinic Manager and the Director of Operations on 1-28-15 at 2:50 PM. The manager and the director indicated the staff had not followed facility policies and procedures.</p> <p>5. The facility's 9-25-13 "Needle Placement for AV Fistula and Graft" procedure states, "Assess, identify cannulation sites, and clean per procedure."</p> <p>6. The facility's 3-26-14 "Post Treatment Fistula Needle Removal" procedure states, "Once hemostasis has been achieved, remove the gauze used for hemostasis and replace the sites with Band-Aids or adhesive dressing or clean tape with gauze dressing."</p> <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- (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,</p>		<p>present audit findings in the monthly QAI meeting/minutes. The QAI Committee is responsible to review, analyze and trend all monitoring results to ensure resolution is both occurring and is sustained.</p>				

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	<p>promote immunization; and (C) Take actions to reduce future incidents. Based on quality assessment performance improvement (QAPI) documentation and facility policy review and interview, the facility failed to ensure infection control practice audits had been completed and reviewed by the QAPI committee in 3 (August, September, and October 2014) of 6 months reviewed creating the potential to affect all of the facility's 137 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The facility's "Facility Quality Assessment and Performance (QAI) Dashboard", included in the 1-20-15 QAPI meeting report, failed to evidence any infection control audits had been completed or reviewed for the months of August, September, and October 2014. 2. The Director of Operations indicated, on 1-28-15 at 2:30 PM, monthly audits of staff infection control practices were designated to be completed in the QAI tools. The director indicated the QAPI documentation did not evidence the audits had been completed or reviewed for August, September, and October 2014. 3. The facility's 4-4-12 "Quality 	V000637	<p>The Director of Operations and the Clinic Manager participated in mandatory Quality Assessment and Performance Improvement Program training on 1/22/15. Education provided by the Regional Quality Manager, Regional Technical Operations Manager and Regional Education Manager.</p> <p>The Director of Operations met with the Clinical Manager on 2/10/15 emphasizing his responsibility to ensure "Quality Assessment and Performance Improvement Program (QAPI)" policy number FMS-CS-IC-I-101-001A and the requirement to follow policy and procedure as written.</p> <p>The Director of Operations will ensure that infection control audits utilizing the QAI Infection Control audit tool are done weekly for 4 weeks, monthly for 3 months, and then as determined by the QAI calendar. Any deficiencies noted during the audits will be addressed by the DO and issue corrective action as appropriate</p> <p>The Clinical Manager is responsible to evaluate and present infection control audit findings in the monthly QAI meeting/minutes. The QAI Committee is responsible to</p>	02/28/2015

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V000765	<p>Assessment and Performance Improvement Program (QAPI)" policy number FMS-CS-IC-I-101-001A states, "QAI Program activities for each facility or program include: . . . Completion and review of the results of required self-audits."</p> <p>494.180(e) GOV-INTERNAL GRIEVANCE SYS ID/IMPLEMENTED The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services.</p> <p>The grievance process must include- (1) A clearly explained procedure for the submission of grievances. (2) Timeframes for reviewing the grievance. (3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance.</p> <p>Based on administrative record and facility policy review and interview, the facility failed to ensure its internal grievance process had been implemented creating the potential to affect all of the facility's 137 current patients.</p> <p>The findings include:</p> <p>1. The complainant indicated in the complaint received at the Indiana State Department of Health that facility</p>	V000765	<p>review, analyze and trend all monitoring results to ensure resolution is both occurring and is sustained.</p> <p>Governing Body oversight will ensure full compliance of the QAPI per policy.</p> <p>The Director of Operations and the Clinic Manager participated in mandatory Quality Assessment and Performance Improvement Program training on 1/22/15. Education provided by the Regional Quality Manager, Regional Technical Operations Manager and Regional Education Manager. This education included but was not limited to the following: •QAI processes including monthly analysis and trending of patient complaints and grievances.</p>	02/28/2015

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	<p>cleanliness and non-compliance with infection control practices had been reported to facility staff. The complainant indicated facility staff stated, "They would work on it."</p> <p>2. The facility's "Patient Grievance Log", for 2014, failed to evidence any complaints regarding facility cleanliness and infection control practices had been documented, investigated, and follow-up had been completed.</p> <p>3. The facility's 1-2-14 "Patient Grievance" policy states, "Grievance is any complaint or concern raised by the patient or the patient's representative . . . Grievances may be filed written or verbally, by the patient or patient's designated representative . . . Timelines outlined in the procedure for acknowledging, investigating, and addressing grievances shall be followed. All patient grievances received at the facility must be reported to the QAI Committee and to the Governing Body . . . Written documentation of the grievances and the actions taken to resolve it must be available in the QAI minutes."</p> <p>4. The facility's 1-2-14 "Patient Grievance" procedure states, "FMS Staff promptly acknowledges and reports all</p>		<p>The Director of Operations met with the Clinical Manager on 2/10/15 emphasizing his responsibility to ensure "Quality Assessment and Performance Improvement Program (QAPI)" policy number FMS-CS-IC-I-101-001A and the requirement to follow policy and procedure as written.</p> <p>The Director of Operations and the Clinic Manager will educate all staff and patients on the grievance process the week of 2/13/15 as described below:</p> <ul style="list-style-type: none"> ·Staff promptly acknowledges and reports all patient grievances to the Nurse in Charge (or Team Leader) as soon as possible. ·The CM will review the Patient Grievance Status Report daily for any new grievances. ·CM will meet with the patient within 5 business days to acknowledge, investigate and address the grievance. ·The CM will report back to the patient when a resolution is attained or considered attained by the facility. ·If the grievance cannot be immediately resolved, the CM will provide the patient/representative with updates periodically on progress. ·The CM will perform monthly grievance log documentation and ensure that all patient grievances are reported to the QAI Committee. 	

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	<p>patient grievances to the Nurse in Charge (or Team Leader) as soon as possible . . . The CM reviews the Patient Grievance Status Report daily. For any new grievances, CM meets with the patient within 5 business days to acknowledge, investigate and address the grievance . . . CM reports back to the patient when a resolution is attained or considered attained by the facility . . . When the grievance cannot be immediately resolved, the CM must provide the patient/representative with updates periodically on progress . . . The CM ensures that all patient grievances are reported to the QAI Committee."</p>		<p>The Director of Operations will review the grievance log weekly for 4 weeks, then monthly per the QAI calendar.</p> <p>The Clinical Manager is responsible to evaluate and present audit findings in the monthly QAI meeting/minutes. The QAI Committee is responsible to review, analyze and trend all monitoring results to ensure resolution is both occurring and is sustained.</p> <p>Governing Body oversight will ensure full compliance of the QAPI per policy.</p>		