

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152503	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 04/22/2016
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE OHIO VALLEY	STREET ADDRESS, CITY, STATE, ZIP CODE 230 BELLEMEADE AVE EVANSVILLE, IN 47713
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V 0000 Bldg. 00	<p>This was a Federal ESRD [CORE] recertification survey and complaint investigation survey.</p> <p>Complaint #: IN000193292; Substantiated, deficiencies related to the complaint are cited at 42 CFR 494.30(a)(1)(i), 42 CFR 494.30(a)(1)(ii), 42 CFR 494.60, 42 CFR 494.60(a), 494.110(a)(2), and 494.110(b).</p> <p>Survey Dates: 4-15-16, 4-18-16, 4-19-16, 4-21-16, and 4-22-16.</p> <p>Facility #: 005150</p> <p>Medicare Provider # 15-2503</p> <p>Medicaid Vendor #: 100248060</p> <p>Census: 62 incenter 7 peritoneal dialysis 69 total patients</p> <p>Fresenius Medical Care Ohio Valley was found to be out of compliance with conditions for coverage 42 CFR 494.30 Infection Control, 494.60 Physical Environment, 494.90 Patient Plan of Care, 494.110 Quality Assessment and Performance Improvement, and 494.150</p>	V 0000		
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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>Responsibilities of the Medical Director.</p> <p>An immediate jeopardy was identified on 4-18-16 at 9:15 AM. Observation and interview identified a registered nurse (employee F) had been delegated as the charge nurse and had been assigned to provide care to all of the patients receiving dialysis on the first shift. This assignment included a patient in the isolation room that was hepatitis B positive and patients who were hepatitis B susceptible. The Clinic Manager and the Director of Operations were notified of the Immediate Jeopardy on 4-18-16 at 12:25 PM.</p> <p>The immediate jeopardy was removed on 4-22-16 at 1:30 PM after verification all staff had been educated regarding caring for patients with hepatitis B and not caring for susceptible patients at the same time, the daily staff assignments had been reviewed to ensure staff had not been assigned to provide care to the hepatitis B positive patient at the same time as susceptible patients, patient seating charts had been arranged so that a buffer zone was in place to prevent staff assigned to care for the hepatitis B patient from providing care to susceptible patients, and an audit of treatment sheets to identify susceptible patients who were potentially placed at risk had been</p>			

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V 0110 Bldg. 00	<p>completed and laboratory tests had been ordered to check these patients.</p> <p>494.30 CFC-INFECTION CONTROL</p> <p>Based on record review, interview, and observation, it was determined the facility failed to maintain compliance with this condition by failing to ensure staff had provided care in accordance with the facility's own infection control and hand hygiene policies and procedures in 8 of 17 infection control observations completed creating the potential to affect all of the facility's 62 current incenter patients (See V 113); by failing to ensure paraprofessional health care providers donned appropriate personal protective equipment (PPE) while on the dialysis treatment floor in 2 of 3 paraprofessional observations completed creating the potential to affect all of the facility's 62 current incenter patients (See V 115); by failing to ensure staff had cleaned and disinfected the dialysis station in accordance with facility policy in 2 of 2 cleaning and disinfection of dialysis</p>	V 0110	<p>As a result of the citations received from the April 22, 2016 CMS Survey and as part of the Developed Plan of Correction, the following Plans of Correction have been approved by the Governing Body (GB) for implementation:</p> <p>Direct patient care (DPC) staff and patient reeducation and reinforcement on Hand Hygiene Policy FMS-CS-IC-155-090A (Please refer to V 113) DPC staff reeducation and reinforcement on Personal Protective Equipment FMS-CS-IC-11-155-080A (Refer to V 115)</p>	05/21/2016

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	<p>station observations completed creating the potential to affect all of the facility's 62 current incenter patients (See V 122); by failing to ensure staff assigned to care for hepatitis B positive patients (# 6) did not care for hepatitis B susceptible patients at the same time in 5 of 5 patients known to be susceptible creating the potential to affect the facility's 20 current incenter patients who are known to be susceptible (See V 131); and by failing to ensure central venous catheter (CVC) care had been provided in accordance with facility policy in 2 of 4 CVC observations completed and failed to ensure CVC exit site care had been provided in accordance with facility policy in 1 of 2 CVC exit site care observations completed and 1 of 1 record reviewed of patients with a CVC (See V 147).</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to provide safe and effective patient care in accordance with infection control policies and procedures.</p> <p>An immediate jeopardy was identified on 4-18-16 at 9:15 AM. Observation and interview identified a registered nurse (employee F) had been delegated as the charge nurse and had been assigned to provide care to all of the patients</p>		<p>DPC staff reeducation and reinforcement on Cleaning and Disinfection FMS-CS-IC-11-155-110A (Refer to V 122)</p> <p>DPC staff reeducation and reinforcement on Dialyzing Patients with Positive Hepatitis B Antigenpolicy FMS-CS-IC-11-155-140A (Refer to V 131)</p> <p>DPC staff reeducation and reinforcement on Hepatitis Policy FMS-CS-IC-1-500-075A (Refer to V 131)</p> <p>DPC staff reeducation and reinforcement on Changing the Catheter Dressing FMS-CS-IC-1-105-032 A (Refer to V 147)</p> <p>Documentation of staff training and attendance are available at the facility for review</p> <p>To monitor for staff and patient compliance to Infection Control practices, the Clinical Manager or designee developed an Infection Control Audit Tool specific to the CMS citations received</p>	

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	<p>receiving dialysis on the first shift. This assignment included a patient in the isolation room that was hepatitis B positive and patients who were hepatitis B susceptible. The Clinic Manager and the Director of Operations were notified of the Immediate Jeopardy on 4-18-16 at 12:25 PM.</p> <p>The immediate jeopardy was removed on 4-22-16 at 1:30 PM after verification all staff had been educated regarding caring for patients with hepatitis B and not caring for susceptible patients at the same time, the daily staff assignments had been reviewed to ensure staff had not been assigned to provide care to the hepatitis B positive patient at the same time as susceptible patients, patient seating charts had been arranged so that a buffer zone was in place to prevent staff assigned to care for the hepatitis B patient from providing care to susceptible patients, and an audit of treatment sheets to identify susceptible patients who were potentially placed at risk had been completed and laboratory tests had been ordered to check these patients.</p>		<p>Monitoring of DPC staff and patient compliance to hand hygiene requirements, appropriate use of personal protective equipment by ambulance transport personnel, cleaning and disinfection, and Hepatitis B infection control practices in accordance to facility policy and procedure and CDC guidelines will be accomplished by direct observation. Rotating disciplines will be responsible to complete infection control audits each patient shift until 100% compliance is achieved as determined by the Governing Body</p> <p>Monitoring of the CVC Care and dressing change will be performed by both the direct observation utilizing the developed infection control audit tool and the CVC monitoring tool</p> <p>The Clinical Manager or designee summarizes the findings of the daily infection control audits and CVC monitoring tool and</p>	

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V 0113 Bldg. 00	<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 record review, observation, and interview, the facility failed to ensure staff had provided care in accordance with the facility's own infection control and hand hygiene policies and procedures in 8 (#s 8, 9, 10, 12, 13, 15, 16, & 17) of 17 infection control observations</p>	V 0113	<p>reports to the Governing Body (GB) weekly and to the Quality Assessment and Performance Improvement (QAPI) program committee monthly All reported events are evaluated for trends, and corrective and/or preventative measures implemented as warranted The QAI Committee is responsible to review this Plan of Correction x 12 months consecutively to ensure sustained compliance</p> <p>The GB Committee may recommend procedural or operational changes that are required to prevent reoccurrence</p> <p>On or before May 12, 2016 the Education Coordinator will reeducate all direct patient care staff on Hand Hygiene Policy FMS-CS-IC-155-090A with:</p>	05/21/2016

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	<p>completed creating the potential to affect all of the facility's 62 current incenter patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Employee F, a registered nurse (RN), was observed to initiate the dialysis treatment on patient number 16 using an arteriovenous fistula on 4-22-16 at 10:50 AM (observation # 8). The RN was observed to evaluate the access by touching the patient's arm. The RN was not observed to change her gloves or cleanse her hands prior to applying antiseptic to the skin over the access site in preparation for needle placement. On 4-15-16 at 11:30 AM, observation noted patient number 16 holding a gauze over the needle insertion site with a glove on the hand after the patient care technician (PCT), employee M, had removed the needles (observation # 9). After the bleeding had stopped, the patient removed the glove from the right hand and walked to the scales and touched the scales to obtain the post dialysis weight. The patient was observed to then leave the facility. <p>The patient was not observed to cleanse the patient's hands after glove removal and prior to touching the scale</p>		<ul style="list-style-type: none"> ·Reeducation and reinforcement on the requirement to remove gloves, disinfect hands and don clean gloves after touching/evaluating the vascular access, and prior to applying antiseptic and cannulation of the access ·Reeducation and reinforcement on the requirement to change gloves and disinfect hands immediately after emptying the prime waste receptacle and prior to initiation of cleaning the dialysis machine ·Reeducation and reinforcement on changing gloves and disinfecting hands when moving from one patient station to another patient station ·Reeducation and reinforcement to the nursing staff on the requirement to disinfect hands and don clean gloves prior to administration of IV medications · The responsibility of all direct patient care staff to remind and encourage 		

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	<p>and leaving the facility. The PCT, employee M, was not observed to encourage or remind the patient to wash the patient's hands after glove removal.</p> <p>3. On 4-15-16 at 2:55 PM, observation noted patient number 17 holding a gauze over the needle insertion site with a glove on the left index finger only after employee L, a PCT, had removed the needle (observation # 10). Visible blood was on the gauze over the needle insertion site. After the bleeding had stopped, the patient was observed to remove the glove, walk to the scales, touch the handrail on the scales and a button on the scales. The patient was then observed to leave the facility.</p> <p>The patient was not observed to cleanse the patient's hands after the glove removal and prior to touching the scales handrail and button. The PCT, employee L, was not observed to encourage the patient to completely don the glove when holding the gauze after the needle removal and was not observed to encourage or remind the patient to wash the patient's hands after glove removal.</p> <p>4. Employee D, and RN, was observed to clean and disinfect the dialysis machine at station # 10 on 4-20-16 at 10:05 AM (observation # 12). The RN was</p>		<p>patients to wash or disinfect hands after gloveremoval and prior to proceeding to the scales and exiting the treatment area</p> <p>On or before May 13, 2016the Clinic Manager or designee will reeducate all patients on Hand Hygienerequirements with emphasis on:</p> <ul style="list-style-type: none"> ·The requirementof hand hygiene after glove removal and prior to proceeding to scales to obtainweight post treatment ·The appropriate way to don a glove (i.e., glove should cover the entire hand, not just a finger) <p>A copy of the staff reeducationwill be maintained available for review at the facility</p> <p>A copy of the patienteducation will be maintained available for review in each patient's respectivemedical record</p> <p>Staff and Patientcompliance to hand hygiene after glove removal will be monitored by directobservation. Rotating</p>	

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	<p>observed to empty the prime waste receptacle and clean the machine. The RN was not observed to change her gloves or cleanse her hands after emptying the prime waste receptacle and prior to cleaning the dialysis machine.</p> <p>5. Employee F, an RN, was observed to administer intravenous medications to patient number 18 on 4-18-16 at 11:45 AM (observation # 13). The RN was observed to prepare the medication and take it to the dialysis station. The RN then donned clean gloves without cleansing her hands.</p> <p>6. On 4-18-16 at 10:45 AM, patient number 19 was observed to don a glove on the left fingers only after the PCT, employee O, had removed the needles from the arteriovenous fistula at the conclusion of the dialysis treatment (observation # 15). After the bleeding had stopped, the patient removed the glove, touched a button on the scales to obtain the post dialysis weight and then departed the facility.</p> <p>The PCT, employee O, was not observed to encourage or remind the patient to don the glove completely or cleanse the patient's hands after glove removal and prior to touching the button on the scales.</p>		<p>disciplines will complete Infection Control Audits each patient shift beginning May 13, 2016 continuing until 100% staff and patient compliance is achieved and sustained as determined by the GB Clinical Manger or designee is responsible to provide a summary of the Infection Control Audit findings to the GB Committee weekly GB will determine, based upon staff and patient compliance when to decrease frequency of the IC audits. CM responsible to provide a summary to the QAI Committee monthly QAI Committee will analyze the findings and assess for trends. If trends are identified, the QAI Committee will direct changes to this action plan</p>		

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	<p>7. On 4-20-16 at 10:35 AM, patient number 10 was observed to hold gauze over the needle insertion sites with a gloved hand after the PCT, employee P, had removed the needles (observation # 16). After the bleeding had stopped, the patient was observed to touch a button on the scale with the glove still on the hand used to hold the gauze. After the post dialysis weight was obtained, the PCT removed the glove from the patient's hand and the patient departed the facility.</p> <p>The PCT, employee P, was not observed to encourage or remind the patient to remove the glove and cleanse the patient's hands prior to touching the button on the scales and leaving the facility.</p> <p>8. On 4-22-16 at 11:15 AM, employee F, an RN, was observed to remove a paper thermometer from the mouth of patient number 16 (observation # 17). The RN was not observed to be wearing gloves. The RN was then observed to go directly to patient number 13, don clean gloves without cleansing her hands, and touch the access.</p> <p>9. The above-stated observations were reviewed with the clinic manager on 4-22-1 at 12:10 PM. The manager</p>			

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V 0115 Bldg. 00	<p>indicated the employees had not provided care in accordance with facility policy.</p> <p>10. The facility's 3-20-13 "Hand Hygiene" policy number FMS-CS-IC-II-155-090A states, "Hands will be . . . Decontaminated using alcohol based hand rub or by washing hands with antimicrobial soap and water Before and after direct patient contact . . . Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medications, 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 . . . Hand Hygiene Patients. Patients should perform hand hygiene if able, prior to and after each dialysis treatment . . . Gloves must be provided to patients when performing procedures which risk exposure to blood or body fluids, such as when self-cannulating or holding access sites post treatment to achieve hemostasis. To help ensure the prevention of cross contamination to their family members or other patients, hand hygiene must be performed."</p> <p>494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK Staff members should wear gowns, face</p>			

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	<p>shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurring or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. Based on observation, record review, and interview, the facility failed to ensure paraprofessional health care providers donned appropriate personal protective equipment (PPE) while on the dialysis treatment floor in 2 (#s 1 and 2) of 3 paraprofessional observations completed creating the potential to affect all of the facility's 62 current incenter patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> On 4-15-16 at 11:10 AM, observation noted 2 ambulance crew members transporting patient number 20 into the dialysis facility on a cart. The crew members were not observed to be wearing any PPE while on the dialysis treatment floor. On 4-20-16 at 11:25 AM, observation noted 2 ambulance crew members transporting patient number 20 into the dialysis facility on a cart. The crew members were not observed to be wearing any PPE while on the dialysis treatment floor. 	V 0115	<p>On or before May 12, 2016the Education Coordinator will reeducate all direct patient care staff on PersonalProtective Equipment FMS-CS-IC-11-155-080A A copy of the staffreeducation will be maintained available for review at the facility.</p> <p>The Clinical Managercontacted the Ambulance Transportation Service via phone and in person on May10, 2016 to inform them of the CMS citation and the mandatory requirement towear full PPE in the treatment area</p> <p>In addition, on May 13,2016, the DO notified the Ambulance Transportation Services via letter of theCMS citation and the mandatory requirement to wear full PPE</p>	05/21/2016

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	<p>3. The clinic manager indicated, on 4-22-16 at 11:30 AM, she was unaware the ambulance crew should don PPE upon entering the treatment floor to transport patients. The manager acknowledged the potential risk for the transmission of and exposure to disease causing organisms while the crew was on the treatment floor.</p> <p>4. The facility's 1-4-12 "Personal Protective Equipment" policy number FMS-CS-IC-II-155-080A states, "Personal protective equipment such as a full face shield or mask and protective eyewear with full sideshield, fluid-resistant gowns and gloves will be worn to protect and prevent employee from blood or other potentially infectious materials to pass through to or reach the employee's skin, eyes, mouth, other mucous membranes, or work clothes when performing procedures during which spurting or splattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood)."</p>		<p>in treatment area</p> <p>-</p> <p>Ambulance personnel compliance to wearing of PPE in the treatment area will be monitored by direct observation. Rotating disciplines will complete Infection Control Audits each patient shift beginning May 13, 2016 continuing until 100% ambulance transport personnel compliance is achieved and sustained as determined by the GB CM or designee is responsible to provide a summary of the Infection Control Audit findings inclusive of ambulance personnel's compliance with wearing PPE to the GB Committee weekly GB will determine, based upon staff and patient compliance when to decrease frequency of the IC audits.</p> <p>CM or designee responsible to provide a summary to the QAI Committee monthly QAI Committee will analyze the findings and assess for trends. If trends are identified, the QAI Committee will direct changes to</p>		

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V 0122 Bldg. 00	<p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing-</p> <p>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]</p> <p>(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.</p> <p>Based on observation, record review, and interview, the facility failed to ensure staff had cleaned and disinfected the dialysis station in accordance with facility policy in 2 (#s 1 and 2) of 2 cleaning and disinfection of dialysis station observations completed creating the potential to affect all of the facility's 62 current incenter patients.</p> <p>The findings include:</p> <p>1. Employee D, a registered nurse (RN), was observed to clean and disinfect the dialysis machine and chair at station number 9 on 4-15-16 at 1:35 PM (observation #1). The RN cleaned the front and right side of the dialysis machine and then empties the prime waste receptacle. The RN then completed the cleaning of the machine.</p>	V 0122	<p>this action plan</p> <p>On or before May 12, 2016 allDirect Patient Care staff, inclusive of RN/Employee D and PCT/Employee N willreceive reeducation from the Education Coordinator on Cleaning and DisinfectionFMS-CS-IC-11-155 -110A A copy of the reeducationwill be maintained at the facility available for review</p> <p>Compliance to dialysisstations disinfection will be monitored by direct observation. Rotating disciplines will complete InfectionControl Audits, each patient shift beginning May 13, 2016 continuing until 100%staff</p>	05/21/2016

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	<p>A. The RN was not observed to clean the dialysate lines or the sharps container. The RN disconnected the dialysate lines from the outlets in the chase cabinet behind the machine and draped them over the clean machine.</p> <p>B. The RN was observed to clean the dialysis chair at 2:00 PM. The RN was not observed to clean the right side of the chair beneath the attached chair side table and was not observed to clean the fronts of the arms of the chair where patients place their hands. The RN was not observed to clean the data entry station.</p> <p>2. Employee N, a patient care technician (PCT), was observed to clean the dialysis chair at station number 10 on 4-20-16 at 10:20 AM (observation number 2). The PCT was not observed to clean the fronts of the arms of the chair where patients place their hands. The PCT was not observed to clean the entire surfaces of the sides of the chair. The employee was not observed to clean the data entry station.</p> <p>3. The above-stated observations were reviewed with the clinic manager on 4-22-1 at 12:10 PM. The manager indicated the employees had not cleaned and disinfected the dialysis station in accordance with facility policy.</p>		<p>compliance is achieved and sustained as determined by the GB</p> <p>-</p> <p>CM or designee is responsible to provide a summary of the Infection Control Audit findings inclusive of Direct Patient Care staff compliance with dialysis stations disinfection to the GB Committee weekly and to the QAI Committee monthly</p> <p>GB will determine, based upon staff and patient compliance when to decrease frequency of the IC audits.</p> <p>QAI Committee will analyze the findings and assess for trends. If trends are identified, the QAI Committee will assist with determination of root cause and direct changes to this action plan as warranted</p>	

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V 0131 Bldg. 00	<p>4. The facility's 1-28-15 "Cleaning and Disinfection" policy number FMS-CS-IC-II-155-110A states, "All work surfaces shall be cleaned and disinfected with 1:100 bleach solution after completion of procedures. Make the surface glisteningly wet and let air dry unless otherwise specified by the manufacturer . . . Externally disinfect the dialysis machine with 1:100 bleach solution after each dialysis treatment."</p> <p>494.30(a)(1)(i) IC-HBV-ISOLATION-STAFFING Isolation of HBV+ Patients</p> <p>Staff members caring for HBsAg positive patients should not care for HBV susceptible patients at the same time, including during the period when dialysis is terminated on one patient and initiated on another.</p> <p>Based on record review, observation, and interview, the facility failed to ensure staff assigned to care for hepatitis B positive patients (# 6) did not care for hepatitis B susceptible patients at the same time in 5 (#s 7, 8, 9, 10, and 11) of 5 patients known to be susceptible creating the potential to affect the facility's 20 current incenter patients who are known to be susceptible.</p> <p>The findings include:</p>	V 0131	<p>To ensure that patient/staff assignments reflect compliance with Hepatitis B positive and buffer zone requirements, the following actions have occurred:</p> <ul style="list-style-type: none"> · On April 18, 2016, Education Coordinator and CM · Reviewed daily staff assignment to ensure one nurse is assigned to provide care to Hepatitis B positive patients and Hepatitis B antibody positive (titer > 10) patients in the buffer zone only · 100% audit of treatment sheets 	05/21/2016

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	<p>1. On 4-18-16 at 8:25 AM, observation noted patient number 6 was receiving a dialysis treatment in the isolation room. The patient was identified as being hepatitis B positive by employee K, the patient care technician (PCT) assigned to provide care to the patient. The facility's "Hepatitis Summary Report" dated 4-18-16 identified patient number 6 as hepatitis B positive.</p> <p>2. Employee F, a registered nurse (RN), indicated, on 4-18-16 at 8:30 AM that she was the charge nurse today and was assigned to all of the patients on the treatment floor during the first shift, including patient number 6. The nurse indicated her duties included assessments, medication administration, putting orders in the computer, call the doctors, "do whatever they tell me to do." The RN stated, "I give [patient number 6] medications last." Observation noted that patients numbered 7, 8, 9, 10, and 11 were also receiving a dialysis treatment at the same time as the patient in the isolation room and were included in the charge nurse's assignment.</p> <p>3. The facility's "Hepatitis Summary Report", dated 4-18-16 identified patients numbered 7, 8, 9, 10, and 11 as susceptible, having an antibody value of less than 10 and identified patient</p>		<p>to identify susceptible patients who were potentially placed at risk for cross contamination on April 18, 2016</p> <ul style="list-style-type: none"> ·On April 19, 2016 the Education Coordinator provided reeducation to all direct patient care staff on <ul style="list-style-type: none"> ·FMS-CS-IC-11-155-140A Dialyzing Patients with Positive Hepatitis B Antigen policy ·FMS-CS-IC-1-500-075A Hepatitis Policy <p>A copy of the staff education will be maintained available for review at the facility</p> <p>Additionally, and to ensure that seroconversion of the susceptible patient has not occurred; the Medical Director will complete the following actions:</p> <ul style="list-style-type: none"> ·On April 18, 2016, the Medical Director agreed to review the following lab reports of the susceptible patient who potentially received care by staff caring for patients in the buffer zone for a minimum of the next 4 months <ul style="list-style-type: none"> ·Hepatitis B antigen as well as the most recent Alanine Aminotransferase (ALT) results to determine if patients have any indications of active hepatitis B infection. <p>To prevent reoccurrence and to ensure that each staff member is</p>	

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	<p>number 6 as hepatitis B positive.</p> <p>A. Clinical record number 6 (the record of the hepatitis B positive patient) included a hemodialysis treatment flow sheet dated 4-18-16 that evidenced employee F, the charge RN, had administered an intravenous medication to the patient at 7:38 AM and had performed intradialytic vital sign checks on the patient at 8:00 AM and 8:30 AM.</p> <p>B. Clinical record number 7 (the record of a hepatitis B susceptible patient) included a hemodialysis treatment flow sheet dated 4-18-16 that evidenced employee F, the charge RN, had administered an intravenous medication to the patient at 7:40 AM.</p> <p>C. Clinical record number 8 (the record of a hepatitis B susceptible patient) included a hemodialysis treatment flow sheet dated 4-18-16 that evidenced employee F, the charge RN, had performed a nursing evaluation on the patient at 6:02 AM.</p> <p>D. Clinical record number 9 (the record of a hepatitis B susceptible patient) included a hemodialysis treatment flow sheet dated 4-18-16 that evidenced employee F, the charge RN, had performed a nursing evaluation at</p>		<p>fully aware of the facility's policy regarding dialyzing patients with positive Hepatitis B Antigen, the following</p> <ul style="list-style-type: none"> ·Beginning immediately the CM is responsible to ensure staff caring for Hepatitis B antigen positive patient care only for Hepatitis B antibody (titer > 10) patients at the same time ·Beginning April 18, 2016, each staff member will be provided education on Hepatitis and the Buffer Zone by the Education Coordinator. This education will continue with an expected completion date of April 19, 2016. Included in this education are the following Hepatitis B policy and procedure: ·FMS-CS-IC-II-155-140 Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+) Policy <p>The CM or designee is responsible to monitor for compliance and will provide oversight directly or through an assigned designee to monitor staff assignment and practice to ensure that patient/staff assignments reflect compliance with Hepatitis B positive and buffer zone requirements. Additionally, the GB will meet weekly for the next 2 months to review continued adherence to the action plan and ensure compliance is achieved and sustained.</p>	

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	<p>6:20 AM and had verified the use of oxygen by the patient at 7:54 AM.</p> <p>E. Clinical record number 10 (the record of a hepatitis B susceptible patient) included a hemodialysis treatment flow sheet dated 4-18-16 that evidenced employee F, the charge RN, had administered an intravenous medication and an oral medication to the patient at 7:55 AM.</p> <p>F. Clinical record number 11 (the record of a hepatitis B susceptible patient) included a hemodialysis treatment flow sheet dated 4-18-16 that evidenced employee F, the charge RN, had performed a nursing evaluation at 7:02 AM and had administered an intravenous medication to the patient at 8:05 AM.</p> <p>4. The clinic manager stated, on 4-18-16 at 12:25 PM, "I thought since she [the charge RN, employee F] gave [patient number 6] medications last, it was ok. She doesn't go back in there [into the isolation room]."</p> <p>5. The facility's 3-20-13 "Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+)" policy number FMS-CS-IC-II-155-140A states, "Staff having any contact with the HBsAg</p>			

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V 0147 Bldg. 00	<p>positive patient must at the same time have NO contact with susceptible patients."</p> <p>6. The facility's 9-25-13 "Hepatitis Policy" number FMS-CS-IS-I-500-075A states, "Known HBsAg positive . . . May be cared for by the same staff member that cares for the patient with known hepatitis B antibodies (Ant-HBs [greater than or equal to] 10mlU/mL) . . . Staff caring for known HBsAg positive . . . Staff members an be assigned to care for both HBsAg positive and HBV protected (Anti-HBs [greater than or equal to] 10mlU/mL patients on the same shift."</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</p>			

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	<p>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 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 record review, the facility failed to ensure central venous catheter (CVC) care had been provided in accordance with facility policy in 2 (#s 1 and 3) of 4 CVC observations completed and failed to ensure CVC exit site care had been provided in accordance with facility policy in 1 (#1) of 2 CVC exit site care observations completed and 1 (#1) of 1 record reviewed of patients with a CVC.</p> <p>The findings include:</p> <p>1. Employee N, a patient care technician (PCT), was observed to initiate the dialysis treatment on patient number 21 using a CVC on 4-15-16 at 11:15 AM (observation #1). The PCT was observed to disinfect the threads of the arterial hub for only 6 seconds prior to initiating the treatment.</p>	V 0147	<p>On or before May 12, 2016 all direct patient care staff, inclusive of Employee N/PCT and Employee F/RN will receive reeducation from Education Coordinator on: Changing the Catheter Dressing FMS-CS-IC-1-105-032A, with specific emphasis on:</p> <ul style="list-style-type: none"> · Reeducation and reinforcement on the policy requirement to change the CVC dressing and to assess the CVC exit site prior to treatment initiation · Reeducation and reinforcement on policy requirement to scrub the CVC hubs minimum of 15 seconds prior to removing the end caps or disconnecting the bloodlines · Reeducation and reinforcement on policy requirement to place a clean blue pad under the CVC limbs prior to treatment initiation and termination. A copy of the education will be maintained available for review at the facility 	05/21/2016

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	<p>2. Employee N, a PCT, was observed to discontinue the dialysis treatment on patient number 18 on 4-15-16 at 2:45 PM (observation # 3). The PCT was observed to open a package of sterile replacement CVC caps and place them on a piece of paper on the chair side table instead of placing them on a clean field. The PCT was then observed to place the caps on the catheter limbs at the conclusion of the disconnect procedure.</p> <p>A. The PCT was not observed to place a clean field under the CVC ports prior to starting the discontinuation procedure.</p> <p>B. The PCT was observed to scrub the threads of the arterial hub for only 4 seconds prior to attaching the saline filled syringes.</p> <p>3. Employee F, a registered nurse (RN), was observed to change the CVC dressing and complete exit site care on patient number 21 at 11:25 AM after the initiation of the treatment.(observation # 1). The dialysis treatment had already been initiated by employee N, a PCT, at 11:20 AM.</p> <p>4. The above-stated observations were reviewed with the clinic manager on</p>		<p>Compliance to CVC exitsite care and dressing change procedure will be monitored by direct observationand treatment sheet review</p> <ul style="list-style-type: none"> ·Rotatingdisciplines will be responsible to complete Infection Control Audits, eachpatient shift, inclusive of CVC dressing change procedure, continuing until100% staff compliance is achieved and sustained as determined by the GB ·Rotatingdisciplines to complete a CVC Monitoring Tool, observing initiation anddiscontinuation procedure for 50% patients with a CVC each patient shiftcontinuing until 100% staff and patient compliance is achieved and sustained asdetermined by the GB ·CM or designee will conduct Treatment sheet audits on every patient with a CVC daily tomonitor for compliance with completion of the CVC exit site assessment, careand documentation before treatment initiation CM or designee isresponsible to provide a summary of the Infection Control Audit, the CVCMonitoring Tool findings and the treatment sheet audit findings to the GBCommittee weekly and to the QAI Committee monthly As based upon staff compliance,the GB will determine when to decrease frequency of the IC and treatment sheet audits. QAI Committee will analyzethe findings and assess for trends. 				

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	<p>4-22-1 at 12:10 PM. The manager indicated the employees had not provided CVC care in accordance with facility policy.</p> <p>5. Clinical record number evidenced a CVC was used to provide the patient's dialysis treatment. The record failed to evidence the CVC dressing change had been completed prior to the initiation of the dialysis treatment.</p> <p>A. A hemodialysis treatment flow sheet dated 3-22-16 evidenced the treatment had been initiated at 6:42 AM and the catheter care had been completed at 8:01 AM.</p> <p>B. A hemodialysis treatment flow sheet dated 3-24-16 evidenced the treatment had been initiated at 5:33 AM and the catheter care had been completed at 12:50 PM.</p> <p>C. A hemodialysis treatment flow sheet dated 3-2-16 evidenced the treatment had been initiated at 6:38 AM and the catheter care had been completed at 8:12 AM.</p> <p>D. A hemodialysis treatment flow sheet dated 3-29-16 evidenced the treatment had been initiated at 6:45 AM and the catheter care had been completed</p>		<p>If trends are identified, the QAI Committee will assist with determination of root cause and will direct changes to this action plan as warranted</p>	

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	<p>at 6:59 AM.</p> <p>E. A hemodialysis treatment flow sheet dated 3-31-16 evidenced the treatment had been initiated at 6:54 AM and the catheter care had been completed at 7:08 AM.</p> <p>F. A hemodialysis treatment flow sheet dated 4-2-16 evidenced the treatment had been initiated at 6:44 AM and the catheter care had been completed at 6:56 AM.</p> <p>G. A hemodialysis treatment flow sheet dated 4-5-16 evidenced the treatment had been initiated at 6:35 AM and the catheter care had been completed at 6:46 AM.</p> <p>H. A hemodialysis treatment flow sheet dated 4-7-16 evidenced the treatment had been initiated at 7:11 AM and the catheter care had been completed at 7:22 AM.</p> <p>I. A hemodialysis treatment flow sheet dated 4-9-16 evidenced the treatment had been initiated at 6:54 AM and the catheter care had been completed at 8:33 AM.</p> <p>J. A hemodialysis treatment flow sheet dated 4-12-16 evidenced the</p>			

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	<p>treatment had been initiated at 6:47 AM and the catheter care had been completed at 7:01 AM.</p> <p>6. The facility's 1-6-14 Termination of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer" procedure number FMS-CS-IC-I-105-028 C states, "Ensure that a clean under pad is below the catheter limbs to protect the work area and the clothing. Put mask on patient . . . Follow the steps below to disinfect the catheter and to disconnect the patient from the extracorporeal system: . . . Using a new sterile alcohol pad, scrub threads of the luer lock (hub) vigorously using back and forth friction for 15 seconds - let dry and discard pad . . . Follow the steps below to flush and prepare the catheter for patient discharge . . . Apply a sterile cap on the end of the lumen maintaining aseptic technique."</p> <p>7. The facility's 1-6-14 "Initiation of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer" procedure number FMS-CS-IC-I-105-002C states, "Follow the steps below to disinfect the catheter connections: . . . Using a new sterile alcohol pad, scrub threads of luer lock (hub) vigorously, using back and forth friction for 15 seconds - let dry and</p>			

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V 0400 Bldg. 00	<p>discard pad."</p> <p>8. The facility's 1-6-14 "Changing the Catheter Dressing" policy number FMS-CS-IC-I-105-032A states, "Complete catheter exit site care and dressing replacement before initiation of treatment."</p> <p>494.60 CFC-PHYSICAL ENVIRONMENT</p> <p>Based on record review, observation, and interview, it was determined the facility failed to maintain compliance with this condition by failing to ensure the treatment floor, the water room, and dialysate mixing area had been maintained in a clean and sanitary manner creating the potential to affect all of the facility's 62 current incenter patients (See V 401); by failing to ensure the treatment floor, the water room, and dialysate mixing area had been maintained creating the potential to affect all of the facility's 62 current incenter patients (See V 402); by failing to ensure all emergency equipment and supplies had been checked in 1 of 22 days reviewed creating the potential to affect all of the facility's 62 current incenter patients (See V 403); by failing to ensure patients were checked at least every 30</p>	V 0400	<p>To ensure that the facility's physical environment is clean and sanitary and appropriately maintained at all times, the following plans of correction have been approved by the Governing Body for implementation:</p> <ul style="list-style-type: none"> · DPC staff reeducation and reinforcement on Housekeeping Policy FMS-CS-IC-11-155-116A (Refer to V 401 and 402) · ATOM and Bio Medical Technician reeducation on the appropriate use and documentation requirements of the facility's QAI Physical Environment Audit Checklist (Refer to V 402) · Thorough sweeping and cleaning of the treatment floor to remove the debris 	05/21/2016

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	<p>minutes in accordance with facility policy in 4 of 5 incenter patient records reviewed creating the potential to affect all of the facility's 62 current incenter patients (See V 407); and by failing to ensure a plan was in place to manage natural disasters and power failures creating the potential to affect all of the facility's 69 current patients (See V 408).</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to maintain a safe and clean environment and ensure the safety of all patients. The facility was found to be out of compliance with this condition, 42 CFR 494.60 Physical Environment.</p>		<p>Thoroughcleaning and disinfection the dialysis chair at station # 16, to remove theblood from the chair arm and side table Thoroughsweeping and cleaning of the water room, dialysate mixing area and storage area(Refer to V 401 and 402)</p> <ul style="list-style-type: none"> ·Completion ofnecessary Physical Environment maintenance to specifically address thecitations with further development of immediate plans for facility renovationsto ensure full resolution of the identified Physical Plant issues (Refer to V 401 and 402) <p>To monitor and to preventreoccurrence,</p> <ul style="list-style-type: none"> ·On or before May17, 2016 the Clinical Manager will develop and implement a daily, weeklyand monthly staff cleaning assignmentschedule to include the treatment area, the water room, the storage area andthe dialysate mixing area ·Effective May 17,2016 the Clinical Manager and/or 	

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			<p>Director of Operations will be responsible to conduct a walkthrough assessment of the dialysis facility, inclusive of the treatment area, the water room and the dialysate mixing area until 100 % compliance is achieved and sustained as determined by the Governing Body Committee</p> <p>- <u>Oversight:</u> CM or Director of Operations is responsible to provide a summary of the facility walkthrough assessment findings and any identified issues with staff compliance to the GB committee weekly and to the QAI Committee monthly</p> <p>The ATOM is responsible to present a weekly update to the Governing Body Committee on the progress of the physical plant renovations and corrective actions as stated in this action plan until full resolution of all issues is achieved</p>	

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			<p>The ATOM will present the findings of the QAI Physical Environment Audit Tool to the QAI Committeemonthly for review, discussion with development and implementation of corrective actions to ensure complete and timely resolution of identified issues</p> <p>The Medical Director will be responsible to sign the QAI Physical Environment Audit Tool as verification of the QAI Committee's discussion with timely and appropriate development and implementation of corrective actions to address the findings</p> <p>The QAI Committee will analyze the findings and assess for trends. If trends are identified, the QAI Committee will assist with determination of root cause and direct changes to this action plan as warranted</p> <p>The QAI Committee is responsible to review this</p>	

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V 0401 Bldg. 00	<p>494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT</p> <p>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.</p> <p>Based on observation, interview, and record review, the facility failed to ensure the treatment floor, the water room, and dialysate mixing area had been maintained in a clean and sanitary manner creating the potential to affect all of the facility's 62 current incenter patients.</p> <p>The findings include:</p> <p>1. On 4-15-16 at 10:15 AM, the following observations were made:</p> <p>A. A used test strip was observed on the floor in front of the dialysis machine</p>	V 0401	<p>Plan of Correction x 12 months to ensure sustained compliance</p> <p>The Governing Body is responsible to provide direct oversight to this action plan The Governing Body may recommend changes to facility processes necessary to maintain compliance</p> <p>On or before May 12, 2016 all Direct Patient Care staff will receive reeducation and reinforcement from Education Coordinator on Housekeeping Policy FMS-CS-IC-11-155-116A with emphasis on the responsibility of each staff member to maintain a clean, sanitary and comfortable environment for patients, staff and visitors</p> <p>A copy of the reeducation will be maintained available for review at the facility</p> <p>In addition, as directed by the Director of Operations and GB</p>	05/21/2016

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	<p>at station number 16.</p> <p>B. A used test strip and a piece of white paper approximately 1 inch by 4 inches was observed on the floor beside the dialysis machine at station number 15. A large gray stain was noted on the floor between the 2 machines at stations 15 and 16.</p> <p>C. A rust-colored stain was observed on the front of the dialysis machine at the port where the dialysate hoses are connected to the machine and running down the front of the machines at stations 14, 15, and 16.</p> <p>D. A stack of 2 x 2 gauze pads approximately 1/2 inch high was observed on the floor under the chair at station number 14. An empty roll of tape was observed on the floor.</p> <p>E. A strip of white paper approximately 1/2 inch by 2 inches was observed on the floor in the isolation room.</p> <p>F. A dark gray stain approximately 2 tiles by 3 tiles in size was observed on the floor between the dialysis machine and chair at stations numbered 11 and 12.</p> <p>G. A dark gray stain was observed on</p>		<p>Committee:</p> <ul style="list-style-type: none"> ·On April 22, 2016the DPC staff and Janitorial staff thoroughly swept and cleaned the treatment floor, thus removing: <ul style="list-style-type: none"> ·The debris including test strips, pieces of whitepaper, 2x2 gauze pads, unopened alcohol prep pads, opened betadinepackage, needle caps, blue glove, (3)blue chux, blue tourniquet, syringe package, candy bar wrapper and clamp fromthe floor ·On April 22, 2016the DPC staff thoroughly cleaned and disinfected the dialysis chair at station# 16, removing the blood from the chair arm and side table ·On April 19, 2016facility staff thoroughly swept and cleaned the water room, dialysate mixing areaand storage area thus removing: <ul style="list-style-type: none"> ·The white powderysubstance under and around the bicarbonate tank ·The used teststrips 	

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	<p>the floor approximately 3 tiles long and 1/2 tile wide between stations 10 and 11 next to the chase cabinet along the wall.</p> <p>H. At station 10 observation noted a dark gray stain on the floor approximately 2 tiles by 6 tiles in size.</p> <p>I. Observation noted the sink at the medication preparation area with water and soap all over the countertop at the sink.</p> <p>J. A dark gray stain was noted on the floor approximately 2 tiles by 3 tiles between the tiles at station number 8. A piece of white paper approximately 1/2 inch by 1 inch was observed on the floor.</p> <p>K. At stations 6 and 7 a dark gray stain approximately 3 tiles by 9 tiles in size was observed.</p> <p>L. At station number 6 observation noted an opened Betadine package on the floor in front of the chair. A rust colored stain on the front of the machine from the port where the dialysate hoses are connected down the front of the machine was observed.</p> <p>M. Observation noted 3 blue Chux pads were on the floor in front of the chase cabinet between stations 5 and 6.</p>		<p>directly in front of the bicarbonate tank and in the doorway from the hall to the preparation area</p> <ul style="list-style-type: none"> ·The white crystalline substance on the top of the first acid storage tank ·The dirty, white crystalline substance on the floor all around the 2 acid storage tanks ·The dry white substance on the black supply storage shelving unit next to the acid tanks ·The dirty, brown crystalline substance and the stalactite formation under the acid storage tanks ·The multiple white crystalline pencil shaped substances from the floor around the stalactite formation ·The white crystalline substance on top of the acid storage tank ·The large amount of water and soap on and around the sinks and countertops in the treatment area <p>In addition as directed</p>		

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	<p>N. The machines at stations numbered 3, 4, and 5 evidenced rust colored stains on the front of the machine from the dialysate hoses ports down the front of the machines.</p> <p>O. Observation noted gray stains between the tiles approximately 3 tiles by 4 tiles at stations numbered 3 and 4. A gray smattered stain approximately 3 by 3 tiles was observed at station number 3.</p> <p>P. A piece of white paper towel approximately 1 inch by 5 inches was observed on the floor at station 2.</p> <p>Q. A 3 by 6 tile gray smattered stain was observed on the floor at station number 1.</p> <p>R. Observation noted 3 portable oxygen tank holder on wheels near the scale. Observation noted rusted areas around the cylinder holders, on the wheels, and on the handle of the holder.</p> <p>S. At 10:40 AM, observation noted rust colored stains on the dialysis machines at stations numbered 17 and 18. Observation also noted dark gray stains approximately 3 by 5 tiles in size.</p> <p>T. Observation noted on another</p>		<p>bythe Medical Director and GB,</p> <ul style="list-style-type: none"> ·On or before May20, 2016 the ATOM and/or Bio-Medical technician removed the rust on front ofmachine #s 3, 4, 5, 6, 7, 14, 15, 16, 17 and 18 ·On or before May20, 2016 the ATOM removed, discarded and replaced the cart on wheels with 2shelves with visible rust on the bottom shelf and white substance on the postbetween the shelves ·On or before May20, 2016 the ATOM will remove and replace the (3) portable Oxygen tank holders withvisible rust ·On or before May11, 2016 the Director of Operations and the ATOM met with Ideal ConstructionCo. to obtain estimate for removal and replacement of the damaged, worncountertop at the sink. Estimatedcompletion date is June 1, 2016. ·On or before May20, 2016 the ATOM will 	

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	<p>clean sink a large amount of water on the counter tops surrounding the sink. A rough coating was worn away from large areas of the countertop on either side of the sink.</p> <p>U. Observation noted a cart on wheels with 2 shelves used to store dialysate jugs. A rust colored stain was observed to cover the entire bottom shelf. The posts between the shelves were covered in a white substance in a drip pattern.</p> <p>2. On 4-15-16 at 11:30 AM, the following observations were made in the dialysate preparation area:</p> <p>A. The floor around and under the bicarbonate tank was covered in a white powdery substance. Observation noted used test strips on the floor directly in front of the bicarbonate tank and on the floor in the doorway from the hall to the preparation area.</p> <p>B. Observation noted 2 large acid storage tanks in the area. A white crystalline substance was observed on the top of the first tank.</p> <p>C. Observation noted a white rectangular plastic container on the floor in front of the first tank with a large</p>		<p>remove, discard and replace the IV medication storage boxat the med prep area</p> <p>·On or before May11, 2016 the Director of Operations and the ATOM met with Ideal ConstructionCo. to obtain estimate to replace flooring in the treatment area and hallwaythus removing the dark gray stained, chipped and missing floor tiles. Estimated completion date is June 1, 2016</p> <p>·On or before May20, 2016 the ATOM removed and replaced the white, rectangular, plastic box onthe floor in front of the first acid tank</p> <p>·On or before May11, 2016 the Director of Operations and the ATOM met with Ideal ConstructionCo. to order a replacement door forthe doorway to the stockroom. Estimated date of installation is June 1, 2016</p> <p>The Clinical Manager isresponsible to ensure that the facility is maintained</p>	

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	<p>amount of a white crystalline substance covering the bottom of the container.</p> <p>D. A dirty, white crystalline substance was observed on the floor all around the 2 tanks. The tanks were sitting up on round, cone shaped black holders. The floor beneath the holders was visible. A large amount of a brown, crystalline substance was observed on the floor under the tanks with a stalactite type of formation hanging from the bottom of the tank reaching to the floor approximately 3 to 4 inches. Observation noted multiple pieces of a white crystalline substance in the shape of pencils on the floor near the formation.</p> <p>E. A black supply storage shelving unit was observed next to the acid tanks. The shelving was covered in a dry white substance. Observation noted 31 boxes of syringes, boxes of gloves, and boxes of personal care wash cloths stored on the shelving unit.</p> <p>3. On 4-15-16 at 1:20 PM, observation noted a moderate amount of blood on the arm of the dialysis chair and on the chair side table at station number 16. A pair of used blue gloves was also observed on the chair side table. At 1:40 PM, observation noted the blood was still on the chair and table.</p>		<p>clean, sanitary and comfortable at all times To monitor and to prevent recurrence, ·On or before May 17, 2016 the Clinical Manager developed and implemented a daily, weekly and monthly staff cleaning assignments schedule to include the treatment area, the water room, the storage area and the dialysate mixing area ·The Area Technical Operations Manager is responsible to complete the FMC QAI Physical Environment Audit Tool monthly ·Effective May 17, 2016 the Clinical Manager and/or Director of Operations will be responsible to conduct a walkthrough of the dialysis facility, inclusive of the treatment area, the water room and the dialysate mixing area daily x 4 weeks, weekly x 4 weeks, then monthly x 4 months or until 100 % compliance is achieved and sustained as determined by the</p>		

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	<p>At 1:45 PM, employee D, a registered nurse, was observed to clean the dialysis chair with the blood. The employee cleaned the blood from the chair and, without changing her gloves or cleansing her hands, cleaned the rest of the chair with a clean cloth.</p> <p>The facility's 1-4-12 "Work Surface Cleaning and Disinfection with Visible Blood [less than] 10 mls [milliliters] and OPIM using Bleach Solutions" procedure number FMS-CS-IC-II-155-110C2 states, "Use a cloth wetted with 1:100 bleach solution to clean the surface. Clean up all visible blood. Discard the used cloth and gloves in appropriate waste container. Perform hand hygiene and don new gloves. After cleaning up all visible blood, use a new cloth wetted with 1:100 bleach solution for a second cleaning of the surface. Make the surface glistening wet and let air dry unless otherwise specified by the manufacturer. Discard the cloth and gloves in the appropriate waste container. Perform hand hygiene."</p> <p>4. On 4-15-16 at 1:25 PM, observation noted the trash can near the medication preparation area was full and overflowing. A stack of 2 x 2 pieces of gauze and a blue glove was observed on</p>		<p>Governing Body Committee</p> <p>- CM or Director of Operations is responsible to provide a summary of the facility walkthrough assessment findings and any identified issues of staff compliance to the GB committee weekly and to the QAI Committee monthly</p> <p>The ATOM is responsible to present a weekly update to the Governing Body Committee on the progress of the physical plant renovations and corrective actions as stated in this action plan until full resolution of all issues is achieved</p> <p>The ATOM will present the findings of the QAI Physical Environment Audit Tool to the QAI Committee monthly for review, discussion with development and implementation of corrective actions to ensure complete and timely resolution of identified issues</p> <p>The QAI Committee</p>	

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	<p>the floor near the trash can.</p> <p>A. At station number 2 a test strip and piece of paper towel approximately 1 inch by 5 inches was observed on the floor. A syringe package was also observed on the floor.</p> <p>B. At station number 4 observation noted a candy bar wrapper, a strip of white paper approximately 1/2 inch by 4 inches, and a piece of a blue glove.</p> <p>C. At station number 5 observation noted 2 strips of white paper approximately 1/2 inch by 3 inches, a 2 x 2 piece of gauze, and a needle cap on the floor.</p> <p>D. At station number 7 observation noted a 2 x 2 piece of gauze and a syringe package on the floor. Observation also noted the floor tiles in front of the chase cabinet were cracked and torn.</p> <p>E. At 1:45 PM, observation noted a blue rubber tourniquet on the floor at station number 8 on the right side of the dialysis chair.</p> <p>5. On 4-18-16 at 8:20 AM, the following observations were made:</p> <p>A. A blue glove was observed on the</p>		<p>will analyze the findings and assess for trends. If trends are identified, the QAI Committee will assist with determination of root cause and direct changes to this action plan as warranted</p> <p>The Governing Body is responsible to provide direct oversight to this action plan</p> <p>The Governing Body may recommend changes to facility processes necessary to maintain compliance</p>	

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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
	<p>floor near the trash can at the nurse's station.</p> <p>B. At station number 11 a piece of white paper 1/2 inch by 1 inch was observed on the floor.</p> <p>C. A piece of white paper 1/2 inch by 3 inches was observed on the floor at station number 9.</p> <p>D. A piece of white paper 1/2 inch by 1 inch was observed on the floor at station number 16.</p> <p>E. At station number 16, observation noted 1/2 of a piece of the floor tile was missing next to the chase cabinet. Bare concrete was visible.</p> <p>6. On 4-18-16 at 11:30 AM, observation noted a white box approximately 12 inches by 18 inches on the counter at the medication preparation area. The box had a fold down door. Multiple rusted areas and tape residue were observed on the outside and the inside of the door and the box. The box was lined with white Styrofoam that was stained a rust color. Multiple medications to be administered to patients intravenously were stored in the box.</p> <p>7. On 4-20-16 at 8:40 AM, the following</p>			

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	<p>observations were made:</p> <p>A. Two unopened alcohol packages were on the floor beside the chair at station number 18.</p> <p>B. A needle cap was observed on the floor in front of the dialysis chair at station number 17.</p> <p>C. A 1/2 inch by 4 inch piece of white paper was observed on the floor in front of the dialysis machine.</p> <p>D. At station number 11, observation noted 2 stacks of 2 x 2 gauze pads approximately 1/2 inch high on the floor.</p> <p>E. At station number 7 observation noted an alcohol pad on the floor in front of the dialysis chair.</p> <p>F. At station number 5 observation noted a white clamp on the floor by the dialysis machine.</p> <p>8. On 4-22-16 at 8:35 AM, observation noted the floor tile was chipped in the doorway to the stockroom. The bottom of the door frame on both sides was worn away and rusted.</p> <p>9. The Director of Operations indicated, on 4-22-16 at 2:25 PM, the facility's</p>			

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V 0402 Bldg. 00	<p>plans to erect a new building had been placed on hold. The Director indicated employee U, the Area Technical Operations Manager was responsible for the physical plant and environment of the building. The Director of Operations indicated there was a massive renovation of the building planned and that an initial site survey was planned for July 2016.</p> <p>10. The facility's 3-20-13 "Housekeeping" policy number FMS-CS-IC-II-155-116A states, "All areas must be kept clean and organized, including but not limited to the treatment area, water/supply room and offices . . . Facility staff are accountability for cleaning rooms/areas not assigned to the contracted cleaning staff. Such cleaning should be done regularly using a schedule developed by the facility."</p> <p>494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public. Based on observation, interview, and record review, the facility failed to ensure the treatment floor, the water room, and dialysate mixing area had been</p>	V 0402	On or before May 12,2016 all DPC staff will receive reeducation and reinforcement on HousekeepingPolicy FMS-CS-IC-11-155-116A with emphasis on the responsibility of	05/21/2016

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	<p>maintained creating the potential to affect all of the facility's 62 current incenter patients.</p> <p>The findings include:</p> <p>1. On 4-15-16 at 10:15 AM, the following observations were made:</p> <p>A. A used test strip was observed on the floor in front of the dialysis machine at station number 16.</p> <p>B. A used test strip and a piece of white paper approximately 1 inch by 4 inches was observed on the floor beside the dialysis machine at station number 15. A large gray stain was noted on the floor between the 2 machines at stations 15 and 16.</p> <p>C. A rust-colored stain was observed on the front of the dialysis machine at the port where the dialysate hoses are connected to the machine and running down the front of the machines at stations 14, 15, and 16.</p> <p>D. A stack of 2 x 2 gauze pads approximately 1/2 inch high was observed on the floor under the chair at station number 14. An empty roll of tape was observed on the floor.</p>		<p>each staffmember to maintain a clean, sanitary and comfortable environment for patients, staff and visitors On or before May 17, 2016 the Regional Quality Manager will provide reeducation to the facility's Area Technical Operations Manager and the Bio Medical Technician on the appropriate use and documentation requirements of the facility's QAI Physical Environment Audit Checklist A copy of the reeducation will be maintained available for review at the facility In addition, as directed by the Medical Director and the Governing Body,</p> <ul style="list-style-type: none"> · On April 22, 2016 the DPC staff and Janitorial staff thoroughly swept and cleaned the treatment floor, thus removing: <ul style="list-style-type: none"> · The debris including test strips, pieces of white paper, 2x2 gauze pads, unopened alcohol prep pads, opened betadine package, needle caps, blue glove, (3) blue chux, blue tourniquet, syringe package, candy bar wrapper and clamp from the floor · On April 22, 2016 the DPC staff thoroughly cleaned and disinfected the dialysis chair at station # 16, removing the blood from the chair arm and side table · On April 19, 2016 the facility staff thoroughly cleaned and swept the water room and dialysate mixing area, thus removing: <ul style="list-style-type: none"> · The white powdery substance 				

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	<p>E. A strip of white paper approximately 1/2 inch by 2 inches was observed on the floor in the isolation room.</p> <p>F. A dark gray stain approximately 2 tiles by 3 tiles in size was observed on the floor between the dialysis machine and chair at stations numbered 11 and 12.</p> <p>G. A dark gray stain was observed on the floor approximately 3 tiles long and 1/2 tile wide between stations 10 and 11 next to the chase cabinet along the wall.</p> <p>H. At station 10 observation noted a dark gray stain on the floor approximately 2 tiles by 6 tiles in size.</p> <p>I. Observation noted the sink at the medication preparation area with water and soap all over the countertop at the sink.</p> <p>J. A dark gray stain was noted on the floor approximately 2 tiles by 3 tiles between the tiles at station number 8. A piece of white paper approximately 1/2 inch by 1 inch was observed on the floor.</p> <p>K. At stations 6 and 7 a dark gray stain approximately 3 tiles by 9 tiles in size was observed.</p>		<p>under and around the bicarbonate tank</p> <ul style="list-style-type: none"> ·The used teststrips directly in front of the bicarbonate tank and in the doorway from thehall to the preparation area ·The whitecrystalline substance on the top of the first acid storage tank ·The dirty, whitecrystalline substance on the floor all around the 2 acid storage tanks ·The dry whitesubstance on the black supply storage shelving unit next to the acid tanks ·The dirty, browncrystalline substance and the stalactite formation under the acid storage tanks ·The multiplewhite crystalline pencil shaped substances from the floor around the stalactiteformation ·The whitecrystalline substance on top of the acid storage tank ·The large amount ofwater and soap on and around the sinks and countertops In addition as directed bythe Medical Director and GB, ·On or before May20, 2016 the ATOM and/or Bio-Medical technician removed the rust on front ofmachine #s 3, 4, 5, 6, 7, 14, 15, 16, 17 and 18 ·On or before May20, 2016 the ATOM removed, discarded and replaced the cart on wheels with 2shelves with visible rust on the bottom shelf and white substance on the postbetween the shelves ·On or before May20, 2016 the 	

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	<p>L. At station number 6 observation noted an opened Betadine package on the floor in front of the chair. A rust colored stain on the front of the machine from the port where the dialysate hoses are connected down the front of the machine was observed.</p> <p>M. Observation noted 3 blue Chux pads were on the floor in front of the chase cabinet between stations 5 and 6.</p> <p>N. The machines at stations numbered 3, 4, and 5 evidenced rust colored stains on the front of the machine from the dialysate hoses ports down the front of the machines.</p> <p>O. Observation noted gray stains between the tiles approximately 3 tiles by 4 tiles at stations numbered 3 and 4. A gray smattered stain approximately 3 by 3 tiles was observed at station number 3.</p> <p>P. A piece of white paper towel approximately 1 inch by 5 inches was observed on the floor at station 2.</p> <p>Q. A 3 by 6 tile gray smattered stain was observed on the floor at station number 1.</p> <p>R. Observation noted 3 portable oxygen tank holder on wheels near the</p>		<p>ATOM will remove and replace the (3) portable Oxygen tank holders with visible rust</p> <p>·On or before May11, 2016 the Director of Operations and the ATOM met with Ideal ConstructionCo. to obtain estimate for removal and replacement of the damaged, worn countertop at the sink. Estimated completion date is June 1, 2016.</p> <p>·On or before May20, 2016 the ATOM will remove, discard and replace the IV medication storage box at the med prep area</p> <p>·On or before May11, 2016 the Director of Operations and the ATOM met with Ideal ConstructionCo. to obtain estimate to replace flooring in the treatment area and hallway thus removing the dark gray stained, chipped and missing floor tiles. Estimated completion date is June 1, 2016</p> <p>·On or before May20, 2016 the ATOM removed and replaced the white, rectangular, plastic box on the floor in front of the first acid tank</p> <p>·On or before May11, 2016 the Director of Operations and the ATOM met with Ideal ConstructionCo. to order a replacement door for the doorway to the stockroom. Estimated date of installation is June1, 2016</p> <p>The Clinical Manager is responsible to ensure that the facility is maintained clean, sanitary and comfortable at all</p>	

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	<p>scale. Observation noted rusted areas around the cylinder holders, on the wheels, and on the handle of the holder.</p> <p>S. At 10:40 AM, observation noted rust colored stains on the dialysis machines at stations numbered 17 and 18. Observation also noted dark gray stains approximately 3 by 5 tiles in size.</p> <p>T. Observation noted on another clean sink a large amount of water on the counter tops surrounding the sink. A rough coating was worn away from large areas of the countertop on either side of the sink.</p> <p>U. Observation noted a cart on wheels with 2 shelves used to store dialysate jugs. A rust colored stain was observed to cover the entire bottom shelf. The posts between the shelves were covered in a white substance in a drip pattern.</p> <p>2. On 4-15-16 at 11:30 AM, the following observations were made in the dialysate preparation area:</p> <p>A. The floor around and under the bicarbonate tank was covered in a white powdery substance. Observation noted used test strips on the floor directly in front of the bicarbonate tank and on the</p>		<p>times To monitor and to prevent recurrence,</p> <p>·On or before May 17, 2016 the Clinical Manager developed and implemented a daily, weekly and monthly staff cleaning assignment schedule to include the treatment area, the water room, and the dialysate mixing area</p> <p>·The Area Technical Operations Manager is responsible to complete the FMC QAI Physical Environment Audit Tool monthly</p> <p>·Effective May 17, 2016 the Clinical Manager and/or Director of Operations will be responsible to conduct a walkthrough of the dialysis facility, inclusive of the treatment area, the water room and the dialysate mixing area daily x 4 weeks, weekly x 4 weeks, then monthly x 4 months or until 100 % compliance is achieved and sustained as determined by the Governing Body Committee</p> <p>·The CM or Director of Operations is responsible to provide a summary of the facility walkthrough assessment findings and any identified issues of staff compliance to the GB committee weekly and to the QAI Committee monthly</p> <p>The ATOM is responsible to present a weekly update to the GB Committee on the progress of the physical plant renovations and corrective actions as stated in this action plan until full resolution of all issues is achieved</p> <p>The ATOM will present the findings of the QAI</p>	

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	<p>floor in the doorway from the hall to the preparation area.</p> <p>B. Observation noted 2 large acid storage tanks in the area. A white crystalline substance was observed on the top of the first tank.</p> <p>C. Observation noted a white rectangular plastic container on the floor in front of the first tank with a large amount of a white crystalline substance covering the bottom of the container.</p> <p>D. A dirty, white crystalline substance was observed on the floor all around the 2 tanks. The tanks were sitting up on round, cone shaped black holders. The floor beneath the holders was visible. A large amount of a brown, crystalline substance was observed on the floor under the tanks with a stalactite type of formation hanging from the bottom of the tank reaching to the floor approximately 3 to 4 inches. Observation noted multiple pieces of a white crystalline substance in the shape of pencils on the floor near the formation.</p> <p>E. A black supply storage shelving unit was observed next to the acid tanks. The shelving was covered in a dry white substance. Observation noted 31 boxes of syringes, boxes of gloves, and boxes of</p>		<p>Physical Environment Audit Tool to the QAI Committeemonthly for review, discussion with development and implementation ofcorrective actions to ensure complete and timely resolution of identifiedissues The Medical Director willbe responsible to sign the QAI Physical Environment Audit Tool as verificationof the QAI Committee's discussion with timely and appropriate development andimplementation of corrective actions to address the findings The QAI Committee willanalyze the findings and assess for trends. If trends are identified, the QAI Committee will assist withdetermination of root cause and direct changes to this action plan as warranted</p>	

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	<p>personal care wash cloths stored on the shelving unit.</p> <p>3. On 4-15-16 at 1:20 PM, observation noted a moderate amount of blood on the arm of the dialysis chair and on the chair side table at station number 16. A pair of used blue gloves was also observed on the chair side table. At 1:40 PM, observation noted the blood was still on the chair and table.</p> <p>At 1:45 PM, employee D, a registered nurse, was observed to clean the dialysis chair with the blood. The employee cleaned the blood from the chair and, without changing her gloves or cleansing her hands, cleaned the rest of the chair with a clean cloth.</p> <p>The facility's 1-4-12 "Work Surface Cleaning and Disinfection with Visible Blood [less than] 10 mls [milliliters] and OPIM using Bleach Solutions" procedure number FMS-CS-IC-II-155-110C2 states, "Use a cloth wetted with 1:100 bleach solution to clean the surface. Clean up all visible blood. Discard the used cloth and gloves in appropriate waste container. Perform hand hygiene and don new gloves. After cleaning up all visible blood, use a new cloth wetted with 1:100 bleach solution for a second cleaning of the surface.</p>			

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	<p>Make the surface glistening wet and let air dry unless otherwise specified by the manufacturer. Discard the cloth and gloves in the appropriate waste container. Perform hand hygiene."</p> <p>4. On 4-15-16 at 1:25 PM, observation noted the trash can near the medication preparation area was full and overflowing. A stack of 2 x 2 pieces of gauze and a blue glove was observed on the floor near the trash can.</p> <p>A. At station number 2 a test strip and piece of paper towel approximately 1 inch by 5 inches was observed on the floor. A syringe package was also observed on the floor.</p> <p>B. At station number 4 observation noted a candy bar wrapper, a strip of white paper approximately 1/2 inch by 4 inches, and a piece of a blue glove.</p> <p>C. At station number 5 observation noted 2 strips of white paper approximately 1/2 inch by 3 inches, a 2 x 2 piece of gauze, and a needle cap on the floor.</p> <p>D. At station number 7 observation noted a 2 x 2 piece of gauze and a syringe package on the floor. Observation also noted the floor tiles in front of the chase</p>			

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	<p>cabinet were cracked and torn.</p> <p>E. At 1:45 PM, observation noted a blue rubber tourniquet on the floor at station number 8 on the right side of the dialysis chair.</p> <p>5. On 4-18-16 at 8:20 AM, the following observations were made:</p> <p>A. A blue glove was observed on the floor near the trash can at the nurse's station.</p> <p>B. At station number 11 a piece of white paper 1/2 inch by 1 inch was observed on the floor.</p> <p>C. A piece of white paper 1/2 inch by 3 inches was observed on the floor at station number 9.</p> <p>D. A piece of white paper 1/2 inch by 1 inch was observed on the floor at station number 16.</p> <p>E. At station number 16, observation noted 1/2 of a piece of the floor tile was missing next to the chase cabinet. Bare concrete was visible.</p> <p>6. On 4-18-16 at 11:30 AM, observation noted a white box approximately 12 inches by 18 inches on the counter at the</p>			

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	<p>medication preparation area. The box had a fold down door. Multiple rusted areas and tape residue were observed on the outside and the inside of the door and the box. The box was lined with white Styrofoam that was stained a rust color. Multiple medications to be administered to patients intravenously were stored in the box.</p> <p>7. On 4-20-16 at 8:40 AM, the following observations were made:</p> <p>A. Two unopened alcohol packages were on the floor beside the chair at station number 18.</p> <p>B. A needle cap was observed on the floor in front of the dialysis chair at station number 17.</p> <p>C. A 1/2 inch by 4 inch piece of white paper was observed on the floor in front of the dialysis machine.</p> <p>D. At station number 11, observation noted 2 stacks of 2 x 2 gauze pads approximately 1/2 inch high on the floor.</p> <p>E. At station number 7 observation noted an alcohol pad on the floor in front of the dialysis chair.</p> <p>F. At station number 5 observation</p>			

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	<p>noted a white clamp on the floor by the dialysis machine.</p> <p>8. On 4-22-16 at 8:35 AM, observation noted the floor tile was chipped in the doorway to the stockroom. The bottom of the door frame on both sides was worn away and rusted.</p> <p>9. The Director of Operations indicated, on 4-22-16 at 2:25 PM, the facility's plans to erect a new building had been placed on hold. The Director indicated employee U, the Area Technical Operations Manager was responsible for the physical plant and environment of the building. The Director of Operations indicated there was a massive renovation of the building planned and that an initial site survey was planned for July 2016.</p> <p>10. The facility's 3-20-13 "Housekeeping" policy number FMS-CS-IC-II-155-116A states, "All areas must be kept clean and organized, including but not limited to the treatment area, water/supply room and offices . . . Facility staff are accountability for cleaning rooms/areas not assigned to the contracted cleaning staff. Such cleaning should be done regularly using a schedule developed by the facility."</p> <p>11. The Medical Director stated, on</p>			

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V 0403 Bldg. 00	<p>4-22-16 at 11:30 AM, "The condition of the building is bad. We are high on the list to get it fixed, I think."</p> <p>494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. Based on record review and interview, the facility failed to ensure all emergency equipment and supplies had been checked in 1 (# 22) of 22 days reviewed creating the potential to affect all of the facility's 62 current incenter patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The facility's monthly AED Daily Inspection/Manual Testing Log" for April 2015 failed to evidence the emergency equipment had been checked on 4-22-16. The log was reviewed at 9:40 AM. The facility had been dialyzing patients since 6:00 AM. 2. The clinic manager was unable to 	V 0403	<p>On or before May 12, 2016the Education Coordinator will reeducate all DPC staff on Use ofthe Cardiac Science – Powerheart® Automated External Defibrillator (AED) FMS-CS-IC-II-130-046A and MonitoringDuring Patient Treatment Policy FMS-CS-IC-I-110-133A toensure daily AED checks and documentation requirements are to becompleted prior to initiation of patient treatments each day</p> <p>A copy of theeducation will be maintained available for review at the facility</p> <p>To preventreoccurrence, the CM or designee will be responsible to review the AED log toensure the</p>	05/21/2016

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	<p>requirement).</p> <p>Based on record review and interview, the facility failed to ensure patients were checked at least every 30 minutes in accordance with facility policy in 4 (#s 1, 2, 3, & 5) of 5 incenter patient records reviewed creating the potential to affect all of the facility's 62 current incenter patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> The facility's 8-20-14 "Patient Monitoring During Patient Treatment" policy number FMS-CS-IC-I-110-133A states, "Monitor the patient at the initiation of treatment and every 30 minutes, or more frequently as necessary." Clinical record number 1 failed to evidence the patient had been monitored at least every 30 minutes during each treatment. <ol style="list-style-type: none"> A hemodialysis treatment flow sheet dated 3-19-16 evidenced the patient had been checked at 8:30 AM and not again until 9:13 AM. A hemodialysis treatment flow sheet dated 3-22-16 evidenced the patient had been checked at 7:29 AM and not again until 8:34 AM. 	V 0407	<p>To ensure that patients are monitored every 30 minutes during treatment in accordance to FMC Policy, on or before May 12, 2016 the Education Coordinator will reeducate all DPC staff on Patient Monitoring During Treatment FMS-CS-IC-1-110-030A.</p> <p>The CM or designee reinforced to all direct patient care staff during this meeting the absolute requirement to ensure that vital signs and machine safety checks are documented on the half hour during all patient treatments</p> <p>A copy of the staff education will be maintained available for review at the facility</p> <p>To monitor for compliance to the process and to prevent reoccurrence, effective May 13, 2016 the CM or designee will review 10 percent of patient treatment sheets daily until 100% staff compliance is achieved and sustained as determined by the GB</p> <p>Results of the treatment sheet audit will be reported to the GB during the weekly GB meetings and to the QAI Committee monthly until such time that the GB determines the clinic and staff to be in full compliance with patient monitoring policies, procedures and guidelines.</p>	05/21/2016			

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	<p>C. A hemodialysis treatment flow sheet dated 3-26-16 evidenced the patient had been checked at 7:32 AM and not again until 8:17 AM. The flow sheet evidenced the patient had been checked at 9:04 AM and not again until 10:02 AM.</p> <p>3. Clinical record number 2 failed to evidence the patient had been monitored at least every 30 minutes during each treatment.</p> <p>A. A hemodialysis treatment flow sheet dated 3-26-16 evidenced the patient had been checked at 7:33 AM and not again until 8:16 AM.</p> <p>B. A hemodialysis treatment flow sheet dated 3-31-16 evidenced the patient had been checked at 7:08 AM and not again until 8:06 AM.</p> <p>4. Clinical record number 3 failed to evidence the patient had been monitored at least every 30 minutes during each treatment.</p> <p>A. A hemodialysis treatment flow sheet dated 3-26-16 evidenced the patient had been checked at 8:38 AM and not again until 9:31 AM.</p>		<p>The QAI Committee will analyze the treatment sheet audit findings and assess for trends. If trends are identified, the QAI Committee will assist with determination of Root Cause and direct changes to this action plan as warranted</p> <p>The GB may recommend changes in facility processes necessary to maintain compliance</p>	

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V 0408 Bldg. 00	<p>B. A hemodialysis treatment flow sheet dated 3-30-16 evidenced the patient had been checked at 9:05 AM and not again until 9:55 AM.</p> <p>C. A hemodialysis treatment flow sheet dated 4-4-16 evidenced the patient had been checked at 1:05 PM and not again until 2:07 PM.</p> <p>D. A hemodialysis treatment flow sheet dated 4-8-16 evidenced the patient had been checked at 11:00 AM and not again until 12:00 PM.</p> <p>5. Clinical record number 5 failed to evidence the patient had been monitored at least every 30 minutes during each treatment.</p> <p>A hemodialysis treatment flow sheet dated 4-8-16 evidenced the patient had been checked at 6:05 AM and not again until 7:13 AM.</p> <p>6. The clinic manager was unable to provide any additional documentation and/or information when asked on 4-22-16 at 10:20 AM.</p> <p>494.60(d) PE-EMERGENCY PREPAREDNESS-PROCEDURES</p>			

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	<p>The dialysis facility must implement processes and procedures to manage medical and non medical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.</p> <p>Based on record review and interview, the facility failed to ensure a plan was in place to manage natural disasters and power failures creating the potential to affect all of the facility's 69 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The facility's "Facility Specific Disaster Safety Plan" failed to include the management of patients and staff in the event of an earthquake or power failure. 2. The clinic manager indicated, on 4-22-16 at 9:00 AM, the facility's disaster management plan did not include the management of patients and/or staff in the event of an earthquake or power failure. 	V 0408	<p>On May 12, 2016 the Education Coordinator educated all DPC staff on Guidelines for Emergency Preparedness, FMS-CS-IC-II-130-014A to follow in the event of an earthquake or power failure. Effective immediately and going forward the CM will conduct semi-annual disaster drills at the facility, rotating the education on specific disasters applicable to the geographical location of the facility to include earthquake and power failure.</p> <p>On or before May 13, 2016 all patients will receive education on earthquake and power failure guidelines. A signed acknowledgement will be obtained to verify their understanding of the information, and will be maintained in each patient's respective medical record</p> <p>On May 13, 2016 the CM or designee updated the Facility Specific Disaster Plan to include the management of patients and staff in the event of an earthquake and/or power failure. The CM is responsible to report to</p>	05/21/2016

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V 0540 Bldg. 00	494.90 CFC-PATIENT PLAN OF CARE Based on record review and interview, it was determined the facility failed to maintain compliance with this condition by failing to ensure plans of care had been updated to include the facility's new arteriovenous fistula (AVF) protocol in 3 (#s 2, 22, and 23) of 3 clinical records reviewed of patients with new fistulas (See V 541); by failing to ensure the necessary care and services had been provided to manage the patient's dry weight in 1 of 5 records reviewed for fluid volume management and failed to provide the necessary care and services to	V 0540	the GB during the weekly meetings that the facility specific disaster plan has been updated to include earthquake and power failure and that 100% staff and patients have received this education The CM is responsible to report completion of the facility specific disaster drills in QAI semiannually The QAI Committee will analyze the findings and assess for trends. If trends are identified, the QAI Committee will direct changes to this action plan as indicated The GB may recommend changes in facility processes as necessary to maintain compliance As a result of the citations received from the April 22, 2016 CMS Survey and as part of the Developed Plan of Correction, the following Plans of Correction have been approved by the Governing Body (GB) for implementation: · Interdisciplinary Team (IDT) reeducation on FMS-CS-IC-1-110-125A Comprehensive Interdisciplinary Assessment	05/21/2016

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	<p>manage the patient's intradialytic blood pressure in 1 of 5 records reviewed for blood pressure management (See V 543); by failing to patients' desired albumin level of greater than or equal to 4.0 grams per deciliter (g/dL) according the Centers for Medicare and Medicaid Services (CMS) Measures Assessment Tool (MAT) had been maintained in 1 of 2 records reviewed for nutritional status (See V 545); by failing to ensure the necessary care had been provided to maintain patients' phosphorous levels within the desired range in 2 of 2 records reviewed for mineral bone disease (See V 546); by failing to ensure staff had followed the facility's policy for the use of new arteriovenous fistulas (AVF) in order to sustain the vascular access in 3 of 3 clinical records reviewed of patients with new fistulas (See V 550: and by failing to ensure the interdisciplinary team (IDT) had collaborated to ascertain reasons for the inability of patients to achieve specified goals and adjusted the plans of care to address any identified reasons in 4 of 5 records reviewed (See V 559).</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to maintain and provide care in accordance with an individualized patient plan of care. The facility was found to be</p>		<p>and Plan of Care policy with emphasis on the IDTs responsibility to:</p> <ul style="list-style-type: none"> ·Timely update thePlan of Care to include the facility's new AVF Cannulation Protocol forpatients with a new AVF to appropriately manage the patients vascular accesses (Referto V 541) ·Provide thenecessary care and services to appropriately manage each patients individualFluid Volume and Blood Pressure needs (Refer to V 543) ·To maintain eachpatients Albumin level greater than or equal to 4.0g/dl to appropriately manage the patients Nutritional status (Referto V 545) ·To maintain eachpatients Phosphorus level 3.5-5.5 to appropriately manage the patient's Boneand Mineral Status (Refer to V 546) ·To ensure thatstaff follow the facility policy for use of the new AVF to sustain new vascularaccesses (Refer to V 550) ·To 	

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	out of compliance with this condition, 42 CFR 494.90 Patient Plan of Care.		<p>appropriatelycollaborate with Extended Care Facilities to ascertain reasons for patientsinability to achieve specified goals and adjust the Plan of Care to address theidentified needs (Refer to V 559)</p> <ul style="list-style-type: none"> ·To appropriatelyand timely collaborate with extended care facility personnel as applicable, toassist in investigation and determination of root causes for patients notmeeting expected quality outcome goals and to adjust the patients Plan of Careto address the identified reasons (Refer to V 559) ·Direct PatientCare (DPC) staff reeducation on: <ul style="list-style-type: none"> ·FMC Hypo and HypertensiveCare Maps FMS-CSIC-I-110-131A - Patient Evaluation and Assessment Pre Dialysis Treatment FMS-CS-IC-1-110-133A- 		

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			<p>Patient Monitoring During Treatment FMS-CS-1C-11-110-132A-- Patient Evaluation Post Treatment Notificationresponsibilities of the PCT/CCHT/LPN to the RN/Team Leader Notificationresponsibilities of the RN/Team Leader to the Nephrologist and/or Primary CarePhysician. (Referto V 543)</p> <ul style="list-style-type: none"> ·New AV-FistulaCannulation Algorithm FMS-CS-IC-1-115-05D1 FMC-OVDC3026 AVF Cannulation Protocol worksheet, specifically the appropriate use of the worksheet anddocumentation requirements (Refer to V 550) ·Designated andGoverning Body approved Expert Cannulator reeducation on the facility's accesspolicies, procedures and protocols related to vascular access management (Referto V 550) Documentation of 	

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			<p>theInterdisciplinary Team and staff reeducation will be maintained available forreview at the facility</p> <p>Immediate actions asdirected by the Medical Director and GB included:</p> <ul style="list-style-type: none"> ·The IDT met tocomplete a comprehensive reassessment and to update the Plans of Care onpatients identified in the Statement of Deficiencies (SOD) as Clinical Record#s 2, 22 and 23 to include thefacilities new arteriovenous fistula protocol (Refer to V 541) ·The IDT met toconduct a comprehensive reassessment on patients identified in the SOD asClinical Record #s 3 and 5 and to update the Plans of Care based on eachpatients Fluid Volume and reassessment findings (Refer to V 543) ·The IDT met toconduct a comprehensive reassessment on the patient identified in the SOD asClinical Record # 2 and to update the patient's Plan of Care based on 	

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			<p>thepatient's nutritional /Albumin reassessment findings (Refer to V 545)</p> <ul style="list-style-type: none"> ·The IDT met toconduct a comprehensive reassessment on the patients identified in the SOD asClinical Record #s 3 and 5, and to update the patient's Plan of Care based onthe patient's mineral metabolism/phosphorus reassessment findings (Refer to V546) ·The IDT met tocomplete comprehensive reassessments and to update each patient's plan of careto include implementation of changes specific to address the issues asidentified in the comprehensive reassessments on: <ul style="list-style-type: none"> ·Patient #1,related to Fluid Volume Management/ noncompliance with fluid restrictions ·Patient #2,related to Nutritional Status specifically, decreased Albumin levels ·Patient #s 3 and5 related to Mineral Metabolism, 	

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			<p>specifically, elevated Phosphorus levels (Refer to V 559)</p> <p>To monitor for compliance,</p> <ul style="list-style-type: none"> · 100% medical record audit completed for all patients with a new AV Fistula to ensure that the Plan of Care is updated to appropriately manage the patients vascular access in accordance to the facility's new AV Fistula Cannulation Protocol <p>Those patients identified in the audit as lacking current and specific Plan of Care documentation to include the new AV Fistula Cannulation Protocol will have the Plan of Care updated by the IDT within 15 days of the audit findings (Refer to V 541)</p> <ul style="list-style-type: none"> · Clinical Managers scheduled to meet with Medical Director to review the eCube Hemodialysis Treatment Detail Report and trend of each patient's fluid volume status inclusive of: 	

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			<ul style="list-style-type: none"> ·EDW (3 monthtrend) ·Weight gains pertreatment and 3 month average ·Fluid removal pertreatment and 3 month average ·Pre and post sittingand standing B/Ps per treatment and 3 month average ClinicalManager or designated Registered Nurse will be responsible to print and toreview the eCube Hemodialysis Treatment Detail Report weekly to assess pre/postand average weights and pre/post and average Blood Pressures. Identified patients not meeting theirestimated dry weight or blood pressure goals will be escalated to the physicianfor further orders and to the IDT for reassessment and Plan of Care update (Referto V 543) ·Clinic Manager inconjunction with the Registered Dietician will be responsible to review 100%patient Albumin and Phosphorus 3 month trend 	

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			<p>monthly, those patients notmeeting goal for Albumin and Phosphorus in 2 or more of the 3 months as statedin the Measures Assessment Tool will be immediately escalated to the physicianfor further orders and to the IDT Committee for reassessment and update to thePlan of Care (Referto V 545 and 546)</p> <ul style="list-style-type: none"> ·The RegisteredDietician is responsible to complete the QAI Albumin Tool monthly (Referto V 545) ·The GoverningBody designated and approved (1) Registered Nurse and (1) Patient CareTechnician as “Expert Cannulators” Everyeffort will be made to ensure that new AV Fistulas are cannulated by thedesignated and approved Expert Cannulators AVFCannualtion Protocol worksheets for patients with a newly placed AV Fistulawill be maintained binder at the Nursing Station until maturation of 	

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			<p>the newaccess is achieved as determined by the Nephrologist</p> <p>TheClinical Manager or designated Registered Nurse will be responsible to printand review the electronic health record treatment sheet and to review the AVFCannulation Protocol worksheet for each patient, following placement of a newAV Fistula for appropriate use of the protocol with appropriate and timelydocumentation, beginning their first treatment at the facility after AVFplacement and continuing each treatment day through week four as outlined inthe protocol (Referto V 550)</p> <p>·The ClinicalManager in conjunction with the IDT will be responsible to review eachpatient's quality outcomes as detailed in the FMC Quality Status Report monthlyto identify those patients not able to achieve expected quality goals. Thosepatients unable to achieve the expected</p>	

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			<p>outcomes will have a comprehensive reassessment and update to the Plan of Care conducted by the IDT within 15 days of the report findings. (Refer to V 559)</p> <p>To provide immediate and ongoing oversight to the process,</p> <p>The Clinical Manager is responsible to review each completed Plan of Care prior to filing in the medical record to ensure appropriate IDT identification and management of the patient's vascular access, fluid volume, blood pressure, Nutritional status, and Bone and Mineral status. (Refer to V541, 543, 545 and 546)</p> <p>The Clinical Manager is responsible to present a summary of the</p> <ul style="list-style-type: none"> · Medical record audit findings, · CM and Medical Directors initial review of all patients (pre and post and average weights and pre and post and average blood pressures) 	

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V 0541	494.90 POC-GOALS=COMMUNITY-BASED		<p>·CM or designatedRN weekly review of patient of all patients fluid volume and blood pressures</p> <p>·CM and RD review ofpatients not meeting expected goals for Albumin and Phosphorus (Initial andmonthly)</p> <p>·CM or designated RNelectronic health record treatment sheet and Cannulation Worksheet review forpatients with new AV Fistulas</p> <p>·Patients not meetingexpected quality outcome goals and IDT compliance with updating the Plans ofCare to the GB during theweekly scheduled meetings and to the QAI Committee monthly</p> <p>The QAI Committee will analyze the findings and assessfor trends. If trends are identified,the QAI Committee will direct changes to this action plan as indicated</p> <p>The QAI Committee isresponsible to review this Plan of Correction x 12 months consecutively toensure sustained compliance</p> <p>The Governing Body mayrecommend changes in facility processes as necessary to maintain compliance</p>	

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Bldg. 00	<p>STANDARDS</p> <p>The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.</p> <p>Based on record review and interview, the facility failed to ensure plans of care had been updated to include the facility's new arteriovenous fistula (AVF) protocol in 3 (#s 2, 22, and 23) of 3 clinical records reviewed of patients with new fistulas.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The clinic manager indicated, on 4-22-16 at 12:10 PM, patients with new AVFs are placed on the facility's undated "FMC-OVDC -3026 AVF Cannulation Protocol" in accordance with the facility's 3-20-13 "Assessment and Cannulation of a New AV-Fistula" procedure number FMS-CS-IC-I-115-015C. 2. Clinical record number 2 failed to evidence the interdisciplinary plan of care had been individualized with an update to 	V 0541	<p>To ensure that the Interdisciplinary Team appropriately updates each patient's Plan of Care to include individualized vascular access management (i.e., implementation of the facility's new AV fistula protocol):</p> <ul style="list-style-type: none"> · On May 12, 2016 the Education Coordinator met with and reeducated the IDT on FMS-CS-IC-1-110-125A Comprehensive Interdisciplinary Assessment and Plan of Care policy with specific emphasis on the IDTs responsibility to manage each patient's vascular access and to ensure updates to the patient's Plan 	05/21/2016

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	<p>include the facility's new AV-Fistula protocol. The record included an "FMC-OVDC-3026 Cannulation Protocol" worksheet that evidenced the protocol had been initiated on 1-12-16.</p> <p>3. Clinical record number 22 failed to evidence the interdisciplinary plan of care had been individualized with an update to include the facility's new AF-Fistula protocol. The record included an "FMC-OVDC-3026 Cannulation Protocol" worksheet that evidenced the protocol had been initiated on 2-23-16.</p> <p>4. Clinical record number 23 failed to evidence the interdisciplinary plan of care had been individualized with an update to include the facility's new AF-Fistula protocol. The record included an "FMC-OVDC-3026 Cannulation Protocol" worksheet that evidenced the protocol had been initiated on 3-17-16.</p> <p>5. The facility's 3-20-13 "Assessment and Cannulation of a New A-V Fistula procedure number FMS-CS-IC-I_115-015C states, "Prior to cannulation it's important to: Know and document in the medical record the type of (i.e., radiocephalic-Cimino-Brescia), brachiocephalic or brachiobasilic transpositions). Confirm the direction of blood flow for the specific access site -</p>		<p>of Care to include changes in applicable facility protocols,policies and procedures</p> <p>Documentation of the IDTreeducation will be maintained available for review at the facility</p> <p>·On May 17, 2016the IDT met to complete a comprehensive reassessment on patient #s 2, 22, and23 as identified in the Statement of deficiencies and to update each patientsPlan of Care to include implementation of the new AV Fistula protocol</p> <p>To monitor for complianceand to prevent reoccurrence:</p> <p>·On or before May13, 2016 the CM or designee will conduct a 100% medical record audit for allpatients with a new AV Fistula to ensure that the Plan of Care is updated toappropriately manage the patients vascular access in</p>		

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	check with surgeon to confirm direction of flow and obtain diagram showing direction of flow for patient charts. Determine if reverse flow (i.e., proximal radial artery) has been created, blood flow direction dictates placement of the arterial and venous needles. Discuss with the physician a heparin management plan during the initial cannulation period to minimize bleeding into the surrounding tissues should infiltration occur. Saline flushes may be necessary during treatments with decreased heparinization."		<p>accordance to the facility's new AV Fistula Cannulation Protocol</p> <ul style="list-style-type: none"> Those patients identified in the audit as lacking current and specific Plan of Care documentation to include the new AV Fistula Cannulation Protocol will have the Plan of Care updated by the IDT within 15 days of the audit findings The CM or designee is responsible to review each completed Plan of Care prior to filing in the medical record to ensure appropriate IDT management of the patient's vascular access <p>The CM or designee is responsible to present a summary of the medical record audit finding to the GB during the scheduled weekly meetings and to the QAI Committee monthly</p> <p>The QAI Committee will analyze the findings and assess for trends. If trends are identified, the QAI Committee will direct</p>	

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V 0543 Bldg. 00	<p>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 record review and interview, the facility failed to ensure the necessary care and services had been provided to manage the patient's dry weight in 1 (# 3) of 5 records reviewed for fluid volume management and failed to provide the necessary care and services to manage the patient's intradialytic blood pressure in 1 (# 5) of 5 records reviewed for blood pressure management.</p> <p>The findings include:</p> <p>1. Clinical record number 3 included physician orders dated 3-30-16 that identified the desired weight after the completion of the dialysis treatment (estimated dry weight, EDW) was 70 kilograms (kg).</p> <p>A. A hemodialysis treatment flow</p>	V 0543	<p>changes to this action plan as indicated</p> <p>The GB may direct changes in facility processes as necessary to maintain compliance</p> <p>To ensure that the IDT provides the necessary care and services to manage each patient's Fluid Volumestatus:</p> <ul style="list-style-type: none"> ·On May 12, 2016the Education Coordinator met with and reeducated the IDT onFMS-CS-IC-1-110-125A ComprehensiveInterdisciplinary Assessment and Plan of Care policy with specific emphasis onthe IDTs responsibility to assess, identify, care plan and appropriately manageeach patients individual fluid volume status ·On May 12, 2016the Education Coordinator 	05/21/2016

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	<p>sheet dated 4-11-16 evidenced the patient's pre-treatment weight was 74.8 kg. The flow sheet states, "in via w/c [wheel chair] usual shortness of breath, crackles throughout . . . full goal not set, request 4.0 kg goal." At 12:54 PM, employee D, a registered nurse (RN) documented "c/o [complained of] chest pain, medicated." The flow sheet evidenced the RN had administered 0.4 milligrams of Nitroglycerin sublingual to the patient. The flow sheet failed to evidence any further reference to the chest pain complaints. The flow sheet evidenced the patient's weight at the end of the treatment was 73.2 kg.</p> <p>B. The record failed to evidence the physician had been notified of the patient's inability to withstand removing the full amount of fluid necessary to meet the ordered EDW, the episode of chest pain, or the patient's inability to attain the ordered EDW at the end of the treatment.</p> <p>C. A "Clinical Notes Report" dated 4-13-16 states, "admitted to [name of hospital] @ 2 am on 4-12-16 for shortness of breath, to be worked up by cardiology."</p> <p>2. Clinical record number 5 failed to evidence low blood pressure readings and extreme fluctuations in blood pressure</p>		<p>reeducated all direct patient care staff on the FMCHypo and Hypertensive Care Maps</p> <p>Documentation of the IDT reeducation will be maintained available for review at the facility</p> <p>·On May 17, 2016 the IDT met to conduct a comprehensive reassessment on patients identified in the SOD as Clinical Records #s 3 and 5 and to update the Plans of Care based on each patient's Fluid Volume and reassessment findings</p> <p>In addition, On May 12, 2016 the Education Coordinator reeducated all IDPC on</p> <p>·FMS-CSIC-I-110-131A - Patient Evaluation and Assessment Pre Dialysis Treatment inclusive of, but not limited to:</p> <p>·B/P sitting and standing ·Weight (neck vein distention, lung sounds) ·Accurate and competent calculation of ultra-filtration rates</p>				

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	<p>readings had been addressed.</p> <p>A. The record included a hemodialysis treatment flow sheet dated 3-21-16 that evidenced the patient's blood pressure ranged from 70/35 to 82/62 throughout the treatment. The flow sheet evidenced the patient's blood pressure reading was 70/35 at 8:33 AM and 193/148 at 9:02 AM and 65/42 at 9:31 AM.</p> <p>B. A hemodialysis treatment flow sheet dated 3-23-16 evidenced the patient's blood pressure ranged from 76/40 to 91/67 throughout the treatment. The flow sheet states, "hypotensive per norm."</p> <p>C. A hemodialysis treatment flow sheet dated 3-25-16 evidenced the patient's blood pressure ranged from 60/44 to 92/66 throughout the treatment. The flow sheet states, "No unusual findings noted."</p> <p>D. A hemodialysis treatment flow sheet dated 3-28-16 evidenced the patient's blood pressure ranged from 62/31 to 78/52 throughout the treatment. The flow sheet evidenced the patient's blood pressure was 171/137 at 8:33 AM and 161/127 at 9:03 AM. The flow sheet evidenced the treatment ended at 9:38</p>		<ul style="list-style-type: none"> ·Accurate and competent of fluid removal goals ·Accurate determination of inter dialytic weight gains ·Any complaints or changes in the patient's condition since last treatment ·FMS-CS-IC-1-110-133A- Patient Monitoring During Treatment inclusive of, but not limited to: <ul style="list-style-type: none"> ·Vital signs every 30 minutes (observe for changes in patient's status) ·Machine and extracorporeal circuit safety checks every 30 minutes. (Assess for changes in the patient's mental status/level of consciousness) ·FMS-CS-1C-11-110-132A- Patient Evaluation Post Treatment <ul style="list-style-type: none"> ·Post weight compared to pre- treatment weight ·Vital signs (B/P sitting and standing) ·If previous complaints have resolved ·Where the patient was discharged to ·and any necessary staff 	

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	<p>AM. The flow sheet states, "hypotensive per norm."</p> <p>E. A hemodialysis treatment flow sheet dated 4-1-16 evidenced the patient's blood pressure ranged from 58/44 to 74/34 throughout the dialysis treatment. The flow sheet states, "b/p [blood pressure] shows side flux but pt [patient] clinical presentation stable."</p> <p>F. A hemodialysis treatment flow sheet dated 4-4-16 evidenced the patient's blood pressure ranged from 74/56 to 96/79 throughout the treatment. The flow sheet states, "no unusual findings noted."</p> <p>G. A hemodialysis treatment flow sheet dated 4-8-16 evidenced the patient's blood pressure ranged from 65/44 to 85/62 throughout the treatment. The flow sheet states, "hypotensive per pt norm."</p> <p>H. A hemodialysis treatment flow sheet dated 4-11-16 evidenced the patient's blood pressure ranged from 56/38 to 87/67 throughout the treatment. The flow sheet states, "hypotensive per norm."</p> <p>I. A hemodialysis treatment flow sheet dated 4-15-16 evidenced the</p>		<p>interventions in the Electronic Health Record</p> <ul style="list-style-type: none"> · Responsibility of the PCT/CCHT/LPN to notify the RN/Team Leader of: · Observations, changes/abnormal findings or new issues in the patient's condition · Symptoms or problems reported by the physician · Inability to reach physician prescribed orders · Responsibility of the RN/Team Leader to immediately notify the primary Nephrologist/Attending Physician of: · Compare data to pre dialysis findings and goals · Significant changes or problems in the patient's condition · Staff interventions · In the event that orders cannot be implemented as prescribed by the physician <p>It is the responsibility of all DPC staff to appropriately document patient assessment and monitoring data (pre, during and post treatment)</p>	

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	<p>patient's blood pressure ranged from 64/33 to 97/34 throughout the treatment. The flow sheet states, "hypotensive per norm."</p> <p>J. The clinic manager was unable to provide documentation the physician was aware of the low blood pressures during the treatment and had addressed when asked on 4-22-16 at 10:30 AM.</p> <p>3. The clinic manager was unable to provide any additional documentation and/or information when asked on 4-22-1 at 10:20 AM.</p> <p>4. The facility's 7-4-12 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Dose of Dialysis . . . Provide necessary care and services to manage the patient's volume status."</p>		<p>inclusive of RN and Physiannotifications in the Electronic Health Record</p> <p>Documentation of the education provided will be maintained available for review at the facility To monitor staff compliance and to prevent reoccurrence,</p> <p>·On May 17, 2016 the Clinical Manager will meet with the Medical Director to review the eCube Hemodialysis Treatment Detail Report and trend of each patient's fluid volume status inclusive of:</p> <ul style="list-style-type: none"> ·EDW (3 month trend) ·Weight gains pertreatment and 3 month average ·Fluid removal pertreatment and 3 month average ·Pre and postsitting and standing B/Ps per treatment and 3 month average <p>·On May 17, 2016 the Clinical Manager updated applicable patients electronic health record to reflect any order changes based upon the Medical</p>		

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			<p>Director's review</p> <ul style="list-style-type: none"> ·Effective May 17,2016 the Clinical Manager or designee will be responsible to print and toreview the eCube Hemodialysis Treatment Detail Report weekly on Friday,beginning May 13, 2016 detailing each patients pre/post and average bloodpressures, pre/post and average weights ·Those patientsidentified during this weekly review as not meeting their prescribed EDW andthose patients having increased or decreased blood pressures as outlined in thefacilities Standing Orders will be escalated to the physician for assessmentand further orders and to the IDT team for reassessment with appropriateupdates to the Plans of Care within 15 days of IDT completion of the patientassessment ·The ClinicalManager is responsible to review each 	

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V 0545 Bldg. 00	494.90(a)(2) POC-EFFECTIVE NUTRITIONAL STATUS The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional		completed Plan of Care prior to filing inthe medical record to ensure appropriate IDT identification and management of thepatients fluid volume needs The CM will present asummary of the Medical Directors review to the GB Committee weekly and to theQAI Committee monthly It is the responsibilityof the QAI Committee to provide direct oversight to the process by analyzing,tracking, and trending the data. If atrend is identified, the QAI Committee will assist in the development of rootcause and direct changes to this action plan The GB may direct changesto the facility processes necessary to prevent reoccurrence		

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	<p>status. A patient's albumin level and body weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate. Based on record review and interview, the facility failed to ensure patients' desired albumin level of greater than or equal to 4.0 grams per deciliter (g/dL) according the Centers for Medicare and Medicaid Services (CMS) Measures Assessment Tool (MAT) had been maintained in 1 (#2) of 2 records reviewed for nutritional status.</p> <p>The findings include:</p> <p>1. Clinical record number 2 included laboratory results that evidenced the patient's albumin levels were 2.6 on 12-19-15, 2.9 on 1-7-16, 3.1 on 2-4-16, 2.9 on 3-3-16, and 2.8 on -7-16. The record failed to evidence the interdisciplinary team had implemented interventions to address the decreasing albumin levels.</p> <p>A. The record included a "Comprehensive RD [registered dietician] Assessment Nutrition History and Assessment" dated 1-16-16. The assessment states, "Pt [patient] alb [albumin] level is low, but has improved, from 2.6 to 2.9 in 2 wks. ONSP [dietary supplement program] added and [adult</p>	V 0545	<p>To ensure that the IDT provides the necessary care and services to manage each patient's Albumin level at greater than or equal to 4.0 grams per deciliter (g/dl) according to the Centers for Medicare and Medicaid Services (CMS) Measures Assessment Tool:</p> <ul style="list-style-type: none"> ·On May 12, 2016 the Education Coordinator met with and reeducated the IDT on FMS-CS-IC-1-110-125A Comprehensive Interdisciplinary Assessment and Plan of Care policy with specific emphasis on the IDTs responsibility to assess, identify, care plan and appropriately manage each patients Nutritional Status <p>Documentation of the IDT reeducation will be maintained available for review at the facility</p> <ul style="list-style-type: none"> ·On May 17, 2016 the IDT 	05/21/2016

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	<p>child] counseled on high pro renal diet.</p> <p>B. A "Nutrition Monthly Progress Note" dated 2-18-16 states, "Counseled pt and pt caregiver on high pro foods & enc [encouraged] to continue good intake. Cont ONSP."</p> <p>C. A "Nutrition Monthly Progress Note" dated 3-8-16 states, "Enc to cont good intake of high pro foods. On ONSP."</p> <p>2. The clinic manager was unable to provide any additional documentation and/or information when asked on 4-22-16 at 10:20 AM.</p> <p>3. The facility's 7-4-12 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Nutritional Status. Provide the necessary care and counseling services to achieve and sustain an effective nutritional status."</p>		<p>met to conduct a comprehensive reassessment on the patient identified in the SOD as Clinical Record # 2 and to update the patient's Plan of Care based on the patient's nutritional reassessment findings</p> <p>To prevent reoccurrence, · On or before May 17, 2016 the Clinical Manager in conjunction with the Registered Dietician (RD) will review a (3) month trend of 100% patients Albumin levels. Those patients not meeting Albumin goal of greater than or equal to 4.0g/dl in 2 of the 3 month trend, will be immediately escalated to the physician for further orders and to the IDT for a comprehensive reassessment of the patient's Nutritional status with appropriate updates to the Plan of Care within 15 days of the reassessment · The Clinical Manager and/or Registered Dietician will be responsible to review a (3) month trend of 100%</p>		

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			<p>patients Albumin levels monthly and to escalate those patientsnot meeting Albumin goal equal to or greater than 4.0 in minimum of 2 of the 3months reviewed to the physician for further orders and to the IDT for acomprehensive reassessment of the patients Nutritional status with appropriateupdates to the Plan of Care</p> <ul style="list-style-type: none"> ·The RegisteredDietician is responsible to complete the Albumin Tool as part of the QAprocess monthly ·The ClinicalManager is responsible to review each completed Plan of Care prior to filing inthe medical record for appropriate IDT identification and management of thepatients nutritional status <p>The Clinical Manager willreport to the Governing Body completion of the initial Nutritional/Albumintrend review during the weekly scheduled GB meetings</p>	

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V 0546 Bldg. 00	494.90(a)(3) POC-MANAGE MINERAL METABOLISM Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease.		<p>The Clinical Manager orRegistered Dietician will present a summary of those patients not meetingAlbumin goal of 4.0 in a minimum of 2 of 3 months to the QAI Committee monthly. The summary will include confirmation of IDTscompletion of a comprehensive Nutritional reassessment and update to the Planof Care</p> <p>It is the responsibilityof the QAI Committee to provide direct oversight to the process by analyzing,tracking, and trending the data. If atrend is identified, the QAI Committee will assist in the development of rootcause and direct changes to this action plan</p> <p>The Governing Body may direct changes to thefacility processes necessary to prevent reoccurrence</p>	

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	<p>Based on record review and interview, the facility failed to ensure the necessary care had been provided to maintain patients' phosphorous levels within the desired range in 2 (#s 3 and 5) of 2 records reviewed for mineral bone disease.</p> <p>The findings include:</p> <ol style="list-style-type: none"> The desired range for phosphorous levels is 3.5 to 5.5 milligrams per deciliter (mg/dL) according to the Center for Medicare and Medicaid Services (CMS) Measures Assessment Tool (MAT) Clinical record number 3 included laboratory results that evidenced the patient's phosphorous level was 7.8 on 1-20-16, 8.3 on 3-2-16, and 11.5 on 4-6-16. The record included a "Nutrition Monthly Progress Note" dated 3-9-16 that states, "Says [the patient's] PO4 [phosphorous] level may be up because [the patient] ate pinto beans the day before labs were drawn." The record failed to evidence any interventions to address the elevated phosphorous levels. Clinical record number 5 included laboratory results that evidenced the patient's phosphorous level was 9.3 on 4-4-16, 7.1 on 4-6-16, 8.2 on 4-8-16, 10.7 	V 0546	<p>To ensure that the IDT provides the necessary care and services to manage each patient's mineral metabolism/phosphorus level at 3.5 – 5.5 milligram per deciliter (mg/dl) in accordance to Centers for Medicare and Medicaid Services (CMS) Measures Assessment Tool (MAT) in order to prevent bone disease:</p> <ul style="list-style-type: none"> On May 12, 2016 the Education Coordinator met with and reeducated the IDT on FMS-CS-IC-1-110-125A Comprehensive Interdisciplinary Assessment and Plan of Care policy with specific emphasis on the IDT's responsibility to assess, identify, care plan and appropriately manage each patient's phosphorus levels <p>Documentation of the IDT reeducation will be maintained available for review at the facility</p> <ul style="list-style-type: none"> On May 17, 2016 the IDT 	05/21/2016

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	<p>on 4-11-16, 10.0 on 4-13-16, and 9.3 on 4-15-16. The record included a "Nutrition Monthly Progress Note" dated 3-11-16 that states, "Talked to pt on 3-9-16, [the patient] told me to go away and [the patient] didn't want to talk to me. Pt said following low phos diet and trying different binders was not helping lower [the patient's] PO4 level." The record failed to evidence any interventions to address the patient's elevated PO4 levels.</p> <p>4. The clinic manager was unable to provide any additional documentation and/or information when asked on 4-22-16 at 10:20 AM.</p> <p>5. The facility's 7-4-12 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Mineral Metabolism. Provide the necessary care to manage mineral metabolism and prevent or treat renal bone or cardiovascular disease."</p>		<p>met to conduct a comprehensive reassessment on the patients identified in the SOD as Clinical Record #s 3 and 5, and to update the patient's Plan of Care based on the patient's mineral metabolism/phosphorus reassessment findings</p> <p>To prevent reoccurrence, · On or before May 17, 2016 the Clinical Manager in conjunction with the Registered Dietician (RD) will review a (3) month trend of 100% patients Phosphorus levels. Those patients not meeting Phosphorus goal of 3.5-5.5 mg/dl in 2 of the 3 month trend, will be immediately escalated to the physician for further orders and to the IDT for a comprehensive reassessment of the patient's Bone and Mineral / Phosphorus status with appropriate updates to the Plan of Care within 15 days of the reassessment · The Clinical Manager and/or Registered Dietician will be responsible to review</p>	

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			<p>a (3) monthtrend of 100% patients Phosphorus levels monthly and to escalate those patientsnot meeting Phosphorus goal of 3.5-5.5mg/dl in minimum of 2 of the 3 monthsreviewed to the physician for further orders and to the IDT for a comprehensivereassessme nt of the patient's Bone and Mineral Status with appropriate updatesto the Plan of Care within 15 days of the reassessment</p> <p>·The ClinicalManager is responsible to review each completed Plan of Care prior to filing inthe medical record for appropriate IDT identification and management of thepatient's Bone and Mineral/phosphorus status</p> <p>The Clinical Manager willreport to the Governing Body completion of the initial Bone and Mineral /Phosphorus trend review during the weekly scheduled GB meetings</p> <p>The Clinical Manager willpresent a summary of</p>	

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V 0550 Bldg. 00	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		those patients not meeting Phosphorus goals in a minimum of 2 of 3 months to the QAI Committee monthly. The summary will include confirmation of IDTs completion of a comprehensive Nutritional reassessment and update to the Plan of Care It is the responsibility of the QAI Committee to provide direct oversight to the process by analyzing, tracking, and trending the data. If a trend is identified, the QAI Committee will assist in the development of root cause and direct changes to this action plan The Governing Body may recommend changes to facility processes necessary to prevent reoccurrence	

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	<p>consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement.</p> <p>Based on record review and interview, the facility failed to ensure staff had followed the facility's policy for the use of new arteriovenous fistulas (AVF) in order to sustain the vascular access in 3 (# 2, 22, and 23) of 3 clinical records reviewed of patients with new fistulas.</p> <p>The findings include:</p> <p>1. The facility's 3-20-13 "New AV-Fistula Cannulation Algorithm" number FMS-CS-IC-I-115-015D1 states, "Week One: Obtain physician order to cannulate AVF . . . When cannulating: AVF with CVC, use one 17-gauge needle to pull from AVF arterial and return to the CVC. If no infiltration, advance to two 17 gauge needles at next hemodialysis treatment. AVF only - use two 17 -gauge needles . . . If Complications Occur: Stop utilizing the AVF. If a CVC is present, resume dialysis through the catheter. Notify physician for evaluation and/or referral to interventionalist/surgeon. Week Two: If no complications: Cannulate AVF using two 16-gauge needles . . . Week Three: If no complications: Advance needle gauge and BFR [blood flow rate] per physician order."</p>	V 0550	<p>To ensure that all DirectPatient Care Staff follow the facility's policy for use of a new Arteriovenous Fistulas(AVF) in order to sustain new vascular accesses, the following correctiveactions were implemented as approved by the Governing Body:</p> <p>On May 12, 2016 theEducation Coordinator reeducated all direct patient care staff on:</p> <ul style="list-style-type: none"> ·New AV-FistulaCannulation Algorithm FMS-CS-IC-1-115-05D1 ·FMC-OVDC 3026 AVFCannulation Protocol worksheet, specifically the appropriate use of theworksheet and documentation requirements <p>Documentation of theeducation and staff attendance will be maintained available for</p>	05/21/2016

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	<p>2. Clinical record number 2 failed to evidence facility staff had followed the new AVF algorithm . The record included a physician's order dated 3-1-16 that states, "May use graft at next dialysis." The record included a physician's "Office Note" dated 2-4-16 that states, "The patient had a right brachiocephalic fistula placed four months ago . . . continues to have problems with dialysis access . . . to assess whether stenting is an option. If not, we will need to go to the other arm with a basilic vein transposition AV fistula."</p> <p>A. The clinic manager stated, on 4-22-16 at 10:25 AM, "The patient came with an AVF. It had to be revised. The patient came from the hospital with an access placed, it was a new one, it had not matured. The patient was not educated to exercise and it did not develop. I don't know why the order says graft. [The patient] has a fistula."</p> <p>B. The record included an "FMC-OVDC 3026 AVF Cannulation Protocol" worksheet. The worksheet evidenced the staff had used one 17 gauze needle on 3-8-16 and 3-10-16 to cannulate the access.</p>		<p>review at the facility</p> <p>To monitor and to prevent reoccurrence as directed by the Medical Director and Governing Body,</p> <ul style="list-style-type: none"> · On May 12, 2016 The facility's management team and the Governing Body designated and approved (1) Registered Nurse and (1) Patient Care Technician as "Expert Cannulators" · On or before May 12, 2016 the Education Coordinator will provide reeducation to the designated Expert Cannulators on the facility's access policies, procedures and protocols · Effective immediately and ongoing, every effort will be made to ensure that new AVFistulas are cannulated by the designated and approved Expert Cannulators at the facility · On May 13, 2016 the CM or designee placed the current, active AVF Cannulation Protocol worksheets for patients with a newly placed 				

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	<p>1.) A hemodialysis treatment flow sheet dated 3-12-16 evidenced the AVF and the CVC had been used to provide the dialysis treatment.</p> <p>2.) The worksheet evidenced two 17-gauge needles had been used on 3-15-16. A hemodialysis treatment flow sheet dated 3-15-16 evidenced both the AVF and the CVC had been used to provide the dialysis treatment.</p> <p>3.) The worksheet evidenced two 17-gauge needles had been used on 3-17-16.</p> <p>4.) A hemodialysis treatment flow sheet dated 3-19-16 evidenced the AVF had been used with two 17-gauge needles.</p> <p>5.) The worksheet and a hemodialysis flow sheet dated 3-22-16 evidenced two 16-gauge needles had been used on 3-22-16.</p> <p>6.) The worksheet evidenced "1 + 1" had been used on 3-24-16. A hemodialysis treatment flow sheet dated 3-24-16 evidenced both the CVC and the AVF had been used.</p> <p>7.) A hemodialysis treatment flow sheet dated 3-26-16 states, "Inability to</p>		<p>AV Fistula in a binder to be maintained at the Nursing Station until maturation of the access is achieved as determined by the Nephrologist</p> <p>The Clinical Manager or designee will be responsible to print and review the electronic health record treatment sheet and to review the AVF Cannulation Protocol worksheet for each patient, following placement of a new AV Fistula for appropriate use of the protocol with appropriate and timely documentation, beginning their first treatment at the facility after AVF placement and continuing each cannulation/treatment day through week four as outlined in the protocol</p> <p>The Clinical Manager or designee will be responsible to initial the printed treatment sheets and the AVF Cannulation worksheets as verification of his or her review</p>		

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	<p>Cannulate" and identified the CVC had been used to provide the treatment. The worksheet failed to evidence an entry dated 3-26-16. The record failed to evidence the physician had been notified of the complication.</p> <p>8.) Hemodialysis treatment flow sheets, dated 3-29-16 and 3-31-16, evidenced the CVC had been utilized to provide the treatments.</p> <p>9.) The worksheet and the hemodialysis treatment flow sheets failed to evidence what gauge of needles had been used on 4-2-16, 4-5-16, and on 4-9-16.</p> <p>10.) The worksheet failed to evidence what gauge of needles had been used on 4-12-16. A hemodialysis treatment flow sheet dated 4-12-16 evidenced the CVC and the AVF had been used to provide the treatment.</p> <p>11.) The worksheet evidenced one 17-gauge needle had been used on 4-16-16 and two 16-gauge needles had been used on 4-19-16.</p> <p>3. Clinical record number 22 included a physician's order dated 2-11-16 that states, "OK to begin using access as of today. Please stick between marks placed</p>		<p>·In the event that a new AV fistula cannot be cannulated as directed per protocol, the Registered Nurse/Team Leader will be responsible to notify the physician for further orders with appropriate and timely documentation in the medical record and on the cannulation worksheet</p> <p>The Clinical Manager will be responsible to provide a summary of the treatment sheet and Cannulation worksheet review to the Governing Body weekly during weekly, scheduled meetings and to the QAI Committee monthly</p> <p>It is the responsibility of the QAI Committee to provide direct oversight to the process by analyzing, tracking, and trending the data. If a trend is identified, the QAI Committee will assist in the development of root cause and direct changes to this action plan</p>				

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	<p>by [name of doctor]."</p> <p>A. Hemodialysis treatment flow sheets, dated 2-13-16, 2-16-16, 2-18-16, and 2-20-16 evidenced the CVC had been utilized to provide the dialysis treatment.</p> <p>B. Hemodialysis treatment flow sheets, dated 2-23-16, 2-25-16, 2-27-16, and 3-1-16, evidenced both the CVC and the AVF had been utilized to provide the treatment.</p> <p>C. The record evidenced the patient was in the hospital from 3-3-16 to 3-16-16 with a hospital discharge diagnosis of "Sepsis, unspecified organism."</p> <p>D. The record included a "Clinical Notes Report" dated 3-8-16 that states, "Cannulation protocol started before hospitalization. Has been in hosp nearing one week today. Will continue sticking upon return to unit and evaluate for catheter removal later in the month."</p> <p>E. A hemodialysis treatment flow sheet dated 3-17-16 evidenced the AVF had been utilized to provide the treatment, but failed to evidence the size of needles used to cannulate the site. The "FMC-OVDC-3026 AVF Cannulation Protocol" worksheet failed</p>		The Governing Body may recommend changes to the facility processes necessary to prevent reoccurrence	

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	<p>to evidence failed to evidence an entry for 3-17-16.</p> <p>F. A hemodialysis treatment flow sheet dated 3-19-16 evidenced two 17-gauge needles had been used to cannulate the access. The worksheet failed to evidence any entry for 3-19-16. A "Clinical Notes Report" dated 3-19-16 states, "unable to place 2 needles today tried 5 times to place second needle with 4 different people trying to achieve a 2nd working needle . . . consult with [name of doctor] on Monday to see about getting perm cath placed on Monday."</p> <p>G. A hemodialysis treatment flow sheet dated 3-21-16 evidenced the AVF had been utilized but failed to evidence the needle size used to cannulate the site. The worksheet failed to evidence an entry for 3-21-16.</p> <p>H. Hemodialysis treatment flow sheets, dated 3-22-16 and 3-24-16, evidenced the CVC had been utilized to provide the dialysis treatment. The worksheet failed to evidence an entry for 3-22-16 and 3-24-16.</p> <p>I. A hemodialysis treatment flow sheet dated 3-26-16 evidenced both the CVC and the AVF had been utilized to provide the treatment. The worksheet</p>			

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	<p>failed to evidence an entry for 3-26-16.</p> <p>J. Hemodialysis treatment flow sheets dated 3-29-16 and 3-31-16 evidenced the AVF had been utilized to provide the dialysis treatment but failed to evidence the needle size used. The worksheet failed to evidence entries for 3-29-16 and 3-31-16. A "Clinical Notes Report" dated 3-29-16 states, "Refuses cannulation today. Catheter running poorly. [Name of doctor] contacted who states it is ok to cannulate next tx." The record failed to evidence the order and failed to evidence the size of needle to be used with the next cannulation.</p> <p>K. A hemodialysis treatment flow sheet dated 4-2-16 evidenced the AVF had been utilized for the treatment and two 17-gauge needles had been used. The worksheet evidenced two 17-gauge needles had been used.</p> <p>L. A hemodialysis treatment flow sheet dated 4-5-16 evidenced the AVF had been utilized for the treatment and the site had been cannulated with two 16-gauge needles. The worksheet evidence an entry that identified two 17-gauge needles had been used on this date.</p> <p>M. Hemodialysis treatment flow</p>			

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	<p>sheets, dated 4-7-16, 4-9-16, 4-12-16, 4-14-16, 4-16-16, 4-19-16, and 4-21-16, evidenced the AVF had been utilized for the treatment but failed to evidence the needle size used to cannulate the site. The worksheet evidenced an entry dated 4-19-16 that evidenced two 16-gauge needles had been used.</p> <p>4. Clinical record number 23 included a physician order dated 3-9-16 that states, "Arteriovenous (AV) fistula is nicely matured and ready for access . . . Given release to use the fistula on March 15th."</p> <p>A. The record evidenced facility staff cannulated the access with one 17-gauge needle the first week (3-17-16, 3-24-16, and 3-31-16) and two 17-gauge needles the 2nd week (4-2-16, 4-5-16, and 4-7-16) per the facility's protocol.</p> <p>B. The record failed to evidence facility staff had cannulated the AVF per the protocol the 3rd and 4th weeks.</p> <p>1.) Hemodialysis treatment flow sheets, dated 4-9-16 and 4-12-16, failed to evidence the size of needle used to cannulate the AVF. The "FMC-OVDC-3026 AVF Cannulation Protocol" worksheet failed to evidence an entry for 4-9-16 and 4-12-16.</p>			

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V 0559 Bldg. 00	<p>2.) A hemodialysis treatment flow sheet dated 4-21-16 failed to evidence the size of needle used to cannulate the AVF.</p> <p>5. The clinic manager was unable to provide any additional documentation and/or information when asked on 4-22-16 at 10:20 AM.</p> <p>6. The facility's 7-4-12 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Vascular Access . . . Provide vascular access monitoring and appropriate, timely referrals to achieve and sustain an AV fistula as the first choice and an AV graft if that is not possible."</p> <p>494.90(b)(3) POC-OUTCOME NOT ACHIEVED-ADJUST POC If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must-</p> <p>(i) Adjust the plan of care to reflect the patient's current condition; (ii) Document in the record the reasons why the patient was unable to achieve the goals; and (iii) Implement plan of care changes to</p>				

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	<p>address the issues identified in paragraph (b)(3)(ii) of this section.</p> <p>Based on record review and interview, the facility failed to ensure the interdisciplinary team (IDT) had collaborated to ascertain reasons for the inability of patients to achieve specified goals and adjusted the plans of care to address any identified reasons in 4 (#s 1, 2, 3, and 5) of 5 records reviewed.</p> <p>The findings include:</p> <p>1. Clinical record number 1 included a fax to the extended care facility (ECF) where the patient resides. The fax cover sheet identifies the patient is "non-compliant [with] fld [fluid] restr [restriction]. Discussed results [with] RD [registered dietician] ECF. difficult goes out to eat & keeps food in room, eating good, [no] pressure sores."</p> <p>A. A nutrition note dated 4-12-16 states, "Discussed fluid intake. Pt says [the patient] has cut back already."</p> <p>B. The record failed to evidence the IDT had collaborated with the ECF staff to implement plan of care changes to address the identified problems related to the excessive fluid intake.</p> <p>2. Clinical record number 2 included</p>	V 0559	<p>To ensure that the IDT understandstheir role in appropriate assessment, identification of reasons, care planningand management of each patient's inability to achieve the facility's expectedquality outcome goals and to ensure that the patient's plan of care is timelyand appropriately updated by the IDT to address the identified reasons,</p> <p>On May 12, 2016 theEducation Coordinator met with and reeducated the IDT on:</p> <p>·FMS-CS-IC-1-110-125A Comprehensive Interdisciplinary Assessmentand Plan of Care policy with specific emphasis on the IDTs role andresponsibility to assess, identify, care plan and appropriately manage eachpatients fluid status, nutritional status/albumin levels and mineralmetabolism/phosph</p>	05/21/2016

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	<p>laboratory results that evidenced the patient's albumin levels were 2.6 on 12-19-15, 2.9 on 1-7-16, 3.1 on 2-4-16, 2.9 on 3-3-16, and 2.8 on -7-16. The record failed to evidence the interdisciplinary team had implemented interventions to address the decreasing albumin levels.</p> <p>A. The record included a "Comprehensive RD [registered dietician] Assessment Nutrition History and Assessment" dated 1-16-16. The assessment states, "Pt [patient] alb [albumin] level is low, but has improved, from 2.6 to 2.9 in 2 wks. ONSP [dietary supplement program] added and [adult child] counseled on high pro renal diet.</p> <p>B. A "Nutrition Monthly Progress Note" dated 2-18-16 states, "Counseled pt and pt caregiver on high pro foods & enc [encouraged] to continue good intake. Cont ONSP."</p> <p>C. A "Nutrition Monthly Progress Note" dated 3-8-16 states, "Enc to cont good intake of high pro foods. On ONSP."</p> <p>D. The record failed to evidence the IDT had identified reasons why the patient was unable to attain the desired albumin levels and had implemented</p>		<p>orus levels</p> <p>·The Medical Director and Governing Body's expectation of the IDT to appropriately and timely collaborate with extended care facility personnel as applicable, to assist in investigation and determination of reasons for patients not meeting expected quality outcome goals</p> <p>Documentation of the IDT education will be maintained available for review at the facility</p> <p>In addition as directed by the Medical Director and Governing Body,</p> <p>·On May 17, 2016 the Clinical Manager or designee will contact RD from the Extended Care Facility to discuss patient #1's noncompliance with fluid management and to investigate possible root causes contributing to the patient's inability to achieve expected fluid management goals</p>	

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	<p>changes to the plan of care to address any identified needs.</p> <p>3. Clinical record number 3 included laboratory results that evidenced the patient's phosphorous level was 7.8 on 1-20-26, 8.3 on 3-2-16, and 11.5 on 4-6-16. The record included a "Nutrition Monthly Progress Note" dated 3-9-16 that states, "Says [the patient's] PO4 [phosphorous] level may be up because [the patient] at pinto beans the day before labs were drawn."</p> <p>The record failed to evidence the IDT had identified reasons for the elevated phosphorous levels and had adjusted the plan of care to address any identified reasons.</p> <p>4. Clinical record number 5 included laboratory results that evidenced the patient's phosphorous level was 9.3 on 4-4-16, 7.1 on 4-6-16, 8.2 on 4-8-16, 10.7 on 4-11-16, 10.0 on 4-13-16, and 9.3 on 4-15-16. The record included a "Nutrition Monthly Progress Note" dated 3-11-16 that states, "Talked to pt on 3-9-16, [the patient] told me to go away and [the patient] didn't want to talk to me. Pt said following low phos diet and trying different binders was not helping lower [the patient's] PO4 level."</p>		<p>On May 17, 2016 the IDT met to complete comprehensive reassessments and to update each patient's plan of care to include implementation of changes specific to address the issues as identified in the comprehensive reassessments on:</p> <ul style="list-style-type: none"> · Patient #1, related to Fluid Volume Management noncompliance with fluid restrictions. · Patient #2, related to Nutritional Status specifically, decreased Albumin levels · Patient #s 3 and 5 related to Mineral Metabolism, specifically, elevated Phosphorus levels <p>To monitor for IDT compliance and to prevent reoccurrence,</p> <ul style="list-style-type: none"> · The Clinical Manager or designee is responsible to review each Plan of Care for appropriate completion by the IDT members prior to filing in the Medical Record 				

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	<p>The record failed to evidence the IDT had identified reasons for the elevated phosphorous levels and had adjusted the plan of care to address any identified problems.</p> <p>5. The clinic manager was unable to provide any additional information and/or documentation when asked on 4-22-16 at 10:20 AM.</p> <p>6. The facility's 7-4-12 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "If the patient specific expected outcome as determined by the attending physician, IDT and patient for the Plan of Care is not achieved within the identified timeframe: Interdisciplinary team must adjust the patient's Plan of Care as described in the Plan of Care/Updates section of this policy in an effort to achieve the specified goal. If the patient is unable to achieve the desired outcomes, the team must adjust the Plan of Care to reflect the patient's current condition, and Document in the medical record the reason(s) why the patient is unable to achieve the goal. Implement Plan of Care changes to address the identified issues."</p>		<p>Effective immediately andgoing forward, the Clinical Manager in conjunction with the IDT will beresponsible to review each patient's quality outcomes as detailed in the FMCQuality Status Report monthly to identify those patients not able to achieveexpected quality goals.</p> <p>Those patients unable toachieve the expected outcome will have a comprehensive reassessment and update to the Plan of Care conducted by the IDT within 15 days of the report findings</p> <p>The Clinical Manager willbe responsible to present a summary of the IDT compliance to the processmonthly to the QAI Committee</p> <p>It is the responsibilityof the QAI Committee to provide direct oversight to the process by analyzing,tracking, and trending the data. If atrend is identified, the QAI</p>		

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V 0625 Bldg. 00	494.110 CFC-QAPI Based on record review, observation, and interview, it was determined the facility failed to maintain compliance with this condition by failing to ensure its quality assessment performance improvement (QAPI) program addressed all aspects of the facility's physical plant and environment in 4 of 4 months reviewed creating the potential to affect all of the facility's 62 current patients (See V 628); by failing to ensure its quality assessment and performance improvement (QAPI) program included monitoring and evaluation of the implementation of the facility's new arteriovenous (AV) fistula policies and procedures in 4 of 4 months reviewed (See V 633); and by failing to ensure performance improvement plans had been implemented to address the condition and status of the physical plant	V 0625	Committee will assist in the development of rootcause and direct changes to this action plan The Governing Body mayrecommend changes to the facility processes necessary to prevent reoccurrence As a result of thecitations received from the April 22, 2016 CMS survey and as is the commitmentof the Governing Body to ensure that its Quality Assessment and PerformanceImprovement program appropriately evaluates, monitors, addresses and timelydevelops improvement plans for: ·Physical Plant(Refer to V 628 and 638) to ensure a clean, sanitary, safe and comfortableenvironment for staff, patients and visitors and to ensure monitoring andidentification of physical plant issues with timely development of correctiveactions to	05/21/2016

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	<p>and environment in 4 of 4 months of quality assessment and performance improvement (QAPI) program meeting minutes reviewed. (See V 638).</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to support and maintain an effective quality assessment and performance improvement program. The facility was found to be out of compliance with this condition, 42 CFR 494.110 Quality Assessment and Performance Improvement.</p>		<p>address identified issues:</p> <ul style="list-style-type: none"> ·Reeducation was provided to the QAPI Committee by the Regional Quality Manager to reinforce their responsibility to measure, analyze, track, and timely identify physical environment issues and to timely develop and implement improvement plans to address the facility's identified physical plant and environment issues ·CM in conjunction with the Area Technical Operations Manager developed and initiated implementation of formal action plans to address the identified physical environment issues as identified in the Statement of Deficiencies (Refer to V 638) ·The QAI Committee is responsible to review the developed action plans and this CMS Plan of Correction monthly x 12 months or until full resolution of all Physical Plant issues is achieved ·The Clinical Manager 	

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			<p>developed and implemented a daily, weekly and monthly staff cleaning assignment schedule to include the treatment area, water room and dialysate mixing area</p> <ul style="list-style-type: none"> The Area Technical Operations Manager will be responsible to complete the FMC QAI Physical Environment Audit Tool monthly The CM and/or the DO will be responsible to conduct a walkthrough of the dialysis facility inclusive of the treatment area, water room and the dialysate mixing area daily x 4 weeks, weekly x 4 weeks, then monthly x 4 months or until 100% compliance is achieved and sustained as determined by the Governing Body CM or Director of Operations is responsible to provide a summary of the facility walkthrough assessment findings and any identified issues of staff compliance to the GB committee weekly and to the QAI Committee 	

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			<p>monthly</p> <ul style="list-style-type: none"> ·The ATOM will present a weekly update to the Governing Body Committee on the physical plant renovations and corrective actions as stated in this action plan until full resolution of all issues is achieved ·The ATOM will present the findings of the QAI Physical Environment Audit Tool to the QAI Committee monthly for review, discussion with development and implementation of corrective actions to ensure complete resolution of identified issues ·The Medical Director is responsible to sign the QAI Physical Environment Audit Tool monthly during the QAI meeting as verification of QAI Committees' discussion with timely and appropriate development and implementation of corrective actions as warranted by the walkthrough and audit findings <p>The QAI Committee</p>	

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			<p>will analyze the findings and assess for trends. If trends are identified, the QAI Committee will assist with determination of root cause and direct changes to this action plan as warranted</p> <p>The QAI Committee is responsible to review this Plan of Correction x 12 months consecutively to ensure sustained compliance</p> <p>The Governing Body will provide direct oversight</p> <ul style="list-style-type: none"> - Vascular Access management to include monitoring of proper staff utilization of the facility's new AVF policies and procedures with appropriate updates to the Plan of Care for patients with new AV Fistulas - Reeducation was provided to the QAPI Committee to reinforce its' responsibility to monitor and evaluate appropriate staff implementation of the facility's new AVF policies and procedures with appropriate updates to the 	

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			<p>Plans of Care to include the newAVF policies and procedures for new AVFs</p> <ul style="list-style-type: none"> ·The GoverningBody designated and approved (1) Registered Nurse and (1) Patient CareTechnician as “Expert Cannulators” ·Reeducation tothe GB approved and designated “Expert Cannulator’s” on the facility’s accesspolicies, procedures and protocols ·The ClinicalManager is responsible to ensure that every effort is made to ensure that newAV Fistulas are cannulated by the designated and approved Expert Cannulators atthe facility ·AVF CannulationWorksheet for patients with a new AV Fistula was placed in a binder to bemaintained at the Nurses Station until maturation of the access is achieved asdetermined by the Nephrologist ·The ClinicalManager or designated Registered Nurse is responsible to print and review theelectronic health record treatment 	

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			<p>sheet and to review the AVF Cannulation Protocol worksheet for each patient following placement of a new AV Fistula for appropriate use of the protocol with appropriate and timely documentation, beginning their first treatment at the facility after AVF placement and continuing each cannulation/treatment day through week four as outlined in the protocol</p> <p>The Clinical Manager will be responsible to provide a summary of the treatment sheet and new AVF Cannulation worksheet review to the Governing Body weekly during weekly, scheduled meetings and to the QAI Committee monthly</p> <p>The QAI Committee will provide direct oversight to the process by analyzing, tracking, and trending the data. If a trend is identified, the QAI Committee will assist in the development of root cause and direct change to this action plan</p> <p>The QAI Committee</p>	

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V 0628 Bldg. 00	<p>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 facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves.</p> <p>Based on record review and interview, the facility failed to ensure its quality assessment performance improvement (QAPI) program addressed all aspects of the facility's physical plant and environment in 4 (December 2015, January 2016, February 2016, and March 2016) of 4 months reviewed creating the potential to affect all of the facility's 62 current patients.</p> <p>The findings include:</p> <p>1. The facility's QAPI meeting minutes, dated 12-15-15, 1-19-16, 2-16-16, and 3-15-15, failed to evidence the facility</p>	V 0628	<p>isresponsible to review this Plan of Correction monthly x 12 months consecutivelyto ensure sustained compliance The Governing Body willprovide direct oversight to this action plan</p> <p>To ensure that thefacility's QAPI Program appropriately monitors and addresses all aspects of thefacility's physical plant and environment inclusive of, but not limited to thefloor, the water room, the dialysate mixing area, the clean supply storageareas and equipment:</p> <p>On May 17, 2016 theRegional Quality Manager will provide reeducation to all members of the QACommittee members on:</p>	05/21/2016	

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	<p>had evaluated the condition of the facility's physical environment to include the floor, the dialysate mixing area, the clean supply storage areas, and equipment used on the treatment floor.</p> <p>A. On 4-15-16 at 10:15 AM, the following observations were made:</p> <p>1.) A large gray stain was noted on the floor between the 2 machines at stations 15 and 16.</p> <p>2.) A rust-colored stain was observed on the front of the dialysis machine at the port where the dialysate hoses are connected to the machine and running down the front of the machines at stations 14, 15, and 16.</p> <p>3.) A dark gray stain approximately 2 tiles by 3 tiles in size was observed on the floor between the dialysis machine and chair at stations numbered 11 and 12.</p> <p>4.) A dark gray stain was observed on the floor approximately 3 tiles long and 1/2 tile wide between stations 10 and 11 next to the chase cabinet along the wall.</p> <p>5.) At station 10 observation noted a dark gray stain on the floor</p>		<p>·Reeducation andreinforcement on the QAPI Committees responsibility to appropriately measure,analyze, track and to timely identify and to develop corrective actions to addressthe facility's physical plant issues to ensure a safe, sanitary and comfortableenvironment Documentation of the QACommittees education will be maintained available at the facility for review</p> <p>In addition, as directedby the Medical Director and Governing Body:</p> <p>·On April 22, 2016the DPC staff and Janitorial staff thoroughly swept and cleaned the treatmentfloor, thus removing:</p> <p>·The debrisincluding test strips, pieces of whitepaper, 2x2 gauze pads, unopened alcohol prep pads, opened betadine package, needle caps, blue glove, (3) blue chux, bluetourniquet, syringe package, candy bar wrapper and clamp from</p>	

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	<p>approximately 2 tiles by 6 tiles in size.</p> <p>6.). A dark gray stain was noted on the floor approximately 2 tiles by 3 tiles between the tiles at station number 8.</p> <p>7.). At stations 6 and 7 a dark gray stain approximately 3 tiles by 9 tiles in size was observed.</p> <p>8.). At station number 6 a rust colored stain on the front of the machine from the port where the dialysate hoses are connected down the front of the machine was observed.</p> <p>9.). The machines at stations numbered 3, 4, and 5 evidenced rust colored stains on the front of the machine from the dialysate hoses ports down the front of the machines.</p> <p>10.) Observation noted gray stains between the tiles approximately 3 tiles by 4 tiles at stations numbered 3 and 4. A gray smattered stain approximately 3 by 3 tiles was observed at station number 3.</p> <p>11.). A 3 by 6 tile gray smattered stain was observed on the floor at station number 1.</p> <p>12.). Observation noted 3 portable oxygen tank holder on wheels near the</p>		<p>the floor</p> <ul style="list-style-type: none"> ·On April 19, 2016the facility staff thoroughly swept and cleaned the water room and dialysatemixing area, thus removing: <ul style="list-style-type: none"> ·The white powderysubstance under and around the bicarbonate tank ·The used teststrips directly in front of the bicarbonate tank and in the doorway from thehall to the preparation area ·The whitecrystalline substance on the top of the first acid storage tank ·The dirty, whitecrystalline substance on the floor all around the 2 acid storage tanks ·The dry whitesubstance on the black supply storage shelving unit next to the acid tanks ·The dirty, browncrystalline substance and the stalactite formation under the acid storage tanks ·The multiplewhite crystalline pencil shaped substances from the floor 		

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	<p>scale. Observation noted rusted areas around the cylinder holders, on the wheels, and on the handle of the holder.</p> <p>13.). At 10:40 AM, observation noted rust colored stains on the dialysis machines at stations numbered 17 and 18. Observation also noted dark gray stains approximately 3 by 5 tiles in size.</p> <p>14.). Observation noted on another clean sink a large amount of water on the counter tops surrounding the sink. A rough coating was worn away from large areas of the countertop on either side of the sink.</p> <p>15.). Observation noted a cart on wheels with 2 shelves used to store dialysate jugs. A rust colored stain was observed to cover the entire bottom shelf. The posts between the shelves were covered in a white substance in a drip pattern.</p> <p>B. On 4-15-16 at 11:30 AM, the following observations were made in the dialysate preparation area:</p> <p>1.). The floor around and under the bicarbonate tank was covered in a white powdery substance. Observation noted used test strips on the floor directly in front of the bicarbonate tank and on</p>		<p>around the stalactiteformation</p> <ul style="list-style-type: none"> ·The whitecrystalline substance on top of the acid storage tank ·The large amountof water and soap on and around the sinks and countertops <p>In addition as directed bythe Medical Director and GB,</p> <ul style="list-style-type: none"> ·On or before May20, 2016 the ATOM and/or Bio-Medical technician removed the rust on front ofmachine #s 3, 4, 5, 6, 7, 14, 15, 16, 17 and 18 ·On or before May20, 2016 the ATOM removed, discarded and replaced the cart on wheels with 2shelves with visible rust on the bottom shelf and white substance on the postbetween the shelves ·On or before May20, 2016 the ATOM will remove and replace the (3) portable Oxygen tank holderswith visible rust ·On or before May11, 2016 the Director of 				

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	<p>the floor in the doorway from the hall to the preparation area.</p> <p>2.). Observation noted 2 large acid storage tanks in the area. A white crystalline substance was observed on the top of the first tank.</p> <p>3.). Observation noted a white rectangular plastic container on the floor in front of the first tank with a large amount of a white crystalline substance covering the bottom of the container.</p> <p>4.). A dirty, white crystalline substance was observed on the floor all around the 2 tanks. The tanks were sitting up on round, cone shaped black holders. The floor beneath the holders was visible. A large amount of a brown, crystalline substance was observed on the floor under the tanks with a stalactite type of formation hanging from the bottom of the tank reaching to the floor approximately 3 to 4 inches. Observation noted multiple pieces of a white crystalline substance in the shape of pencils on the floor near the formation.</p> <p>5.). A black supply storage shelving unit was observed next to the acid tanks. The shelving was covered in a dry white substance. Observation noted 31 boxes of syringes, boxes of gloves,</p>		<p>Operations and the ATOM met with Ideal ConstructionCo. to obtain estimate for removal and replacement of the damaged, worn countertop at the sink. Estimated completion date is June 1, 2016. ·On or before May20, 2016 the ATOM will remove, discard and replace the IV medication storage box at the med prep area ·On or before May11, 2016 the Director of Operations and the ATOM met with Ideal ConstructionCo. to obtain estimate to replace flooring in the treatment area and hallway thus removing the dark gray stained, chipped and missing floor tiles. Estimated completion date is June 1, 2016 ·On or before May20, 2016 the ATOM removed and replaced the white, rectangular, plastic box on the floor in front of the first acid tank ·On or before May11, 2016 the Director of</p>	

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	<p>and boxes of personal care wash cloths stored on the shelving unit.</p> <p>C. On 4-15-16 at 1:20 PM, observation noted at station number 7 the floor tiles in front of the chase cabinet were cracked and torn.</p> <p>D. On 4-18-16 at 8:20 AM, the following observations were made:</p> <p>At station number 16, observation noted 1/2 of a piece of the floor tile was missing next to the chase cabinet. Bare concrete was visible.</p> <p>E. On 4-18-16 at 11:30 AM, observation noted a white box approximately 12 inches by 18 inches on the counter at the medication preparation area. The box had a fold down door. Multiple rusted areas and tape residue were observed on the outside and the inside of the door and the box. The box was lined with white Styrofoam that was stained a rust color. Multiple medications to be administered to patients intravenously were stored in the box.</p> <p>F. On 4-22-16 at 8:35 AM, observation noted the floor tile was chipped in the doorway to the stockroom. The bottom of the door frame on both</p>		<p>Operations and the ATOM met with Ideal ConstructionCo. to order a replacement door forthe doorway to the stockroom. Estimated date of installation is June1, 2016</p> <p>The Clinical Manager isresponsible to ensure that the facility is maintained clean, sanitary andcomfortable at all times</p> <p>To monitor and to preventreoccurrence,</p> <ul style="list-style-type: none"> ·On or before May17, 2016 the Clinical Manager developed and implemented a daily, weeklyand monthly staff cleaning assignmentschedule to include the treatment area, the water room, and the dialysatemixing area ·The AreaTechnical Operations Manager is responsible to complete the FMC QAI PhysicalEnvironment Audit Tool monthly ·Effective May 17,2016 the Clinical Manager and/or Director of Operations will 	

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	<p>sides was worn away and rusted.</p> <p>2. The clinic manager stated, on 4-22-16 at 1:10 PM, "The physical plant portions of the QAPI meeting minutes do not include any discussion of the floors and equipment. They are aware but kept putting it off due to the possibility of getting a new building."</p> <p>3. The Medical Director stated, on 4-22-16 at 11:30 AM, "The condition of the building is bad. We are high on the list to get it fixed, I think."</p> <p>4. The facility's 4-4-12 "Quality Assessment and Performance Improvement Program (QAPI) policy number FMS-CS-IC-I-101-001A states, "Elements to be reviewed in the QAI meeting include: . . . Technical Operations."</p>		<p>be responsible to conduct a walkthrough of the dialysis facility, inclusive of the treatment area, the water room and the dialysate mixing area daily x 4 weeks, weekly x 4 weeks, then monthly x 4 months or until 100 % compliance is achieved and sustained as determined by the Governing Body Committee</p> <p>- CM or Director of Operations is responsible to provide a summary of the facility walkthrough assessment findings and any identified issues of staff compliance to the GB committee weekly and to the QAI Committee monthly</p> <p>The ATOM will present a weekly update to the Governing Body Committee on the physical plant corrective actions as stated in this action plan until full resolution of all issues is achieved</p> <p>The ATOM will present the findings of the QAI</p>	

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			<p>Physical Environment Audit Tool to the QAI Committeemonthly for review, discussion with development and implementation ofcorrective actions to ensure complete resolution of identified issues</p> <p>The Medical Director willbe responsible to sign the QAI Physical Environment Audit Tool monthly duringthe QAI meeting as verification of QAI Committees' discussion with timely andappropriate development and implementation of corrective actions as warrantedby the walkthrough and audit findings</p> <p>The QAI Committee willanalyze the findings and assess for trends. If trends are identified, the QAI Committee will assist withdetermination of root cause and direct changes to this action plan as warranted</p> <p>The QAI Committee</p>	

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V 0633 Bldg. 00	<p>494.110(a)(2)(v) QAPI-INDICATOR-VASCULAR ACCESS The program must include, but not be limited to, the following: (v) Vascular access.</p> <p>Based on record review and interview, the facility failed to ensure its quality assessment and performance improvement (QAPI) program included monitoring and evaluation of the implementation of the facility's new arteriovenous (AV) fistula policies and procedures in 4 (December 2015, January 2016, February 2016, and March 2016) of 4 months reviewed.</p> <p>The findings include:</p> <p>1. The facility's QAPI meeting minutes, dated 12-15-15, 1-19-16, 2-16-16, and 3-15-15, failed to evidence the facility had monitored and evaluated the implementation and effectiveness of the new AV-Fistula policies and procedures.</p> <p>A. Clinical record number 2 failed to</p>	V 0633	<p>isresponsible to review this Plan of Correction monthly x 12 months The Governing Body willprovide direct oversight The Governing Body may recommend changes tofacility processes as necessary to sustain compliance</p> <p>To ensure that thefacility's QAPI Program appropriately monitors and evaluates Vascular Accessesinclusive of the facility's new Arteriovenous (AV) fistula policies andprocedures:</p> <p>On May 17, 2016 theRegional Quality Manager will provide reeducation to all members of the QAI Committeemembers on:</p> <ul style="list-style-type: none"> ·Reeducation andreinforcement on the QAPI Committees responsibility to appropriately measure,analyze, track and manage vascular accesses 	05/21/2016

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	<p>evidence facility staff had followed the new AVF algorithm . The record included a physician's order dated 3-1-16 that states, "May use graft at next dialysis." The record included a physician's "Office Note" dated 2-4-16 that states, "The patient had a right brachiocephalic fistula placed four months ago . . . continues to have problems with dialysis access . . . to assess whether stenting is an option. If not, we will need to go to the other arm with a basilic vein transposition AV fistula."</p> <p>1.) The clinic manager stated, on 4-22-16 at 10:25 AM, "The patient came with an AVF. It had to be revised. The patient came from the hospital with an access placed, it was a new one, it had not matured. The patient was not educated to exercise and it did not develop. I don't know why the order says graft. [The patient] has a fistula."</p> <p>2.) The record included an "FMC-OVDC 3026 AVF Cannulation Protocol" worksheet. The worksheet evidenced the staff had used one 17 gauze needle on 3-8-16 and 3-10-16 to cannulate the access.</p> <p>a. A hemodialysis treatment flow sheet dated 3-12-16 evidenced the</p>		<p>A copy of the QACommittees education will be maintained available at the facility for review</p> <p>On May 12, 2016 theEducation Coordinator reeducated all direct patient care staff on:</p> <ul style="list-style-type: none"> ·New AV-FistulaCannulation Algorithm FMS-CS-IC-1-115-05D1 ·FMC-OVDC 3026 AVFCannulation Protocol worksheet, specifically the appropriate use of theworksheet and documentation requirements <p>A copy of the educationand staff attendance will be maintained available for review at the facility</p> <ul style="list-style-type: none"> ·On May 12, 2016 thefacility's management team and the Governing Body designated and approved (1)Registered Nurse and (1) Patient Care Technician at the facility as "ExpertCannulators" ·On or before May12, 				

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	<p>AVF and the CVC had been used to provide the dialysis treatment.</p> <p>b. The worksheet evidenced two 17-gauge needles had been used on 3-15-16. A hemodialysis treatment flow sheet dated 3-15-16 evidenced both the AVF and the CVC had been used to provide the dialysis treatment.</p> <p>c.) The worksheet evidenced two 17-gauge needles had been used on 3-17-16.</p> <p>d. A hemodialysis treatment flow sheet dated 3-19-16 evidenced the AVF had been used with two 17-gauge needles.</p> <p>e. The worksheet and a hemodialysis flow sheet dated 3-22-16 evidenced two 16-gauge needles had been used on 3-22-16.</p> <p>f. The worksheet evidenced "1 + 1" had been used on 3-24-16. A hemodialysis treatment flow sheet dated 3-24-16 evidenced both the CVC and the AVF had been used.</p> <p>g. A hemodialysis treatment flow sheet dated 3-26-16 states, "Inability to Cannulate" and identified the CVC had been used to provide the treatment. The</p>		<p>2016 the Education Coordinator will provide reeducation to the designated Expert Cannulators on all facility's access policies, procedures and protocols related to vascular access management</p> <p>A copy of the Expert Cannulator reeducation will be maintained available for review at the facility to monitor for compliance and to prevent reoccurrence, as directed by the Medical Director and Governing Body Committee:</p> <ul style="list-style-type: none"> · On May 12, 2016 The facility's management team and the Governing Body designated and approved (1) Registered Nurse and (1) Patient Care Technician as "Expert Cannulators" · On or before May 12, 2016 the Education Coordinator will provide reeducation to the designated Expert Cannulators on the facility's access policies, procedures and protocols · Effective immediately and ongoing, every effort will be made to ensure that new 		

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	<p>worksheet failed to evidence an entry dated 3-26-16. The record failed to evidence the physician had been notified of the complication.</p> <p>h. Hemodialysis treatment flow sheets, dated 3-29-16 and 3-31-16, evidenced the CVC had been utilized to provide the treatments.</p> <p>i. The worksheet and the hemodialysis treatment flow sheets failed to evidence what gauge of needles had been used on 4-2-16, 4-5-16, and on 4-9-16.</p> <p>j. The worksheet failed to evidence what gauge of needles had been used on 4-12-16. A hemodialysis treatment flow sheet dated 4-12-16 evidenced the CVC and the AVF had been used to provide the treatment.</p> <p>k. The worksheet evidenced one 17-gauge needle had been used on 4-16-16 and two 16-gauge needles had been used on 4-19-16.</p> <p>B. Clinical record number 22 included a physician's order dated 2-11-16 that states, "OK to begin using access as of today. Please stick between marks placed by [name of doctor]."</p>		<p>AVFistulas are cannulated by the designated and approved Expert Cannulators atthe facility</p> <ul style="list-style-type: none"> ·On May 13, 2016 theCM or designee placed the current, active AVF Cannulation Protocol worksheetsfor patients with a newly placed AV Fistula in a binder to be maintained at theNursing Station until maturation of the access is achieved as determined by theNephrologist ·The ClinicalManager or designated Registered Nurse will be responsible to print and reviewthe electronic health record treatment sheet and to review the AVF CannulationProtocol worksheet for each patient, following placement of a new AV Fistula for appropriate use of the protocol withappropriate and timely documentation, beginning their first treatment at thefacility after AVF placement and continuing each cannulation/treatment daythrough week four as 	

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	<p>1.). Hemodialysis treatment flow sheets, dated 2-13-16, 2-16-16, 2-18-16, and 2-20-16 evidenced the CVC had been utilized to provide the dialysis treatment.</p> <p>2.). Hemodialysis treatment flow sheets, dated 2-23-16, 2-25-16, 2-27-16, and 3-1-16, evidenced both the CVC and the AVF had been utilized to provide the treatment.</p> <p>3.). The record evidenced the patient was in the hospital from 3-3-16 to 3-16-16 with a hospital discharge diagnosis of "Sepsis, unspecified organism."</p> <p>4.). The record included a "Clinical Notes Report" dated 3-8-16 that states, "Cannulation protocol started before hospitalization. Has been in hosp nearing one week today. Will continue sticking upon return to unit and evaluate for catheter removal later in the month."</p> <p>5.). A hemodialysis treatment flow sheet dated 3-17-16 evidenced the AVF had been utilized to provide the treatment, but failed to evidence the size of needles used to cannulate the site. The "FMC-OVDC-3026 AVF Cannulation Protocol" worksheet failed to evidence failed to evidence an entry for 3-17-16.</p>		<p>outlined in the protocol</p> <p>The Clinical Manager or designee will be responsible to initial the printed treatment sheets and the AVF Cannulation worksheets as verification of his or her review</p> <p>·In the event that a new AV fistula cannot be cannulated as directed per protocol, the Registered Nurse/Team Leader will be responsible to notify the physician for further orders with appropriate and timely documentation in the medical record and on the cannulation worksheet</p> <p>The Clinical Manager will be responsible to provide a summary of the treatment sheet and Cannulation worksheet review to the Governing Body weekly during weekly, scheduled meetings and to the QAI Committee monthly</p> <p>It is the responsibility of the QAI Committee to provide</p>				

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	<p>6.). A hemodialysis treatment flow sheet dated 3-19-16 evidenced two 17-gauge needles had been used to cannulate the access. The worksheet failed to evidence any entry for 3-19-16. A "Clinical Notes Report" dated 3-19-16 states, "unable to place 2 needles today tried 5 times to place second needle with 4 different people trying to achieve a 2nd working needle . . . consult with [name of doctor] on Monday to see about getting perm cath placed on Monday."</p> <p>7.). A hemodialysis treatment flow sheet dated 3-21-16 evidenced the AVF had been utilized but failed to evidence the needle size used to cannulate the site. The worksheet failed to evidence an entry for 3-21-16.</p> <p>8.). Hemodialysis treatment flow sheets, dated 3-22-16 and 3-24-16, evidenced the CVC had been utilized to provide the dialysis treatment. The worksheet failed to evidence an entry for 3-22-16 and 3-24-16.</p> <p>9.). A hemodialysis treatment flow sheet dated 3-26-16 evidenced both the CVC and the AVF had been utilized to provide the treatment. The worksheet failed to evidence an entry for 3-26-16.</p>		<p>direct oversight to the process by analyzing, tracking, and trending the data. If atrend is identified, the QAI Committee will assist in the development of rootcause and direct changes to this action plan The QAI Committee is responsible to review this Plan of Correction x 12 consecutive months</p> <p>The Governing Body may recommend changes to the facility processes necessary to prevent reoccurrence</p>	

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	<p>10.) Hemodialysis treatment flow sheets dated 3-29-16 and 3-31-16 evidenced the AVF had been utilized to provide the dialysis treatment but failed to evidence the needle size used. The worksheet failed to evidence entries for 3-29-16 and 3-31-16. A "Clinical Notes Report" dated 3-29-16 states, "Refuses cannulation today. Catheter running poorly. [Name of doctor] contacted who states it is ok to cannulate next tx." The record failed to evidence the order and failed to evidence the size of needle to be used with the next cannulation.</p> <p>11.) A hemodialysis treatment flow sheet dated 4-2-16 evidenced the AVF had been utilized for the treatment and two 17-gauge needles had been used. The worksheet evidenced two 17-gauge needles had been used.</p> <p>12.) A hemodialysis treatment flow sheet dated 4-5-16 evidenced the AVF had been utilized for the treatment and the site had been cannulated with two 16-gauge needles. The worksheet evidence an entry that identified two 17-gauge needles had been used on this date.</p> <p>13.) Hemodialysis treatment flow sheets, dated 4-7-16, 4-9-16, 4-12-16, 4-14-16, 4-16-16, 4-19-16, and 4-21-16,</p>			

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	<p>evidenced the AVF had been utilized for the treatment but failed to evidence the needle size used to cannulate the site. The worksheet evidenced an entry dated 4-19-16 that evidenced two 16-gauge needles had been used.</p> <p>C. Clinical record number 23 included a physician order dated 3-9-16 that states, "Arteriovenous (AV) fistula is nicely matured and ready for access . . . Given release to use the fistula on March 15th."</p> <p>1.) The record evidenced facility staff cannulated the access with one 17-gauge needle the first week (3-17-16, 3-24-16, and 3-31-16) and two 17-gauge needles the 2nd week (4-2-16, 4-5-16, and 4-7-16) per the facility's protocol.</p> <p>2.) The record failed to evidence facility staff had cannulated the AVF per the protocol the 3rd and 4th weeks.</p> <p>a. Hemodialysis treatment flow sheets, dated 4-9-16 and 4-12-16, failed to evidence the size of needle used to cannulate the AVF. The "FMC-OVDC-3026 AVF Cannulation Protocol" worksheet failed to evidence an entry for 4-9-16 and 4-12-16.</p> <p>b. A hemodialysis treatment</p>			

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V 0638 Bldg. 00	<p>flow sheet dated 4-21-16 failed to evidence the size of needle used to cannulate the AVF.</p> <p>2. The clinic manager was unable to provide any additional documentation and/or information when asked on 4-22-16 at 1:10 PM.</p> <p>3. The facility's 4-4-12 "Quality Assessment and Performance Improvement Program" policy number FMC-CS-IC-I-101-001A states, "Elements to be reviewed in the QAI meeting include: Patient Care Outcomes."</p> <p>494.110(b) QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time. Based on record review and interview, the facility failed to ensure performance improvement plans had been implemented to address the condition and status of the physical plant and environment in 4 (December 2015, January 2016, February 2016, and March</p>	V 0638	To ensure that the QAPI program identifies and directs the development and implementation of improvement plans to address the facility's identified	05/21/2016

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	<p>2016) of 4 months of quality assessment and performance improvement (QAPI) program meeting minutes reviewed.</p> <p>The findings include:</p> <p>1. The facility's QAPI meeting minutes, dated 12-15-15, 1-19-16, 2-16-16, and 3-15-15, failed to evidence the facility had monitored and evaluated the status and condition of the facility's treatment floor, dialysate mixing area, and equipment used by facility staff.</p> <p>2. On 4-15-16 at 10:15 AM, the following observations were made:</p> <p>A. A used test strip was observed on the floor in front of the dialysis machine at station number 16.</p> <p>B. A used test strip and a piece of white paper approximately 1 inch by 4 inches was observed on the floor beside the dialysis machine at station number 15. A large gray stain was noted on the floor between the 2 machines at stations 15 and 16.</p> <p>C. A rust-colored stain was observed on the front of the dialysis machine at the port where the dialysate hoses are connected to the machine and running down the front of the machines at stations</p>		<p>physical plant and environment issues, inclusive of, but not limited to the floor, the water room, the dialysate mixing area, the clean supply storage areas and equipment:</p> <p>On May 17, 2016 the Regional Quality Manager will provide reeducation to all members of the QA Committee members on:</p> <ul style="list-style-type: none"> The QA Committees responsibility to appropriately measure, analyze, track and to timely identify issues and to develop corrective actions to address the facility's physical plant issues to ensure a safe, sanitary and comfortable environment <p>A copy of the QA Committees education will be maintained available at the facility for review</p> <ul style="list-style-type: none"> On or before May 17, 2016 the Clinical Manager in conjunction with the Area Technical Operations Manager will be 	

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	<p>14, 15, and 16.</p> <p>D. A stack of 2 x 2 gauze pads approximately 1/2 inch high was observed on the floor under the chair at station number 14. An empty roll of tape was observed on the floor.</p> <p>E. A strip of white paper approximately 1/2 inch by 2 inches was observed on the floor in the isolation room.</p> <p>F. A dark gray stain approximately 2 tiles by 3 tiles in size was observed on the floor between the dialysis machine and chair at stations numbered 11 and 12.</p> <p>G. A dark gray stain was observed on the floor approximately 3 tiles long and 1/2 tile wide between stations 10 and 11 next to the chase cabinet along the wall.</p> <p>H. At station 10 observation noted a dark gray stain on the floor approximately 2 tiles by 6 tiles in size.</p> <p>I. Observation noted the sink at the medication preparation area with water and soap all over the countertop at the sink.</p> <p>J. A dark gray stain was noted on the floor approximately 2 tiles by 3 tiles</p>		<p>responsible to develop and implement formal action plans related to the identified physical environment issues as identified in the Statement of Deficiencies</p> <p>In addition, as directed by the Medical Director and Governing Body,</p> <ul style="list-style-type: none"> · On April 22, 2016 the DPC staff and Janitorial staff thoroughly swept and cleaned the treatment floor, thus removing: <ul style="list-style-type: none"> · The debris including test strips, pieces of white paper, 2x2 gauze pads, unopened alcohol prep pads, opened betadine package, needle caps, blue glove, (3) blue chux, blue tourniquet, syringe package, candy bar wrapper and clamp from the floor · On April 22, 2016 the DPC staff thoroughly cleaned and disinfected the dialysis chair at station # 16, removing the blood from the chair arm and side table · On April 19, 2016 the 		

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	<p>between the tiles at station number 8. A piece of white paper approximately 1/2 inch by 1 inch was observed on the floor.</p> <p>K. At stations 6 and 7 a dark gray stain approximately 3 tiles by 9 tiles in size was observed.</p> <p>L. At station number 6 observation noted an opened Betadine package on the floor in front of the chair. A rust colored stain on the front of the machine from the port where the dialysate hoses are connected down the front of the machine was observed.</p> <p>M. Observation noted 3 blue Chux pads were on the floor in front of the chase cabinet between stations 5 and 6.</p> <p>N. The machines at stations numbered 3, 4, and 5 evidenced rust colored stains on the front of the machine from the dialysate hoses ports down the front of the machines.</p> <p>O. Observation noted gray stains between the tiles approximately 3 tiles by 4 tiles at stations numbered 3 and 4. A gray smattered stain approximately 3 by 3 tiles was observed at station number 3.</p> <p>P. A piece of white paper towel approximately 1 inch by 5 inches was</p>		<p>facility staff thoroughly cleaned and swept the water room and dialysatemixing area, thus removing:</p> <ul style="list-style-type: none"> ·The white powderysubstance under and around the bicarbonate tank ·The used teststrips directly in front of the bicarbonate tank and in the doorway from the hallto the preparation area ·The whitecrystalline substance on the top of the first acid storage tank ·The dirty, whitecrystalline substance on the floor all around the 2 acid storage tanks ·The dry whitesubstance on the black supply storage shelving unit next to the acid tanks ·The dirty, browncrystalline substance and the stalactite formation under the acid storage tanks ·The multiplewhite crystalline pencil shaped substances from the floor around the stalactiteformation 	

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	<p>observed on the floor at station 2.</p> <p>Q. A 3 by 6 tile gray smattered stain was observed on the floor at station number 1.</p> <p>R. Observation noted 3 portable oxygen tank holder on wheels near the scale. Observation noted rusted areas around the cylinder holders, on the wheels, and on the handle of the holder.</p> <p>S. At 10:40 AM, observation noted rust colored stains on the dialysis machines at stations numbered 17 and 18. Observation also noted dark gray stains approximately 3 by 5 tiles in size.</p> <p>T. Observation noted on another clean sink a large amount of water on the counter tops surrounding the sink. A rough coating was worn away from large areas of the countertop on either side of the sink.</p> <p>U. Observation noted a cart on wheels with 2 shelves used to store dialysate jugs. A rust colored stain was observed to cover the entire bottom shelf. The posts between the shelves were covered in a white substance in a drip pattern.</p> <p>3. On 4-15-16 at 11:30 AM, the</p>		<ul style="list-style-type: none"> ·The whitocrystalline substance on top of the acid storage tank ·The large amountof water and soap on and around the sinks and countertops <p>In addition as directed bythe Medical Director and GB,</p> <ul style="list-style-type: none"> ·On or before May20, 2016 the ATOM and/or Bio-Medical technician removed the rust on front ofmachine #s 3, 4, 5, 6, 7, 14, 15, 16, 17 and 18 ·On or before May20, 2016 the ATOM removed, discarded and replaced the cart on wheels with 2shelves with visible rust on the bottom shelf and white substance on the postbetween the shelves ·On or before May20, 2016 the ATOM will remove and replace the (3) portable Oxygen tank holderswith visible rust ·On or before May11, 2016 the Director of Operations and the ATOM met with Ideal 		

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	<p>following observations were made in the dialysate preparation area:</p> <p>A. The floor around and under the bicarbonate tank was covered in a white powdery substance. Observation noted used test strips on the floor directly in front of the bicarbonate tank and on the floor in the doorway from the hall to the preparation area.</p> <p>B. Observation noted 2 large acid storage tanks in the area. A white crystalline substance was observed on the top of the first tank.</p> <p>C. Observation noted a white rectangular plastic container on the floor in front of the first tank with a large amount of a white crystalline substance covering the bottom of the container.</p> <p>D. A dirty, white crystalline substance was observed on the floor all around the 2 tanks. The tanks were sitting up on round, cone shaped black holders. The floor beneath the holders was visible. A large amount of a brown, crystalline substance was observed on the floor under the tanks with a stalactite type of formation hanging from the bottom of the tank reaching to the floor approximately 3 to 4 inches. Observation noted multiple pieces of a white</p>		<p>ConstructionCo. to obtain estimate for removal and replacement of the damaged, worn countertop at the sink. Estimated completion date is June 1, 2016. ·On or before May20, 2016 the ATOM will remove, discard and replace the IV medication storage box at the med prep area ·On or before May11, 2016 the Director of Operations and the ATOM met with Ideal ConstructionCo. to obtain estimate to replace flooring in the treatment area and hallway thus removing the dark gray stained, chipped and missing floor tiles. Estimated completion date is June 1, 2016 ·On or before May20, 2016 the ATOM removed and replaced the white, rectangular, plastic box on the floor in front of the first acid tank ·On or before May11, 2016 the Director of Operations and the ATOM met with Ideal</p>	

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	<p>crystalline substance in the shape of pencils on the floor near the formation.</p> <p>E. A black supply storage shelving unit was observed next to the acid tanks. The shelving was covered in a dry white substance. Observation noted 31 boxes of syringes, boxes of gloves, and boxes of personal care wash cloths stored on the shelving unit.</p> <p>4. On 4-15-16 at 1:20 PM, observation noted a moderate amount of blood on the arm of the dialysis chair and on the chair side table at station number 16. A pair of used blue gloves was also observed on the chair side table. At 1:40 PM, observation noted the blood was still on the chair and table.</p> <p>At 1:45 PM, employee D, a registered nurse, was observed to clean the dialysis chair with the blood. The employee cleaned the blood from the chair and, without changing her gloves or cleansing her hands, cleaned the rest of the chair with a clean cloth.</p> <p>The facility's 1-4-12 "Work Surface Cleaning and Disinfection with Visible Blood [less than] 10 mls [milliliters] and OPIM using Bleach Solutions" procedure number FMS-CS-IC-II-155-110C2 states, "Use a</p>		<p>ConstructionCo. to order a replacement door forthe doorway to the stockroom. Estimated date of installation is June1, 2016</p> <p>The Clinical Manager isresponsible to ensure that the facility is maintained clean, sanitary andcomfortable at all times</p> <p>To monitor and to preventreoccurrence, ·On or before May17, 2016 the Clinical Manager developed and implemented a daily, weeklyand monthly staff cleaning assignmentschedule to include the treatment area, the water room, and the dialysatemixing area ·The AreaTechnical Operations Manager is responsible to complete the FMC QAI PhysicalEnvironment Audit Tool monthly ·Effective May 17,2016 the Clinical Manager or designee and/or Director of Operations will</p>	

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	<p>cloth wetted with 1:100 bleach solution to clean the surface. Clean up all visible blood. Discard the used cloth and gloves in appropriate waste container. Perform hand hygiene and don new gloves. After cleaning up all visible blood, use a new cloth wetted with 1:100 bleach solution for a second cleaning of the surface. Make the surface glistening wet and let air dry unless otherwise specified by the manufacturer. Discard the cloth and gloves in the appropriate waste container. Perform hand hygiene."</p> <p>5. On 4-15-16 at 1:25 PM, observation noted the trash can near the medication preparation area was full and overflowing. A stack of 2 x 2 pieces of gauze and a blue glove was observed on the floor near the trash can.</p> <p>A. At station number 2 a test strip and piece of paper towel approximately 1 inch by 5 inches was observed on the floor. A syringe package was also observed on the floor.</p> <p>B. At station number 4 observation noted a candy bar wrapper, a strip of white paper approximately 1/2 inch by 4 inches, and a piece of a blue glove.</p> <p>C. At station number 5 observation noted 2 strips of white paper</p>		<p>beresponsible to conduct a walkthrough of the dialysis facility, inclusive of the treatment area, the water room and the dialysate mixing area daily x 4 weeks, weekly x 4 weeks, then monthly x 4 months or until 100 % compliance is achieved and sustained as determined by the Governing Body Committee - CM or Director of Operations is responsible to provide a summary of the facility walkthrough assessment findings and any identified issues of staff compliance to the GB committee weekly and to the QAI Committee monthly</p> <p>The ATOM will present a weekly update to the Governing Body Committee on the physical plant renovations and corrective actions as stated in this action plan until full resolution of all issues is achieved</p> <p>The ATOM will present</p>	

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	<p>approximately 1/2 inch by 3 inches, a 2 x 2 piece of gauze, and a needle cap on the floor.</p> <p>D. At station number 7 observation noted a 2 x 2 piece of gauze and a syringe package on the floor. Observation also noted the floor tiles in front of the chase cabinet were cracked and torn.</p> <p>E. At 1:45 PM, observation noted a blue rubber tourniquet on the floor at station number 8 on the right side of the dialysis chair.</p> <p>6. On 4-18-16 at 8:20 AM, the following observations were made:</p> <p>A. A blue glove was observed on the floor near the trash can at the nurse's station.</p> <p>B. At station number 11 a piece of white paper 1/2 inch by 1 inch was observed on the floor.</p> <p>C. A piece of white paper 1/2 inch by 3 inches was observed on the floor at station number 9.</p> <p>D. A piece of white paper 1/2 inch by 1 inch was observed on the floor at station number 16.</p>		<p>thefindings of the QAI Physical Environment Audit Tool to the QAI Committeemonthly for review, discussion with development and implementation ofcorrective actions to ensure complete resolution of identified issues</p> <p>The Medical Director willbe responsible to sign the QAI Physical Environment Audit Tool monthly duringthe QAI meeting as verification of QAI Committees' discussion with timely andappropriate development and implementation of corrective actions as warrantedby the walkthrough and audit findings</p> <p>The QAI Committee willanalyze the findings and assess for trends. If trends are identified, the QAI Committee will assist with determinationof root cause and direct changes to this action plan as warranted The QAI Committee</p>	

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	<p>E. At station number 16, observation noted 1/2 of a piece of the floor tile was missing next to the chase cabinet. Bare concrete was visible.</p> <p>7. On 4-18-16 at 11:30 AM, observation noted a white box approximately 12 inches by 18 inches on the counter at the medication preparation area. The box had a fold down door. Multiple rusted areas and tape residue were observed on the outside and the inside of the door and the box. The box was lined with white Styrofoam that was stained a rust color. Multiple medications to be administered to patients intravenously were stored in the box.</p> <p>8. On 4-20-16 at 8:40 AM, the following observations were made:</p> <p>A. Two unopened alcohol packages were on the floor beside the chair at station number 18.</p> <p>B. A needle cap was observed on the floor in front of the dialysis chair at station number 17.</p> <p>C. A 1/2 inch by 4 inch piece of white paper was observed on the floor in front of the dialysis machine.</p> <p>D. At station number 11, observation</p>		<p>isresponsible to review this Plan of Correction monthly x 12 months to ensuresustained compliance The Governing Body willprovide direct oversight The Governing Body may recommend changes tofacility processes as necessary to sustain compliance</p>				

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	<p>noted 2 stacks of 2 x 2 gauze pads approximately 1/2 inch high on the floor.</p> <p>E. At station number 7 observation noted an alcohol pad on the floor in front of the dialysis chair.</p> <p>F. At station number 5 observation noted a white clamp on the floor by the dialysis machine.</p> <p>9. On 4-22-16 at 8:35 AM, observation noted the floor tile was chipped in the doorway to the stockroom. The bottom of the door frame on both sides was worn away and rusted.</p> <p>10. The Director of Operations indicated, on 4-22-16 at 2:25 PM, the facility's plans to erect a new building had been placed on hold. The Director indicated employee U, the Area Technical Operations Manager was responsible for the physical plant and environment of the building. The Director of Operations indicated there was a massive renovation of the building planned and that an initial site survey was planned for July 2016.</p> <p>11. The facility's 3-20-13 "Housekeeping" policy number FMS-CS-IC-II-155-116A states, "All areas must be kept clean and organized, including but not limited to the treatment</p>			

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V 0710 Bldg. 00	<p>area, water/supply room and offices . . . Facility staff are accountability for cleaning rooms/areas not assigned to the contracted cleaning staff. Such cleaning should be done regularly using a schedule developed by the facility."</p> <p>12. The Medical Director stated, on 4-22-16 at 11:30 AM, "The condition of the building is bad. We are high on the list to get it fixed, I think."</p> <p>13. The clinic manager stated, on 4-22-16 at 1:10 PM, "The physical plant portions of the QAPI meeting minutes do not include any discussion of the floors and equipment. They are aware but kept putting it off due to the possibility of getting a new building."</p> <p>Based on observation, interview, and record review, it was determined the facility failed to maintain compliance with this condition by failing to ensure the medical director had ensured the facility's quality assessment performance</p>	V 0710	The Medical Director of this facility takes seriously his responsibility to ensure the facility's Quality Assessment Performance Improvement Program	05/21/2016

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	<p>improvement (QAPI) program addressed all aspects of the facility's physical plant and environment creating the potential to affect all of the facility's 62 current patients (See V 712); by failing to ensure the medical director had ensured the biomedical technician had received sufficient training to ensure competence in the performance of the biomedical job duties creating the potential to affect all of the facility's 62 current incenter patients (See V 713); and by failing to ensure the medical director had ensured as needed (prn) medications had been administered and documented in accordance with facility policy in 1 of 1 record reviewed of patients that received as needed medications and failed to ensure the facility's care of the hepatitis B positive patient was in accordance with facility policy in 1 of 1 hepatitis positive B patient on census (See V 715).</p> <p>The cumulative effect of these systemic problems resulted in the facility being found out of compliance with this condition, 42 CFR 494.150 Responsibilities of the Medical Director.</p>		<ul style="list-style-type: none"> ·Addresses allaspects of the facility's physical plant and environment, ·Ensure that theall staff, inclusive of the bio medical technician is trained, proficient andcompetent in their job functions ·Ensures PRN medicationsare administered and documented in accordance with facility policy <p>As such, he has agreed toactively participate in the weekly Governing Body meetings and has been activelyinvolved in the development and the implementation of the corrective actions asstated in this Plan of Correction including:</p> <ul style="list-style-type: none"> ·A review of hisresponsibilities to provide oversight to the Quality Assessment and ImprovementProgram including: ·To ensure thatthe condition of the physical environment is routinely evaluated and maintainedto ensure a clean, safe and sanitary environment for 		

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			<p>patients, staff andvisitors at all times</p> <ul style="list-style-type: none"> ·To provide oversightto staff education, training and performance of all facility staff, includingthe bio medical technician ·To provide oversightto ensure patient care, infection control and patient safety policies andprocedures are strictly adhered to by the direct patient care staff withemphasis on PRN medication administration and documentation <p>Documentation of theMedical Directors review will be maintained available for review at thefacility</p> <ul style="list-style-type: none"> ·In conjunction withthe Governing Body, directed staff reeducation on: <ul style="list-style-type: none"> ·PhysicalEnvironment: (Refer to V 712) ·Staff Education, Training and Performance: (Refer to V 713) ·PRN medication administrationand documentation: (Refer to V 715) <p>Documentation of the staffreeducation will be</p>	

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			<p>maintained available for review at the facility</p> <ul style="list-style-type: none"> ·Directed actionsand monitoring processes related to the Physical Plant/Environment (Referto V 712) ·Directed immediate actionsand monitoring processes related to the biomedical technician: (Refer to V 713) ·Directedimmediate actions and monitoring processes related to PRN MedicationAdministration and Documentation (Refer to V 715) <p>Results of the statedaudits and monitoring processes will be summarized to the GB during the weeklyscheduled calls and to the QAI Committee monthly</p> <p>The QAI Committee willanalyze the data and assess for trends, if trends are identified, the QAICommittee may direct changes to this action plan as warranted</p> <p>The QAI Committee will beresponsible to review this Plan of Correction monthly</p>	

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V 0712 Bldg. 00	<p>494.150(a) MD RESP-QAPI PROGRAM Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program.</p> <p>Based on record review and interview, the medical director failed to ensure the facility's quality assessment performance improvement (QAPI) program addressed all aspects of the facility's physical plant and environment creating the potential to affect all of the facility's 62 current patients.</p> <p>The findings include:</p> <p>1. The facility's QAPI meeting minutes, dated 12-15-15, 1-19-16, 2-16-16, and 3-15-15, failed to evidence the facility had evaluated the condition of the facility's physical environment to include the floor, the dialysate mixing area, and equipment used on the treatment floor.</p> <p>A. On 4-15-16 at 10:15 AM, the following observations were made:</p>	V 0712	<p>x 12 consecutive monthsto ensure sustained compliance The Governing Body, ofwhich the Medical Director is a member, will provide direct oversight</p> <p>To ensure that the MedicalDirector fully understands his responsibility to ensure the QAPI programappropriately and timely addresses all aspects of the facility's physical plantand environment,</p> <p>·On or before May17, 2016, the Regional Quality Manager will review with the Medical Director,his responsibility to provide oversight to the Quality Assessment andImprovement Program including, but not limited to ensuring that the conditionof the physical environment is routinely evaluated and maintained</p>	05/21/2016

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	<p>1.) A large gray stain was noted on the floor between the 2 machines at stations 15 and 16.</p> <p>2.) A rust-colored stain was observed on the front of the dialysis machine at the port where the dialysate hoses are connected to the machine and running down the front of the machines at stations 14, 15, and 16.</p> <p>3.) A dark gray stain approximately 2 tiles by 3 tiles in size was observed on the floor between the dialysis machine and chair at stations numbered 11 and 12.</p> <p>4.) A dark gray stain was observed on the floor approximately 3 tiles long and 1/2 tile wide between stations 10 and 11 next to the chase cabinet along the wall.</p> <p>5.) At station 10 observation noted a dark gray stain on the floor approximately 2 tiles by 6 tiles in size.</p> <p>6.) A dark gray stain was noted on the floor approximately 2 tiles by 3 tiles between the tiles at station number 8.</p> <p>7.) At stations 6 and 7 a dark gray stain approximately 3 tiles by 9 tiles in</p>		<p>to ensure a clean, safe and sanitary environment for patients, staff and visitors at all times</p> <p>Documentation of the Medical Director review will be maintained available for review at the facility</p> <p>In addition, the Medical Director as head of the GB directed and/or actively participated in the following immediate facility actions:</p> <ul style="list-style-type: none"> · Actively participated in the development and implementation of this Plan of Correction · Agreed to meet weekly with the Governing Body for the next 2 months to review continued adherence to the action plan and ensure compliance is achieved and sustained <p>The Medical Director and Governing Body directed the following staff reeducation:</p> <ul style="list-style-type: none"> · On or before May 12, 2016 all DPC staff will receive reeducation and reinforcement on Housekeeping Policy FMS-CS-IC-11-155-116A with emphasis on the responsibility of each staff member to maintain a 	

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	<p>size was observed.</p> <p>8.). At station number 6 a rust colored stain on the front of the machine from the port where the dialysate hoses are connected down the front of the machine was observed.</p> <p>9.). The machines at stations numbered 3, 4, and 5 evidenced rust colored stains on the front of the machine from the dialysate hoses ports down the front of the machines.</p> <p>10.) Observation noted gray stains between the tiles approximately 3 tiles by 4 tiles at stations numbered 3 and 4. A gray smattered stain approximately 3 by 3 tiles was observed at station number 3.</p> <p>11.). A 3 by 6 tile gray smattered stain was observed on the floor at station number 1.</p> <p>12.). Observation noted 3 portable oxygen tank holder on wheels near the scale. Observation noted rusted areas around the cylinder holders, on the wheels, and on the handle of the holder.</p> <p>13.). At 10:40 AM, observation noted rust colored stains on the dialysis machines at stations numbered 17 and 18. Observation also noted dark gray stains</p>		<p>clean, sanitary and comfortable environment for patients,staff and visitors</p> <p>·On or before May 17,2016 will provide reeducation to the facility's Area Technical OperationsManager and the Bio Medical Technician on the appropriate use and documentationrequirements of the facility's QAI Physical Environment Audit Checklist</p> <p>·On or before May 17,2016 the Regional Quality Manager will provide reeducation to the QAI Committeemembers on their responsibility to provide direct oversight to evaluation ofphysical environment issues with timely development of corrective actions toresolve the issues</p> <p>·The Medical Director willsign the QAI Physical Environment Audit Tool monthly as verification that thetool was appropriately reviewed in the QAI meeting with discussion and timelydevelopment of corrective actions to address identified issues</p> <p>Documentation of thereeducation will be maintained available for review at the facility</p> <p>The</p>	

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	<p>approximately 3 by 5 tiles in size.</p> <p>14.). Observation noted on another clean sink a large amount of water on the counter tops surrounding the sink. A rough coating was worn away from large areas of the countertop on either side of the sink.</p> <p>15.). Observation noted a cart on wheels with 2 shelves used to store dialysate jugs. A rust colored stain was observed to cover the entire bottom shelf. The posts between the shelves were covered in a white substance in a drip pattern.</p> <p>B. On 4-15-16 at 11:30 AM, the following observations were made in the dialysate preparation area:</p> <p>1.). The floor around and under the bicarbonate tank was covered in a white powdery substance. Observation noted used test strips on the floor directly in front of the bicarbonate tank and on the floor in the doorway from the hall to the preparation area.</p> <p>2.). Observation noted 2 large acid storage tanks in the area. A white crystalline substance was observed on the top of the first tank.</p>		<p>MedicalDirector/Governing Body directed the following immediate facility level actions:</p> <ul style="list-style-type: none"> ·On or before May17, 2016 the Clinical Manager in conjunction with the Area Technical OperationsManager will be responsible to develop and implement formal action plansrelated to the identified physical environment issues as identified in theStatement of Deficiencies: ·On April 22, 2016the DPC staff and Janitorial staff thoroughly swept and cleaned the treatmentfloor, thus removing: <ul style="list-style-type: none"> ·The debrisincluding test strips, pieces of whitepaper, 2x2 gauze pads, unopened alcohol prep pads, opened betadinepackage, needle caps, blue glove, (3)blue chux, blue tourniquet, syringe package, candy bar wrapper and clamp fromthe floor ·On April 22, 2016the DPC staff thoroughly 				

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	<p>3.). Observation noted a white rectangular plastic container on the floor in front of the first tank with a large amount of a white crystalline substance covering the bottom of the container.</p> <p>4.). A dirty, white crystalline substance was observed on the floor all around the 2 tanks. The tanks were sitting up on round, cone shaped black holders. The floor beneath the holders was visible. A large amount of a brown, crystalline substance was observed on the floor under the tanks with a stalactite type of formation hanging from the bottom of the tank reaching to the floor approximately 3 to 4 inches. Observation noted multiple pieces of a white crystalline substance in the shape of pencils on the floor near the formation.</p> <p>5.). A black supply storage shelving unit was observed next to the acid tanks. The shelving was covered in a dry white substance. Observation noted 31 boxes of syringes, boxes of gloves, and boxes of personal care wash cloths stored on the shelving unit.</p> <p>C. On 4-15-16 at 1:20 PM, observation noted at station number 7 the floor tiles in front of the chase cabinet were cracked and torn.</p>		<p>cleaned and disinfected the dialysis chair at station# 16, removing the blood from the chair arm and side table</p> <ul style="list-style-type: none"> ·On April 19, 2016the facility staff thoroughly cleaned and swept the water room and dialysatemixing area, thus removing: <ul style="list-style-type: none"> ·The white powderysubstance under and around the bicarbonate tank ·The used teststrips directly in front of the bicarbonate tank and in the doorway from thehall to the preparation area ·The whitecrystalline substance on the top of the first acid storage tank ·The dirty, whitecrystalline substance on the floor all around the 2 acid storage tanks ·The dry whitesubstance on the black supply storage shelving unit next to the acid tanks ·The dirty, browncrystalline substance and the stalactite formation under the acid storage tanks 		

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	<p>D. On 4-18-16 at 8:20 AM, the following observations were made:</p> <p>At station number 16, observation noted 1/2 of a piece of the floor tile was missing next to the chase cabinet. Bare concrete was visible.</p> <p>E. On 4-18-16 at 11:30 AM, observation noted a white box approximately 12 inches by 18 inches on the counter at the medication preparation area. The box had a fold down door. Multiple rusted areas and tape residue were observed on the outside and the inside of the door and the box. The box was lined with white Styrofoam that was stained a rust color. Multiple medications to be administered to patients intravenously were stored in the box.</p> <p>F. On 4-22-16 at 8:35 AM, observation noted the floor tile was chipped in the doorway to the stockroom. The bottom of the door frame on both sides was worn away and rusted.</p> <p>2. The clinic manager stated, on 4-22-16 at 1:10 PM, "The physical plant portions of the QAPI meeting minutes do not include any discussion of the floors and equipment. They are aware but kept putting it off due to the possibility of</p>		<ul style="list-style-type: none"> ·The multiplewhite crystalline pencil shaped substances from the floor around the stalactiteformation ·The whitecrystalline substance on top of the acid storage tank ·The large amountof water and soap on and around the sinks and countertops <p>In addition as directed bythe Medical Director and GB,</p> <ul style="list-style-type: none"> ·On or before May20, 2016 the ATOM and/or Bio-Medical technician removed the rust on front ofmachine #s 3, 4, 5, 6, 7, 14, 15, 16, 17 and 18 ·On or before May20, 2016 the ATOM discarded and replaced the cart on wheels with 2 shelves withvisible rust on the bottom shelf and white substance on the post between theshelves ·On or before May20, 2016 the ATOM will remove and replace the (3) portable Oxygen tank holderswith 				

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	<p>getting a new building."</p> <p>3. The Medical Director stated, on 4-22-16 at 11:30 AM, "The condition of the building is bad. We are high on the list to get it fixed, I think."</p> <p>4. The facility's 4-4-12 "Quality Assessment and Performance Improvement Program (QAPI) policy number FMS-CS-IC-I-101-001A states, "Elements to be reviewed in the QAI meeting include: . . . Technical Operations."</p>		<p>visible rust</p> <ul style="list-style-type: none"> ·On or before May11, 2016 the Director of Operations and the ATOM met with Ideal ConstructionCo. to obtain estimate for removal and replacement of the damaged, worncountertop at the sink. Estimatedcompletion date is June 1, 2016. ·On or before May20, 2016 the ATOM will remove, discard and replace the IV medication storagebox at the med prep area ·On or before May11, 2016 the Director of Operations and the ATOM met with Ideal ConstructionCo. to obtain estimate to replace flooring in the treatment area and hallwaythus removing the dark gray stained, chipped and missing floor tiles. Estimated completion date is June 1, 2016 ·On or before May20, 2016 the ATOM removed and replaced the white, rectangular, plastic box onthe floor in front of the 	

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			<p>first acid tank</p> <ul style="list-style-type: none"> ·On or before May11, 2016 the Director of Operations and the ATOM met with Ideal ConstructionCo. to order a replacement door forthe doorway to the stockroom. Estimated date of installation is June1, 2016 <p>The Clinical Manager is responsibleto ensure that the facility is maintained clean, sanitary and comfortable atall times</p> <p>To monitor and to preventreoccurrence,</p> <ul style="list-style-type: none"> ·On or before May17, 2016 the Clinical Manager or designee developed and implemented a daily,weekly and monthly staff cleaningassignment schedule to include the treatment area, the water room, and thedialysate mixing area ·The AreaTechnical Operations Manager is responsible to complete the FMC QAI 	

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			<p>PhysicalEnvironment Audit Tool monthly</p> <ul style="list-style-type: none"> Effective May 17,2016 the Clinical Manager and/or Director of Operations will be responsible toconduct a walkthrough of the dialysis facility, inclusive of the treatmentarea, the water room and the dialysate mixing area daily x 4 weeks, weekly x 4weeks, then monthly x 4 months or until 100 % compliance is achieved andsustained as determined by the Governing Body Committee CM or Director ofOperations is responsible to provide a summary of the facility walkthroughassessment findings and any identified issues of staff compliance to the GBcommittee weekly and to the QAI Committee monthly <p>The ATOM will present aweekly update to the Governing Body Committee on the physical plant correctiveactions as stated in this action plan until full</p>	

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			<p>resolution of all issues is achieved</p> <p>The ATOM will present the findings of the QAI Physical Environment Audit Tool to the QAI Committeemonthly for review, discussion with development and implementation of corrective actions to ensure complete resolution of identified issues</p> <p>The Medical Director will be responsible to sign the QAI Physical Environment Audit Tool monthly during the QAI meeting as verification of QAI Committees' discussion with timely and appropriate development and implementation of corrective actions as warranted by the walkthrough and audit findings</p> <p>The QAI Committee will analyze the findings and assess for trends. If trends are identified, the QAI Committee will assist</p>	

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V 0713 Bldg. 00	<p>494.150(b) MD RESP-STAFF ED, TRAINING & PERFORM Medical director responsibilities include, but are not limited to, the following: (b) Staff education, training, and performance. Based on record review and interview, the medical director failed to ensure the biomedical technician was had received sufficient training to ensure competence in the performance of the biomedical job duties creating the potential to affect all of the facility's 62 current incenter patients.</p> <p>The findings include:</p> <p>1. On 4-18-16 at 1:00 PM, the facility's water and preventative programs were reviewed with employee Q, the biomedical technician for the facility.</p>	V 0713	<p>withdetermination of root cause and direct changes to this action plan as warranted</p> <p>The Governing Body will providedirect oversight</p> <p>The Governing Body may recommend changes tofacility processes as necessary to sustain compliance</p> <p>On or before May 17, 2016the Regional Quality Manager will review with the Medical Director, hisresponsibility to provide oversight to staff education, training andperformance</p> <p>A copy of the MedicalDirector review will be maintained available for review at the facility</p> <p>The Medical Director isresponsible for the safety and quality of the water used</p>	05/21/2016	

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	<p>A. The product water microbial and endotoxin results for January 2016 through April 2016 were reviewed. The biomedical technician was unable to verbalize the acceptable limits for either the microbial results (lower than 200 CFU/mL) or the endotoxin results (2 EU/mL.)</p> <p>B. The biomedical technician was unable to verbalize the facility's contingency plans to cover the failure of its water purification system.</p> <p>C. The facility's daily "RO Machine Log" for January 2016 through April 2016 was reviewed. The biomedical technician was unable to verbalize what value on the log measured the product water quality.</p> <p>D. The biomedical technician was able to verbalize that deionization (DI) would be used in the event of the failure of the facility's reverse osmosis machine. The biomedical technician was unable to verbalize how the water quality would be monitored and that the DI should not be used if the resistivity fell below 1 megohm.cm.</p> <p>2. The biomedical technician, employee Q, indicated she had been a biomedical technician for "just over a year." The</p>		<p>for patient treatments</p> <p>The Medical Director of this facility takes seriously his responsibility to ensure that facility staff responsible for water treatment maintenance is proficiently educated to the facility's policies and procedures and that the staff is properly monitored for adherence. As such, the Medical Director implemented the following measures:</p> <ul style="list-style-type: none"> · On May 9, 2016 the bio-medical technician was prohibited from conducting water treatment maintenance task as detailed in this citation until knowledge and proficiency is demonstrated and documented with approval of the Governing Body · As of May 9, 2016 the ATOM assumed the bio medical responsibilities at this facility in the areas cited in the Statement of Deficiencies pending demonstrated and documented knowledge and proficiency of the Bio 	

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	<p>technician indicated she received a week of classroom training and the "on the job training". The technician stated, "I can call my supervisor [employee U, the Area Technical Operations Manager] any time when I have questions. I do call him when I need to."</p> <p>3. Employee U, the Area Technical Operations Manager, stated, on 4-21-16 at 10:35 AM, "[Employee Q] was just very nervous when you interviewed her. She really does know all of this stuff. She can tell me everytime I ask her a question. We have not had any problems at this facility. She calls me all the time with questions and never does anything she is not sure of without calling me." The manager was unsure how employee Q would react if an urgent situation arose in the facility and there was not time to call for help.</p> <p>4. The facility's administrative records included documentation of the biomedical technician training provided to employee Q. The records evidenced employee Q completed the biomedical technician training on 10-31-2014 and had been re-evaluated for the competent performance of her job duties on 7-21-2015.</p>		<p>Medical Technician with approval of the Governing Body to resume fullresponsibilities of the Bio Medical Technician role</p> <p>In addition as directed bythe Medical Director and the Governing Body, the ATOM will be responsible toconduct a weekly walkthrough of the water room with the Bio Medical Technicianbeginning, May 10, 2016 to assess her knowledge and ability to articulate thewater system components, functions and her responsibilities as the Bio MedicalTechnician of this facility inclusive of, but not limited to:</p> <ul style="list-style-type: none"> ·Acceptable limitsfor microbial results (cultures and endotoxins) ·Facility'sAlternative Water Supply/Contingency Plan to cover the failure of the WaterPurification system ·The RO logdocumentation, specifically the percent rejection ·Proper use of Dltanks in 		

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			<p>the event of RO failure, inclusive of safe resistivity level > 1meghohm.cm</p> <p>The Bio Medical Technician will be given a post quiz weekly following his walkthrough of the water room with the ATOM. In addition, on or before May 10, 2016, the Bio Medical Technician will be required to complete a Bio MedTech competency exam specifically related to the Bio Med Tech position responsibilities dealing with water treatment. A copy of the competency exam and the weekly quizzes will be maintained available for review at the facility.</p> <p>The ATOM is responsible to provide a summary of the results of the weekly walkthrough and the Bio Med Tech quiz and competency exam results to the GB weekly and the QAI Committee monthly. Identified deficient areas will require retraining with</p>	

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V 0715 Bldg. 00	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; Based on record review and interview, the medical director failed to ensure as needed (prm) medications had been administered and documented in accordance with facility policy in 1 (#s 3) of 1 record reviewed of patients that received as needed medications and failed to ensure the facility's care of the hepatitis B positive patient was in accordance with facility policy in 1 (#6)	V 0715	appropriate documentation The QAI Committee willanalyze the findings and assess for trends. If trends are identified, the QAI Committee will assist with determinationof root cause and direct changes to this action plan as warranted The Governing Body willprovide direct oversight The Governing Body may recommend changes tofacility processes as necessary to sustain compliance On May 17, 2016 theRegional Quality Manager met with the Medical Director to review the hisresponsibility to provide direct oversight to ensure patient care, infectioncontrol and patient safety policies and procedures are strictly adhered to bythe direct patient care staff	05/21/2016

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	<p>of 1 hepatitis positive B patient on census.</p> <p>The findings include:</p> <p>Regarding PRN medications:</p> <ol style="list-style-type: none"> 1. Clinical record number 3 included a hemodialysis treatment flow sheet dated 4-11-16 that evidenced the registered nurse (RN), employee D, had administered Nitroglycerin 0.4 to the patient at 12:54 PM for complaints of "chest pain." The documentation failed to evidence the intensity of the chest pain, the exact location, the type of pain, or any other associated symptoms. At 1:00 PM, the RN documented "feeling somewhat better." The documentation failed to evidence a description of the patient's pain or any other associated symptoms at this time. 2. The clinic manager was unable to provide any additional documentation and/or information when asked on 4-22-16 at 10:20 AM. 3. The facility's 1-28-15 "Medication Preparation and Administration" policy number FMS-CS-IC-I-120-040A states, "Document all patient symptoms leading to PRN drug administration and patient's response to the PRN medication 		<p>To ensure that PRN medications are administered and documented in accordance to facility policy,</p> <p>On, May 12, 2016 the Education Coordinator reeducated the Registered Nursing staff on Medication Administration and documentation requirements specifically related to PRN medication administration including, but not limited to:</p> <ul style="list-style-type: none"> · Documentation of the patient's complaint /reason for the PRN medication administration (i.e, type of pain, exact location of the pain, intensity of pain, or any other associated symptoms relating to the pain) · Documentation of post PRN medication administration/ follow up patient evaluation <p>Documentation of the staff education will be maintained available for review at the facility</p>	

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	<p>on treatment sheet or electronic medical record."</p> <p>Regarding the care of a hepatitis B positive patient:</p> <ol style="list-style-type: none"> 1. On 4-18-16 at 8:25 AM, observation noted patient number 6 was receiving a dialysis treatment in the isolation room. The patient was identified as being hepatitis B positive by employee K, the patient care technician (PCT) assigned to provide care to the patient. The facility's "Hepatitis Summary Report" dated 4-18-16 identified patient number 6 as hepatitis B positive. 2. Employee F, a registered nurse (RN), indicated, on 4-18-16 at 8:30 AM that she was the charge nurse today and was assigned to all of the patients on the treatment floor during the first shift, including patient number 6. The nurse indicated her duties included assessments, medication administration, putting orders in the computer, call the doctors, "do whatever they tell me to do." The RN stated, "I give [patient number 6] medications last." Observation noted that patients numbered 7, 8, 9, 10, and 11 were also receiving a dialysis treatment at the same time as the patient in the isolation room and were included in the charge nurse's assignment. 		<p>To monitor for complianceto the PRN medication administration and documentation process and to preventreoccurrence, as directed by the Medical Director and Governing Body,</p> <p>The Clinical Manager ordesignee will be responsible to audit patient treatment sheets 100% for PRNmedication administration and documentation daily until 100% RN staffcompliance is achieved and sustained as determined by the GB The Clinical Manager ordesignee will provide a summary of RN staff compliance to PRN medicationadministration and documentation to the GB weekly and to the QAI Committeemonthly</p> <p>The QAI Committee willanalyze the findings and assess for trends. If trends are identified, the QAI Committee will assist withdetermination of root</p>	

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	<p>3. The facility's "Hepatitis Summary Report", dated 4-18-16 identified patients numbered 7, 8, 9, 10, and 11 as susceptible, having an antibody value of less than 10 and identified patient number 6 as hepatitis B positive.</p> <p>A. Clinical record number 6 (the record of the hepatitis B positive patient) included a hemodialysis treatment flow sheet dated 4-18-16 that evidenced employee F, the charge RN, had administered an intravenous medication to the patient at 7:38 AM and had performed intradialytic vital sign checks on the patient at 8:00 AM and 8:30 AM.</p> <p>B. Clinical record number 7 (the record of a hepatitis B susceptible patient) included a hemodialysis treatment flow sheet dated 4-18-16 that evidenced employee F, the charge RN, had administered an intravenous medication to the patient at 7:40 AM.</p> <p>C. Clinical record number 8 (the record of a hepatitis B susceptible patient) included a hemodialysis treatment flow sheet dated 4-18-16 that evidenced employee F, the charge RN, had performed a nursing evaluation on the patient at 6:02 AM.</p>		<p>cause and direct changes to this action plan as warranted</p> <p>The Governing Body will provide direct oversight</p> <p>The Governing Body may recommend changes to facility processes as necessary to sustain compliance</p> <p>To ensure that patient/staff assignments reflect compliance with Hepatitis B positive and buffer zone requirements, the following actions have occurred:</p> <ul style="list-style-type: none"> · On April 18, 2016, Education Coordinator and Clinical Manager · Reviewed daily staff assignment to ensure one nurse is assigned to provide care to Hepatitis B positive patients and Hepatitis B antibody positive (titer > 10) patients in the buffer zone only · 100% audit of treatment sheets to identify susceptible patients who were potentially placed at risk for cross contamination on April 18, 2016 · On April 19, 2016 the Education Coordinator provided reeducation to all direct patient care staff on · FMS-CS-IC-11-155-140A Dialyzing Patients with Positive Hepatitis B Antigen policy · FMS-CS-IC-1-500-075A Hepatitis Policy 	

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	<p>D. Clinical record number 9 (the record of a hepatitis B susceptible patient) included a hemodialysis treatment flow sheet dated 4-18-16 that evidenced employee F, the charge RN, had performed a nursing evaluation at 6:20 AM and had verified the use of oxygen by the patient at 7:54 AM.</p> <p>E. Clinical record number 10 (the record of a hepatitis B susceptible patient) included a hemodialysis treatment flow sheet dated 4-18-16 that evidenced employee F, the charge RN, had administered an intravenous medication and an oral medication to the patient at 7:55 AM.</p> <p>F. Clinical record number 11 (the record of a hepatitis B susceptible patient) included a hemodialysis treatment flow sheet dated 4-18-16 that evidenced employee F, the charge RN, had performed a nursing evaluation at 7:02 AM and had administered an intravenous medication to the patient at 8:05 AM.</p> <p>4. The clinic manager stated, on 4-18-16 at 12:25 PM, "I thought since she [the charge RN, employee F] gave [patient number 6] medications last, it was ok. She doesn't go back in there [into the isolation room]."</p>		<p>A copy of the staff education will be maintained available for review at the facility</p> <p>Additionally, and to ensure that seroconversion of the susceptible patient has not occurred; the Medical Director will complete the following actions:</p> <ul style="list-style-type: none"> · On April 18, 2016, the Medical Director agreed to review the following lab reports of the susceptible patient who potentially received care by staff caring for patients in the buffer zone for a minimum of the next 4 months · Hepatitis B antigen as well as the most recent Alanine Aminotransferase (ALT) results to determine if patients have any indications of active hepatitis B infection. <p>To prevent reoccurrence and to ensure that each staff member is fully aware of the facility's policy regarding dialyzing patients with positive Hepatitis B Antigen, the following</p> <ul style="list-style-type: none"> · Beginning immediately the Clinical Manager is responsible to ensure staff caring for Hepatitis B antigen positive patient care only for Hepatitis B antibody (titer >10) patients at the same time · Beginning April 18, 2016, each staff member will be provided 				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152503	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 04/22/2016
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	<p>5. The facility's 3-20-13 "Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+)" policy number FMS-CS-IC-II-155-140A states, "Staff having any contact with the HBsAg positive patient must at the same time have NO contact with susceptible patients."</p> <p>6. The facility's 9-25-13 "Hepatitis Policy" number FMS-CS-IS-I-500-075A states, "Known HBsAg positive . . . May be cared for by the same staff member that cares for the patient with known hepatitis B antibodies (Ant-HBs [greater than or equal to] 10mlU/mL) . . . Staff caring for known HBsAg positive . . . Staff members an be assigned to care for both HBsAg positive and HBV protected (Anti-HBs [greater than or equal to] 10mlU/mL patients on the same shift."</p>		<p>education on Hepatitis and the BufferZone by the Education Coordinator. This education will continue with an expected completion date of April 19, 2016. Included in this educationare the following Hepatitis B policy and procedure:</p> <p>·FMS-CS-IC-II-155-140ADialyzing Patients with Positive Hepatitis B Antigen (HBsAg+) Policy</p> <p>The Clinical Manageris responsible to monitor for compliance and will provide oversight directly orthrough an assigned designee to monitor staff assignment and practice to ensurethat patient/staff assignments reflect compliance with Hepatitis B positive andbuffer zone requirements. Additionally, theGoverning Body will meet weekly for the next 2 months to review continuedadherence to the action plan and ensure compliance is achieved and sustained.</p>	