STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152525	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING	(X3) DATE SURVEY COMPLETED 05/01/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FRESENIUS MEDICAL CARE INDIANAPOLIS NORTH	1225 W 86TH ST INDIANAPOLIS, IN 46260

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V0000	This was a federal recertification and relocation survey. Survey dates: April 23, 24, 25, 26, 27, and 30 and May 1, 2012. Facility: 005139 Medicaid Vendor: 100217180A Surveyor: Vicki Harmon, RN, PHNS An immediate jeopardy was identified on 4-27-12. The Director of Operations was notified of the immediate jeopardy on 4-27-12 at 3:20 PM. The Immediate Jeopardy remained unremoved at the survey exit. Fresenius Medical Care Indianapolis North was found to be out of compliance with Conditions for Coverage 42 CFR 494.30 Infection Control related to the immediate jeopardy. Quality Review: Joyce Elder, MSN, BSN, RN May 4, 2012 In addition, Fresenius Medical Care	V0000	Unable to post 0V544 and 0V562 unable to postNo report available for Life Safety Code Survey completed on 5/14/2012	

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

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

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	Indianapolis North was found to be out of compliance with the Conditions for Coverage 42 CFR 494.60 Physical Environment, 494.90 Patient Plan of Care, 494.110 Quality Assurance and Performance Improvement, and 494.150 Responsibilities of the Medical Director. Quality Review: Joyce Elder, MSN, BSN, RN May 15, 2012			

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V0110	494.30 CFC-INFECTION CONTROL Based on observation, interview, administrative record and clinical record review, and facility policy review, it was determined the facility failed to ensure infection control policies and procedures had been implemented and patients protected from the spread of the hepatitis B virus by failing to ensure staff changed gloves and performed hand hygiene appropriately during the provision of care in 6 of 10 patient care observations creating the potential to affect all of the facility's 124 current patients (See V 113); by failing to ensure personal protective equipment was utilized appropriate in 2 of 10 patient care observations creating the potential to affect all of the facility's 124 current patients (See V 115); by failing to ensure appropriate bleach solutions were readily available on 3 of 3 days observed creating the potential to affect all of the facility's 124 current patients (See V 122); by failing to ensure hepatitis antibody status was known for 23 of 91 hepatitis records reviewed and failed to ensure monthly antigen testing had been completed for 21 of 46 patients known to be susceptible or whose antibody status was unknown creating the potential to affect all of the facility's 92 current incenter patients (See V 124); by failing to ensure all susceptible patients had been	V0110	As a result of the citations from the May 1 st survey and as part of the developed plan of correction, the following corrective actions have been implemented: ·Implemented an intensive monitoring process, reeducated staff and reinforced the mandatory requirement of direct patient care staff to comply with all aspects of the facility's hand hygiene policy. Please refer to V-113 ·Implemented an intensive monitoring process, reeducated staff and reinforced the mandatory requirement of direct patient care staff to comply with all aspects of the facility's PPE program. Please refer to V-115 ·Implemented a daily assignment for preparation of bleach solutions, along with an intensive monitoring process, reeducated staff and reinforced the mandatory requirement of direct patient care staff to comply with all aspects of the facility's cleaning and disinfection policy daily to ensure readily available bleach solution.	05/01/2012

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	offered the vaccine against hepatitis B in 6 of 15 susceptible patient records reviewed creating the potential to affect all of the facility's 92 current incenter patients (See V 126); by failing to ensure anti-HB testing was completed for 5 of 13 patients that completed the primary vaccine series creating the potential to affect all of the facility's 92 incenter patients (See V 127); and by failing to ensure staff assigned to care for hepatitis B positive patients did not care for hepatitis B susceptible patients at the same time in 13 of 46 patients known to be susceptible or whose antibody status was unknown creating the potential to affect all of the facility's 92 current incenter patients (See V 131). The cumulative effect of these systemic problems resulted in the facility's inability to meet the requirements of the Condition for Coverage 42 CFR 494.30 Infection Control. Thes findings at V131 resulted in the determination that an Immediate Jeopardy existed. The immediate jeopardy was identified on 4-27-12. The Director of Operations was notified of the immediate jeopardy on 4-27-12 at 3:20 PM. The Immediate Jeopardy remained unremoved at the survey exit due to the facility's failure to ensure staff were not assigned to		Please refer to V-122 ·Reeducation of the Clinical Manager and reinforcement their responsibility to ensure that the hepatitis antigen status of each patient is known and each patient is managed in accordance to facility policy. Please refer to V-124 ·Reeducation and the reinforcement of the Clinical Manager's responsibility to monitoring of Hepatitis Lab results and ensure the administration of the hepatitis vaccine as prescribed. Please refer to V 126 ·Implemented a monitoring process through QAI to ensure that patients who are susceptible to HBV and have consented to be inoculated against Hepatitis B virus are offered and receive the full vaccination series. Refer to V127 ·Reeducation of the Facility Management and Direct Patient Care staff along with reinforcement of the mandatory requirement to maintaining a buffer zone to ensure that staff assigned to the care of the Hepatitis B positive patient only care for patients with verification of HBsAb. Please refer to V-131	

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	care for hepatitis B positive patients at the same time as susceptible and/or status unknown patients.		The staff education, implemented monitoring processes, and the staff/patient assignments document these corrective actions and are available at the facility for review. The Director of Operations and Governing Body takes seriously its' responsibility to ensure that dialysis and support services are delivered in a manner which – at all times - ensures the health and safety of its patients. As such, the Governing Body, which includes the facility's Medical Director, met on May 1, 2012, to review the surveyor's comments made during the exit interview and to formulate a corrective action plan to bring this facility into compliance with the ESRD Conditions of Coverage. The Governing Body met again on May 15, 2012, after the receipt of the Statement of Deficiencies, to review the citations and to formulate a corrective action plan to bring this facility into compliance with the ESRD Conditions of Coverage.	

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			The Governing Body has committed to weekly Governing Body meetings. Upon Governing Body determination of facility compliance, the Governing Body will meet monthly for an additional six months and revert to is routine meeting schedule if no reoccurrence of infection control deficiencies are identified	

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V0113	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station. Based on observation, interview, and facility policy and daily log review, the facility failed to ensure staff changed gloves and performed hand hygiene appropriately during the provision of care in 6 (#s 2, 4, 6, 7, 8, and 9) of 10 patient care observations creating the potential to affect all of the facility's 124 current patients. The findings include: 1. The facility's 1-4-12 "Infection Control Overview" policy number FMS-CS-IC,II,155-060A states, "All infection control policies are consistent with recommendation of the Centers for Disease Control (CDC). All infection control policies will adhere to CMS and OSHA rules and regulation . . . Mandatory Components of Program: Adherence to standard and dialysis precautions . . . Infection control training and education, including maintenance of training records . . . Infection Control Policies: . . . Hand Hygiene, Dialysis unit precautions (including the use of personal protective equipment) . . . Rinsing,	V0113	As a result of the citations from the April 23 – May 1, 2012 CMS Recertification and Relocation survey and to ensure that the facility fully complies with the Centers of Disease Control and Prevention guidelines to decrease the transmission of infection within the dialysis facility in regards to the use of gloves and hand hygiene, the following corrective actions have been implemented by the Governing Body and facility management team: · On May 1, 2012, the Regional Vice President presented the preliminary findings of the survey to all facility staff. Reinforced during this meeting was the expectation of compliance of facility staff to fully comply with all aspects of the facility Infection Control Polices inclusive of: o Hand Hygiene, o Glove usage o Dialysis Precautions	05/01/2012

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	cleaning, disinfection, preparation, and storage of reused items conforming to CMS requirement for use." A. The facility's 1-4-12 "Hand Hygiene" policy number FMS-CS-IC-II-155-090A policy 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 . . . Immediately after removing gloves, After contact with body fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly soiled, After contact with inanimate objects near the patient, When moving from a contaminated body site to a clean body site of the same patient." B. The facility's 1-4-12 "Personal Protective Equipment" policy number FMS-CS-IC-II-155-080A policy states, "Change gloves and practice hand hygiene between each patient contact and/or station to prevent cross-contamination. Remove gloves and wash hands after each patient contact . . . Avoid touching surfaces with gloves hands that will be touched with ungloved hands (for ex. patient charts and computers)." 2. The CDC Morbidity and Mortality Weekly Report (MMWR) October 25,		· On May 16 th upon receipt of the Statement of Deficiencies, the Director of Operations further reinforced with each direct patient care staff member their obligation to comply with the facility polices, procedures and CDC's guidelines to prevent the transmission of infections in the dialysis setting. On April 27, 28 and 30, 2012 the facility's management team in conjunction with the Education Coordinator developed and presented the following Infection Control reeducation for all direct patient care staff. · Reeducation and reinforcement on Blood borne Pathogen Program and Infection Control Policy: Hand Hygiene; FMS-CS-IC-II-155-090A, · Reeducation and reinforcement on Bloodborne Pathogen Program and Infection Control Policy: Dialysis Precautions; FMS-CS-IC-II-155-080A · Personal Protective Equipment FMS-CS-IC-II-155-080 with emphasis on glove usage.	

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	2002, Volume 51 No. RR-16 "Guideline for Hand Hygiene in Health-Care Setting" states, "Recommendations: Indications for handwashing and hand antisepsis . . . Decontaminate hands before having direct contact with patients . . . Decontaminate hands after contact with a patient's intact skin . . . Decontaminate hands if moving from a contaminated body site to a clean body site during patient care. Decontaminate hands after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient. Decontaminate hands after removing gloves." 3. Patient care observation number 2 was completed on 4-23-12 at 2:00 PM. Employee G, a patient care technician (PCT), was observed to touch the machine at station # 20 (patient number 1) and hand a glove to patient number 1. The employee changed his gloves but failed to cleanse his hands after removal of the dirty gloves and prior to donning clean gloves. The PCT then discontinued the patient's dialysis treatment. 4. Patient care observation number 4 was completed on 4-24-12 at 11:20 AM in the home services department. Employee P, a registered nurse (RN), was observed to provide care to patient number 4, a peritoneal dialysis patient.		In order to monitor staff adherence to the appropriate use of gloves and hand hygiene, the Director of Operations incorporated the observation of the facility's hand hygiene requirements in the Plan of Correction Monitoring Tool As such, the following has been implemented: · On April 30, 2012 the Regional Director of Education presented the developed Plan of Correction monitoring tool to the Education Coordinators and Facility Management team. · Beginning April 30, 2012, the Education Coordinators will complete the tool during each patient shift on each employee including the home therapies staff whenever they are seeing patients · Any identified issues of staff non compliance will have an immediate intervention by the Education Coordinator or Management team member providing oversight. The non compliance and intervention will be documented on the PoC monitoring tool. · The Clinical Manager or	

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	A. The employee prepared to complete a blood draw on the patient. The RN was observed to draw up normal saline into a syringe and then wash her hands. The RN applied a tourniquet onto the patient's right hand and palpate the hand to find a vein. The employee then donned clean gloves without cleansing her hands. The RN removed another syringe from the package and drew up some normal saline into this syringe. The RN then cleansed the site for the needle stick, got up and touched the door to the room to close it, and without changing her gloves or cleansing her hands, the employee then proceeded to stick the patient and withdraw a blood sample into a laboratory tube. B. After drawing the blood, the RN started to administered intravenous (IV) iron to the patient through the needle and tubing placed in the patient's right hand. The RN slowly pushed a very small portion of the medication through the tubing. The RN the removed her gloves and touched the door to the room to ask another employee to obtain another syringe for her. The employee then reached into her pocket and obtained a pen and wrote on the laboratory tube. The RN donned clean gloves without cleansing her hands and continued to push		Director of Operations will review the tool and administer corrective action as needed. The Clinical Manager reviews the copies of the completed rounding tool, identified noncompliance and the applied interventions with the Director of Operations and Medical Director daily. Upon full resolution of staff noncompliance with the facility's hand hygiene requirements, the infection control audit be progressively decreased at the following frequencies; weekly for 4 weeks and if compliance is maintained, the infection control audit revert back to the facility's routine QAI schedule. The report is summarized and reviewed, during the monthly QAI meeting. The QAI may recommend procedural or operational changes that are required to prevent reoccurrence of significant events. Target dates for implementation should be included. QAI minutes document this	

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	the IV iron. C. The RN opened the syringe brought in by the other employee, removed the glove from her left hand, reached into a supply drawer and obtained an alcohol swab and then donned a clean glove without cleansing her hand. The RN then administered the second iron infusion. D. After the infusion was completed, the RN flushed the IV line and withdrew the needle from the patient's hand. The RN then cleaned the trash from the table top, washed a portion of the tabletop with a water soaked cloth, removed her gloves and washed her hands. E. The RN then gathered more supplies, touched the patient's abdomen and donned clean gloves without cleansing her hands. The RN pulled the dressing on the patient's abdomen up and looked at the peritoneal catheter exit site. The RN removed her gloves, and without cleansing her hands, reached into the supply drawer and obtained a roll of tape. The RN then left the room and obtained some Alcavis, a cleanser, opened a package of gauze and laid the clean gauze on the tabletop with no barrier. The RN then poured some of the Alcavis onto the gauze and washed her hands.		activity and will be available for review at the facility. The Clinical Manager is responsible and the QAI committee monitors to ensure on going compliance.	

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	F. The RN observed the patient infuse fluid into the abdomen. While the fluid was infusing, the RN touched her own hair, touched the patient and the tubing, and reached into the supply drawer to obtain an alcohol swab. The RN cleansed the tubing, touched her own hair, continued cleaning the tubing, touched her own hair, touched the door handle to the room, and then washed her hands. 5. Patient care observation number 6 was completed on 4-25-12 at 3:45 PM. Employee M, a PCT, was observed to discontinue the dialysis treatment on patient number 6. The employee touched the machine and tubing, placed a glove on the patient's left hand, and removed the needles from the patient's access. The PCT then removed the tubing from the machine and discarded it into the biohazard trash container. The PCT then changed his gloves without cleansing his hands. 6. Patient care observation number 7 was completed on 4-25-12 at 3:55 PM. Employee G, a PCT, was observed to initiate the dialysis treatment on patient number 14. The employee placed the needles, removed his gloves and cleansed his hands. The employee then touched the computer keyboard, cleansed his			

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	hands, and donned clean gloves. The employee touched the machine and the tubing, and without changing his gloves or cleansing his hands, the employee then connected the patient to the machine. 7. Patient care observation number 8 was completed on 4-26-12 at 10:00 AM. Employee D, a PCT, was observed to initiate the dialysis treatment on patient number 11. After changing the central venous catheter (CVC) dressing, the PCT touched the machine, removed her gloves and failed to cleanse her hands. The PCT touched the computer keyboard and then donned clean gloves without cleansing her hands. The PCT then checked the machine settings, changed her gloves without cleansing her hands and touched the computer keyboard with her gloved hand. A. The PCT then touched the machine next to patient number 11 without changing her gloves and cleansing her hands. B. After touching the machine at the next station, the employee changed her gloves and cleansed her hands. The PCT touched patient number 11's machine and tubing and connected the tubing to the patient without changing her gloves or cleansing her hands.			

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	8. Patient care observation number 9 was completed on 4-26-12 at 10:40 AM. Employee I, a registered nurse, was observed to remove her cover gown and enter the isolation room where patient number 15 was dialyzing. The employee was not observed to cleanse her hands prior to entering the isolation room. The employee donned a clean gown and gloves. The employee then removed the gown and stepped outside the isolation room and retrieved her face shield. The employee was not observed to remove her gloves prior to leaving the isolation room and was not observed to change her gloves upon entering the isolation room. The employee was observed to discontinue the dialysis treatment on patient number 15. 9. Employee O, the Director of Operations, indicated, on 4-27-12 at 10:50 AM, she was unaware of the breaks in the infection control practices out of the treatment floor. The employee stated, "The Regional Quality Manager was just here in January and did an audit. She did not say anything to me about it [the breaks in the infection control practices] except a problem with the sharps container lids not staying on." The Director indicated she was unable to locate any infection control audits			

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	completed by the former clinic manager. 10. The medical director, employee V, stated, on 4-24-11 at 2:45 PM, "I know our infection control practices are not 100%."			

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FRESENIUS MEDICAL CARE INDIANAPOLIS NORTH	1225 W 86TH ST INDIANAPOLIS, IN 46260

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PERCEDED 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
V0115	494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. Based on observation, interview, and review of facility policy, the facility failed to ensure personal protective equipment was utilized appropriately in 2 (#s 1 and 7) of 10 patient care observations creating the potential to affect all of the facility's 124 current patients. The findings include: 1. Patient care observation number 1 was completed on 4-23-12 at 2:00 PM. Employee G, a patient care technician (PCT), was observed to discontinue the dialysis treatment on patient number 16. The employee was wearing protective glasses and a face mask. The face mask was not observed to cover the employee's nose. 2. Patient care observation number 7 was completed on 4-25-12 at 3:55 PM. Employee G, a PCT, was observed to	V0115	The Governing Body at its April 30, 2012 meeting determined that the use of masks with “goggles” for eye protection is prohibited in this facility and that all staff will use face shields to provide full face protection. To ensure that all staff understands the correct application and the mandatory wearing of Personal Protective Equipment (PPE), the Clinical Manager contacted the educational department and arranged for the formal reeducation of all staff to be completed no later than May 1, 2012. This reeducation is inclusive of but not limited to the following: · FMS-CS-IC-11-155-080 Personal Protective Equipment o Gloves o Fluid Resistant Gowns o Face Shields	05/01/2012

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	initiate dialysis on patient number 14. The employee was wearing protective glasses and a face mask. The face mask was not observed to cover the employee's nose. Observation noted the employee was wearing a gown that was open in the back. The gown was observed to be hanging off the employee's left shoulder leaving his arm and back exposed. 3. Employee O, the Director of Operations, indicated, on 4-27-12 at 10:50 AM, she was unaware of the breaks in the infection control practices out on the treatment floor. The employee stated, "The Regional Quality Manager was just here in January and did an audit. She did not say anything to me about it [the breaks in the infection control practices] except a problem with the sharps container lids not staying on." The Director indicated she was unable to locate any infection control audits completed by the former clinic manager. 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		The educational agenda and attendance sheet document the training, and participation, and is available for review at the facility. Staff compliance is further monitored by the Education Coordinators, Director of Operations and Clinical Manager as follows: · Observing staff's adherence to properly wear/secure required PPE · Observing staff compliance to remove all PPE prior to exiting the isolation area · Immediate intervention, consisting of reeducation up to disciplinary action, to address and correct identified noncompliance with the appropriate staff member In order to monitor staff adherence to the correct application of personal protective equipment (PPE), the Director of Operations incorporated the observation of the facility's PPE requirements in the Plan of Correction Monitoring Tool. As such, the following has been implemented: · On April 30, 2012 the Regional Director of Education presented the developed Plan of Correction monitoring tool to the Education Coordinators and Facility Management team. · Beginning April 30, 2012, the Education Coordinators will complete the tool during each patient shift on each employee	

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	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)."		including the home therapies staff whenever they are seeing patients · Any identified issues of staff noncompliance will have an immediate intervention by the Education Coordinator or Management team member providing oversight. The noncompliance and intervention will be documented on the PoC monitoring tool. · The Clinical Manager or Director of Operations will review the tool and administer corrective action as needed. The Clinical Manager reviews the copies of the completed rounding tool, identified noncompliance and the applied interventions with the Director of Operations and Medical Director daily. Upon full resolution of staff noncompliance with the facility's PPE requirements, the infection control audit be progressively decreased at the following frequencies; weekly for 4 weeks and if compliance is maintained, the infection control audit revert back to the facility's routine QAI schedule. The report is summarized and reviewed, during the monthly QAI meeting. The QAI may recommend procedural or operational changes that are required to prevent	

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			reoccurrence of significant events. Target dates for implementation should be included. QAI minutes document this activity and will be available for review at the facility. The Clinical Manager is responsible and the QAI committee monitors to ensure on going compliance.	

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V0122	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. Based on observation, interview, and facility policy and daily log review, the facility failed to ensure appropriate bleach solutions were readily available on 3 (days 1, 4, and 7) of 3 days observed creating the potential to affect all of the facility's 124 current patients. The findings include: Regarding not following infection control policies and procedures: 1. The facility's 1-4-12 "Infection Control Overview" policy number FMS-CS-IC,II,155-060A states, "All infection control policies are consistent with recommendation of the Centers for Disease Control (CDC). All infection control policies will adhere to CMS and OSHA rules and regulation . . . Mandatory Components of Program: Adherence to standard and dialysis precautions . . . Infection control training	V0122	Hand hygiene and proper use of gloves/PPE have been addressed as evidenced in depth above in V 113 and V 115. To ensure that all staff fully complies and has available bleach disinfection solution, the Director of Operations arranged for the Education Department to reeducate all staff to the following: ·Daily assignment of bleach mixing as part of the facility's patient assignment process ·Bleach Mixing FMS-CS-IC-II-155-115-C ·Documentation requirements emphasizing immediate documentation by the preparer. Monitoring of staff compliance to required disinfection with prepared solution has been incorporated into the plan of	05/01/2012

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	and education, including maintenance of training records . . . Infection Control Policies: . . . Hand Hygiene, Dialysis unit precautions (including the use of personal protective equipment) . . . Rinsing, cleaning, disinfection, preparation, and storage of reused items conforming to CMS requirement for use." A. The facility's 1-4-12 "Hand Hygiene" policy number FMS-CS-IC-II-155-090A policy 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 . . . Immediately after removing gloves, After contact with body fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly soiled, After contact with inanimate objects near the patient, When moving from a contaminated body site to a clean body site of the same patient." B. The facility's 1-4-12 "Personal Protective Equipment" policy number FMS-CS-IC-II-155-080A policy states, "Change gloves and practice hand hygiene between each patient contact and/or station to prevent cross-contamination. Remove gloves and wash hands after each patient contact . . . Avoid touching surfaces with gloves hands that will be		correction monitoring tool. In the event that a staff member is found to continually not follow the facility procedures for infection control, the Clinical Manager will be notified and is responsible to address the findings with the identified staff member. The Clinical Manager's action will be structured to reinforce by further education following through as necessary with the application of progressive disciplinary action. The Clinical Manager will summarize the findings and report to the QAI Committee and to the Governing Body monthly who will determine further audit frequency by decreasing the frequency incrementally. Once compliance has been established the monitoring will revert to the QAI infection control audit tool The Clinical Manager is responsible and the QAI Committee and the Governing Body monitor for ongoing compliance **Completion Date:**	

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	touched with ungloved hands (for ex. patient charts and computers)." 2. The CDC Morbidity and Mortality Weekly Report (MMWR) October 25, 2002, Volume 51 No. RR-16 "Guideline for Hand Hygiene in Health-Care Setting" states, "Recommendations: Indications for handwashing and hand antisepsis . . . Decontaminate hands before having direct contact with patients . . . Decontaminate hands after contact with a patient's intact skin . . . Decontaminate hands if moving from a contaminated body site to a clean body site during patient care. Decontaminate hands after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient. Decontaminate hands after removing gloves." 3. Patient care observation number 2 was completed on 4-23-12 at 2:00 PM. Employee G, a patient care technician (PCT), was observed to touch the machine at station # 20 (patient number 1) and hand a glove to patient number 1. The employee changed his gloves but failed to cleanse his hands after removal of the dirty gloves and prior to donning clean gloves. The PCT then discontinued the patient's dialysis treatment. 4. Patient care observation number 4 was			

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	completed on 4-24-12 at 11:20 AM in the home services department. Employee P, a registered nurse (RN), was observed to provide care to patient number 4, a peritoneal dialysis patient. A. The employee prepared to complete a blood draw on the patient. The RN was observed to draw up normal saline into a syringe and then wash her hands. The RN applied a tourniquet onto the patient's right hand and palpate the hand to find a vein. The employee then donned clean gloves without cleansing her hands. The RN removed another syringe from the package and drew up some normal saline into this syringe. The RN then cleansed the site for the needle stick, got up and touched the door to the room to close it, and without changing her gloves or cleansing her hands, the employee then proceeded to stick the patient and withdraw a blood sample into a laboratory tube. B. After drawing the blood, the RN started to administered intravenous (IV) iron to the patient through the needle and tubing placed in the patient's right hand. The RN slowly pushed a very small portion of the medication through the tubing. The RN the removed her gloves and touched the door to the room to ask another employee to obtain another			

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	syringe for her. The employee then reached into her pocket and obtained a pen and wrote on the laboratory tube. The RN donned clean gloves without cleansing her hands and continued to push the IV iron. C. The RN opened the syringe brought in by the other employee, removed the glove from her left hand, reached into a supply drawer and obtained an alcohol swab and then donned a clean glove without cleansing her hand. The RN then administered the second iron infusion. D. After the infusion was completed, the RN flushed the IV line and withdrew the needle from the patient's hand. The RN then cleaned the trash from the table top, washed a portion of the tabletop with a water soaked cloth, removed her gloves and washed her hands. E. The RN then gathered more supplies, touched the patient's abdomen and donned clean gloves without cleansing her hands. The RN pulled the dressing on the patient's abdomen up and looked at the peritoneal catheter exit site. The RN removed her gloves, and without cleansing her hands, reached into the supply drawer and obtained a roll of tape. The RN then left the room and obtained			

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	some Alcavis, a cleanser, opened a package of gauze and laid the clean gauze on the tabletop with no barrier. The RN then poured some of the Alcavis onto the gauze and washed her hands. F. The RN observed the patient infuse fluid into the abdomen. While the fluid was infusing, the RN touched her own hair, touched the patient and the tubing, and reached into the supply drawer to obtain an alcohol swab. The RN cleansed the tubing, touched her own hair, continued cleaning the tubing, touched her own hair, touched the door handle to the room, and then washed her hands. 5. Patient care observation number 5 was completed on 4-25-12 at 3:30 PM. Patient number 8 was observed standing at station number 18 with a blood pressure cuff attached to the patient's arm. Employee K, a PCT, was observed placing tubing on the dialysis machine in preparation for the next patient to dialyze. The BP cuff was observed to "pop" off patient number 8's arm and land on the floor. Employee K was observed to pick the BP cuff up and place it in the basket on the side of the dialysis machine without cleansing the cuff and connected tubing. The patient was observed to obtain a			

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	coat from the back of the dialysis chair. Employee K donned clean gloves without cleansing her hands and continued to place the tubing on the machine. After the tubing was placed, the employee then cleaned the dialysis chair. The employee failed to clean the back of the chair where patient number 8's coat had been hanging. 6. Patient care observation number 6 was completed on 4-25-12 at 3:45 PM. Employee M, a PCT, was observed to discontinue the dialysis treatment on patient number 6. The employee touched the machine and tubing, placed a glove on the patient's left hand, and removed the needles from the patient's access. The PCT then removed the tubing from the machine and discarded it into the biohazard trash container. The PCT then changed his gloves without cleansing his hands. 7. Patient care observation number 7 was completed on 4-25-12 at 3:55 PM. Employee G, a PCT, was observed to initiate the dialysis treatment on patient number 14. The employee placed the needles, removed his gloves and cleansed his hands. The employee then touched the computer keyboard, cleansed his hands, and donned clean gloves. The employee touched the machine and the tubing, and without changing his gloves			

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	or cleansing his hands, the employee then connected the patient to the machine. 8. Patient care observation number 8 was completed on 4-26-12 at 10:00 AM. Employee D, a PCT, was observed to initiate the dialysis treatment on patient number 11. After changing the central venous catheter (CVC) dressing, the PCT touched the machine, removed her gloves and failed to cleanse her hands. The PCT touched the computer keyboard and then donned clean gloves without cleansing her hands. The PCT then checked the machine settings, changed her gloves without cleansing her hands and touched the computer keyboard with her gloved hand. A. The PCT then touched the machine next to patient number 11 without changing her gloves and cleansing her hands. B. After touching the machine at the next station, the employee changed her gloves and cleansed her hands. The PCT touched patient number 11's machine and tubing and connected the tubing to the patient without changing her gloves or cleansing her hands. 9. Patient care observation number 9 was completed on 4-26-12 at 10:40 AM.			

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	Employee I, a registered nurse, was observed to remove her cover gown and enter the isolation room where patient number 15 was dialyzing. The employee was not observed to cleanse her hands prior to entering the isolation room. The employee donned a clean gown and gloves. The employee then removed the gown and stepped outside the isolation room and retrieved her face shield. The employee was not observed to remove her gloves prior to leaving the isolation room and was not observed to change her gloves upon entering the isolation room. The employee was observed to discontinue the dialysis treatment on patient number 15. 10. Employee O, the Director of Operations, indicated, on 4-27-12 at 10:50 AM, she was unaware of the breaks in the infection control practices out of the treatment floor. The employee stated, "The Regional Quality Manager was just here in January and did an audit. She did not say anything to me about it [the breaks in the infection control practices] except a problem with the sharps container lids not staying on." The Director indicated she was unable to locate any infection control audits completed by the former clinic manager. 11. The medical director, employee V,			

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	stated, on 4-24-11 at 2:45 PM, "I know our infection control practices are not 100%." Regarding the availability of bleach solution: 1. The facility's 1-4-12 "Cleaning and Disinfection" policy number FMS-CS-IC-II-155-110A states, "Bleach solutions should be made daily. Keep bleach solution in a location convenient to all dialysis stations/machines. Bleach solution will be stored in labeled covered opaque containers to prevent disintegration of the chemical (sodium hypochlorite) when exposed to sunlight and air. Bleach solution will be mixed in the appropriate dilution in accordance to the type of cleaning and disinfection required . . . Place used plastic pressure clamps and plastic hemostat clamps in a labeled opaque plastic container filled with a 1:100 bleach solution." 2. On 4-23-11 (day 1) at 4:30 PM, employee M, a patient care technician (PCT), was observed to place used plastic pressure clamps in a container with a clear solution. The employee indicated the solution was a bleach solution but was unable to state the concentration of the solution. The container was observed to			

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	be without a lid or cover. 3. On 4-26-11 (day 4) at 9:45 AM, the facility's daily logs failed to evidence any bleach solutions had prepared for this date. Employee L, a registered nurse, stated, "We have to make our bleach water yet." The employee indicated the first patient had been placed on a machine at 6 AM and did not know know why the bleach solutions had not been prepared. The registered nurse assigned the task to employee M, a patient care technician, to prepare the bleach solutions. Observation noted 2 carts, on opposite sides of the treatment floor, with containers used to store the bleach solution. A. Employee M started to pour liquid from a small quirt bottle located on one of the carts into a measuring cup. When asked if the small squirt bottle contained bleach or a bleach solution, the employee stated, "I don't know." Employee L, the RN, stated, "No, [employee M] you need to get pure bleach. That's the 1:10 bleach solution." Employee M stated, "I guess I need to go to the back and get the bottle of bleach." The employee left the treatment floor and returned with a bottle of bleach. The employee was observed to pour 30 milliliters (ml) of bleach into a measuring cup. The employee then filled a large container half-way with water.			

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	When asked how many ml of water he had placed in the container, the employee replied, "I don't know." The employee then asked two registered nurses, employees L and I, how much water was in the container. They both indicated they did not know. Employee M poured the 30 ml of bleach into the half full container of water. Employee L was observed to pour the entire mixture into a large measuring cup and determined the amount of liquid in the large container was 3000 ml." B. Employee M was observed to repeat the procedure for the bleach container on the opposite side of the treatment room. C. Observations throughout the day failed to evidence any employee had prepared new bottles of the 1:10 bleach mixture. 4. On 5-1-12 at 8:50 AM, observation noted the 1:10 bleach solution bottle on one side of the treatment floor was empty. The large container of bleach solution failed to evidence a lid or cover. On the opposite side of the treatment floor, the container that was labeled 1:100 bleach solution was empty. The small bottle labeled 1:10 bleach solution was dated 4-30-12.			

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V0124	494.30(a)(1)(i) IC: HBV: TEST ALL,REV RESULTS/STATUS B4 ADMIT Routine Testing for Hepatitis B The HBV serological status (i.e. HBsAg, total anti-HBc and anti-HBs) of all patients should be known before admission to the hemodialysis unit. Routinely test all patients [as required by the referenced schedule for routine testing for Hepatitis B Virus]. Promptly review results, and ensure that patients are managed appropriately based on their testing results. Based on administrative record and facility policy review and interview, the facility failed to ensure hepatitis antibody status was known for 23 (#s 1 and 17 through 37) of 91 hepatitis records reviewed and failed to ensure monthly antigen testing had been completed for 21 (#s 9, 12, 21, 22, 25, 26, 28, 29, 31, 32, 33, 34, 35, 36, 38, 39, 40, 41, 42, and 43) of 46 patients known to be susceptible or whose antibody status was unknown creating the potential to affect the facility's 31 current incenter patients who were susceptible or whose antibody status was unknown. The findings include: 1. The facility's 1-4-12 "Patient Testing and Vaccination for Hepatitis B" policy number FMS-CS-IC-II-155-142A policy states, "The following schedule shall be	V0124	As a result of the citations from the April 23 – May.1, 2012 CMS Recertification and Relocation survey and to ensure that the facility fully complies with the Centers of Disease Control and Prevention guidelines to decrease the transmission of infection within the dialysis facility in regards to the care and services of the Hepatitis B positive patient, the following corrective actions have been implemented by the Governing Body and facility management team: · On May 1, 2012, the Regional Vice President presented the preliminary findings of the survey to all facility staff. Reinforced during this meeting was the	05/01/2012

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	adhered to when testing patients for Hepatitis B: . . . All patients on admission HBsAg [hepatitis B surface antigen], Anti-HBc [antibody to hepatitis B core antigen], Anti-HBs [antibody to hepatitis B surface antigen], HBV -(susceptible), including nonresponders to vaccine HBsAg monthly, Anti-HBs positive (10 mIU/mL), anti-HBc negative: annual Anti-HBs, Anti-HBs positive and positive anti_HBc: no additional HBV testing needed." 2. The facility's "Hepatitis Status - Detail" report for the date range 4-25-11 to 4-25-12 evidenced the hepatitis B antibody status was unknown for 23 patients. (#s 1 and 17 through 37). 3. The facility's "Hepatitis Status - Detail" report for the date range 4-25-11 to 4-25-12 evidenced monthly hepatitis B antigen testing had not been completed for patients who were known to be susceptible or whose antibody status was unknown. A. The hepatitis status report evidenced the antibody status for patient number 9 was less than 10. The report failed to evidence monthly antigen testing had been completed in January, February, March, and April 2012.		requirement of all staff to fully comply with all aspects of the facility Infection Control Polices inclusive of o Routine testing for Hepatitis B · On May 16 th upon receipt of the Statement of Deficiencies, the Director of Operations further reinforced with the Clinical Manager her obligation to ensure staff compliance with all facility polices, inclusive of Infection Control Procedures and CDC's guidelines to prevent the transmission of infections in the dialysis setting in the care and services rendered to the Hepatitis B positive antigen patient. To further ensure compliance and to prevent reoccurrence, on April 27, 28 and 30 2012, the facility's management team in conjunction with the Education Coordinator developed and presented the following Infection Control reeducation for all the Clinical Manager and Nursing staff: · Reeducation and reinforcement of FMS-CS-IC-11-155-142A Policy Patient Testing and	

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	B. The hepatitis status report evidenced the antibody status was unknown for patient number 12. The report failed to evidence any monthly antigen testing had been completed. C. The hepatitis status report evidenced the antibody status was unknown for patient number 18. The report failed to evidence monthly antigen testing had been completed in February, March, and April 2012. D. The hepatitis status report evidenced the antibody status was unknown for patient number 21. The report failed to evidence monthly antigen testing had been completed in February, March, and April 2012. E. The hepatitis status report evidenced the antibody status was unknown for patient number 22. The report failed to evidence monthly antigen testing had been completed in March and April 2012. F. The hepatitis status report evidenced the antibody status was unknown for patient number 25. The report failed to evidence any monthly antigen testing had been completed. G. The hepatitis status report		Vaccination for Hepatitis B with emphasis on: Routine testing of all patients, prompt review of results and ensuring that patients are managed appropriately based on their results inclusive of, but not limited to: o All new patients o Any existing patients A copy of the education provided is maintained available at the facility for review. On April 29 2012, all existing patients were tested for Hepatitis B antigens and antibodies. Any patient found to be susceptible will be offered the Hepatitis B vaccine. The acceptance or refusal of the vaccine will be documented on the Consent/Declination form and stored as part of their medical record. It will also be tracked on the Vaccination tracking tool as a part of the QAI program. To ensure compliance, the Clinical Manager reviews the Hepatitis B detailed report and the Vaccination tool with the Medical Director weekly. Once the condition is lifted the	

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	evidenced the antibody status was unknown for patient number 26. The report failed to evidence any monthly antigen testing had been completed. H. The hepatitis status report evidenced the antibody status was unknown for patient number 28. The report failed to evidence any monthly antigen testing had been completed. I. The hepatitis status report evidenced the antibody status was unknown for patient number 29. The report failed to evidence any monthly antigen testing had been completed. J. The hepatitis status report evidenced the antibody status was unknown for patient number 31. The report failed to evidence any monthly antigen testing had been completed. K. The hepatitis status report evidenced the antibody status was unknown for patient number 32. The report failed to evidence any monthly antigen testing had been completed. L. The hepatitis status report evidenced the antibody status was unknown for patient number 33. The report failed to evidence any monthly antigen testing had been completed in		Vaccination tracking tool will be reviewed monthly as part of the facility's routine QAI program during which identified variances are summarized and reported as part of the Infection Control review during the monthly QAI meeting. The Clinical Manager is responsible and the QAI committee monitors for compliance	

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	January, February, March, and April 2012. M. The hepatitis status report evidenced the antibody status was unknown for patient number 34. The report failed to evidence any monthly antigen testing had been completed in January, February, March, and April 2012. N. The hepatitis status report evidenced the antibody status was unknown for patient number 35. The report failed to evidence any monthly antigen testing had been completed in March and April 2012. O. The hepatitis status report evidenced the antibody status was unknown for patient number 36. The report failed to evidence any monthly antigen testing had been completed in January, February, March, and April 2012. P. The hepatitis status report evidenced patient number 38 had an antibody value of less than 10. The report failed to evidence a monthly antigen test had been completed in March of 2012. Q. The hepatitis status report evidenced on 8-2-11 patient number 39			

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	had an antibody value of less than 10. The report failed to evidence monthly antigen testing had been completed in September, October, November, and December 2011 or in February, March, and April 2012. R. The hepatitis status report evidenced patient number 40 had an antibody value of less than 10. The report failed to evidence a monthly antigen test had been completed in February, March, and April 2012. S. The hepatitis status report evidenced patient number 41 had an antibody value of less than 10. The report failed to evidence monthly antigen testing had been completed in January, February, March, and April 2012. T. The hepatitis status report evidenced patient number 42 had an antibody value of less than 10. The report failed to evidence monthly antigen testing had been completed in January, February, March, and April 2012. U. The hepatitis status report evidenced patient number 43 had an antibody value of less than 10. The report failed to evidence monthly antigen testing had been completed in January, March, and April 2012.			

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	4. Employee O, the Director of Operations, indicated, on 4-27-12 at 10:50 AM, she was unaware the hepatitis antibody and antigen status was unknown for some patients and that monthly antigen testing had not been completed as required. 5. The Medical Director stated, on 4-30-12 at 9:10 AM, "We have infection control policies and procedures in place. This was a glaring oversight on our part. I was not aware staff members were taking care of the patients in isolation at the same time as susceptible patients. I rely on the corporate audits and the education people to oversee these things. I am not here all the time. I only see a 'snapshot' when I am here."			

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V0126	494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF Hepatitis B Vaccination Vaccinate all susceptible patients and staff members against hepatitis B. Based on administrative record and facility policy review and interview, the facility failed to ensure all susceptible patients had been offered the vaccine against hepatitis B in 6 (#s 14, 38, 39, 44, 45, and 46) of 15 susceptible patient records reviewed creating the potential to affect the facility's 15 susceptible current incenter patients. The findings include: 1. The facility's 1-4-12 "Patient Testing and Vaccination for Hepatitis B" policy number FMS-CS-IC-155-142A policy states, "The hepatitis B vaccine shall be offered to all susceptible patient including peritoneal and home hemodialysis patients . . . Patients shall sign a vaccination consent/declination form." 2. The facility's hepatitis status report evidenced patient number 14 was susceptible with an antibody value of less than 10 on 6-6-11. The report failed to evidence the vaccine series had been offered or completed and if a second series had been offered or completed.	V0126	As a result of the citations from the April 23 – May.1, 2012 CMS Recertification and Relocation survey and to ensure that the facility fully complies with the Centers of Disease Control and Prevention guidelines to decrease the transmission of infection within the dialysis facility in regards to the care and services of the Hepatitis B positive patient, the following corrective actions have been implemented by the Governing Body and facility management team: · On May 1, 2012, the Regional Vice President presented the preliminary findings of the survey to all facility staff. Reinforced during this meeting was the requirement of all staff to fully comply with all aspects of the facility Infection Control Polices inclusive of o Routine testing for Hepatitis B · On May 16, 2012, the Director of Operations further	05/01/2012

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	3. The facility's hepatitis status report evidenced patient number 38 was susceptible with antibody values of less than 10 on 7-5-11. The report failed to evidence if the vaccine series had been offered or completed. 4. The hepatitis status report evidenced patient number 39 was susceptible with an antibody value of less than 10 on 8-2-11. The report failed to evidence if the vaccine series had been offered or completed. 5. The facility's hepatitis status report evidenced patient number 44 was susceptible with antibody values of less than 10 on 8-17-11 and 2-27-12. The report failed to evidence if the vaccine series had been offered or completed. 6. The hepatitis status report evidenced patient number 45 was susceptible with antibody values of less than 10 on 6-29-11, 8-3-11, 10-10-11, 12-23-11, and 4-23-12. The report failed to evidence if the vaccine series had been offered or completed. 7. The hepatitis status report evidenced patient number 46 was susceptible with an antibody value of less than 10 on 3-2-12. The report failed to evidence if the vaccine series had been offered or		reinforced the Clinical Manager her obligation to ensure adherence to the facility's facility polices, inclusive of Infection Control Procedures and CDC's guidelines to prevent the transmission of infections in the dialysis setting in the care and services rendered to the Hepatitis B positive antigen patient. To further ensure compliance and to prevent reoccurrence, on April 27, 28 and 30 2012, the facility's management team in conjunction with the Education Coordinator developed and presented the following Infection Control reeducation Clinical Manager and Nursing staff: · Reeducation and reinforcement of FMS-CS-IC-11-155-142A Policy Patient Testing and Vaccination for Hepatitis B with emphasis on: Routine testing of all patients, prompt review of results and ensuring that patients are managed appropriately based on their results inclusive of, but not limited to: o All new patients	

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	completed. 8. Employee O, the Director of Operations, indicated, on 4-27-12 at 10:50 AM, she was unaware susceptible patients had not been offered the vaccine series or that antibody testing had not been completed as required. 9. The Medical Director stated, on 4-30-12 at 9:10 AM, "We have infection control policies and procedures in place. This was a glaring oversight on our part. I was not aware staff members were taking care of the patients in isolation at the same time as susceptible patients. I rely on the corporate audits and the education people to oversee these things. I am not here all the time. I only see a 'snapshot' when I am here."		o Any existing patients A copy of the education provided is maintained available at the facility for review. On April 29 2012, all existing patients were tested for Hepatits B antigens and antibodies. Any patient found to be susceptible will be offered the Hepatitis B vaccine. The acceptance or refusal of the vaccine will be documented on the Consent/Declination form and stored as part of their medical record. It will also be tracked on the Vaccination tracking tool as a part of the QAI program. To ensure that each patient is offered the vaccine upon admission and receives the vaccination in accordance to prescribed orders, the Clinical Manager has initiated the following: ·Reviews patient hepatitis status prior to admission ·Assigns a nurse to initiate patient assessment prior to the first treatment and as part of this assessment the following occurs: ·Patient education on the	

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			hepatitis virus ·Patient education on the benefit of vaccination to hepatitis virus ·Obtains the patient consent/declination indicated by patient signature on the appropriate form The Clinical Manager reviews the new patient admission Hepatitis Tracking Tool paper work inclusive of required consents for completion and patient preference. The Clinical Manager is responsible to update the Hepatitis Tracking Tool accordingly no less than 30 days after patient admission. Each month, as part of the monthly QAI process, the Clinical Manager will present the following to the QAI Committee: ·A summary of patients susceptible to Hepatitis B ·A summary of patients currently receiving Hepatitis B vaccination series ·Any patients that have specific, documented reasons for not receiving scheduled doses of Hepatitis B vaccine. The QAI Committee will assess for an opportunity for	

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			improvement. If an opportunity for improvement is identified, the QAI Committee will initiate a formal action plan to be followed through to a resolution. The committee may recommend procedural or operational changes that are required to prevent reoccurrence of significant events. Target dates for implementation should be included. QAI minutes document this activity and will be available for review at the facility The Clinical Manager is responsible and the QAI Committee monitors for compliance	

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V0127	494.30(a)(1)(i) IC-HBV-TEST PTS/STAFF POST LAST DOSE Hepatitis B Screening: Patients and Staff Test all vaccines [patients and staff] for anti-HBs 1-2 months after last primary vaccine dose. -- If anti-HBs is <10 mIU/mL, consider patient or staff member susceptible, revaccinate with an additional three doses, and retest for anti-HBs. -- If anti-HBs are =10 mIU/mL, consider immune, and retest patients annually. -- Give booster dose of vaccine to patients if anti-HBs declines to <10 mIU/mL and continue to retest patients annually. Based on administrative record and facility policy review and interview, the facility failed to ensure anti-HB testing was completed for 5 (#s 17, 21, 22, 40, & 47) of 13 patients that completed the primary vaccine series creating the potential to affect the facility's 31 current incenter patients who were susceptible or whose antibody status was unknown. The findings include: 1. The facility's 1-4-12 "Patient Testing and Vaccination for Hepatitis B" policy number FMS-CS-IC-155-142A policy states, "Test patients who have received hepatitis B vaccine for anti-HBs 1-2 months after the final dose of vaccine per physician order . . . Patients who do not respond to the primary vaccine series	V0127	As a result of the citations from the April 23 – May 1, 2012 CMS Recertification and Relocation survey and to ensure that the facility fully complies with the Centers of Disease Control and Prevention guidelines to decrease the transmission of infection within the dialysis facility in regards to the care and services of the Hepatitis B positive patient, the following corrective actions have been implemented by the Governing Body and facility management team: · On May 1, 2012, the Regional Vice President presented the preliminary findings of the survey to all	05/01/2012

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	should be revaccinated with three additional doses and retested for response." 2. The facility's hepatitis status report evidenced patient number 17 received the primary series of 3 vaccines on 5-2-11, 5-25-11, and 9-5-11. The report failed to evidence the patient had been tested for anti-HBs after the series had been completed. 3. The hepatitis status report evidenced patient number 21 had received the vaccine series on 8-5-11, 9-21-11, 10-10-11, and 1-4-12. The report failed to evidence the patient had been tested for anti-HBs after the series had been completed. 4. The hepatitis status report evidenced patient number 22 had received a 6-month vaccine on 5-7-11. The report failed to evidence the patient had been tested for anti-HBs after the series had been completed. 5. The hepatitis status report evidenced patient number 40 had received a 6-month vaccine on 5-7-11. The report failed to evidence the patient had been tested for anti-HBs after the series had been completed.		facility staff. Reinforced during this meeting was the requirement of all staff to fully comply with all aspects of the facility Infection Control Polices inclusive of o Retesting for Hepatitis B at the completion of a series · ON May 16, 2012, the Director of Operations further reinforced each staff members obligation to comply with all facility polices, inclusive of Infection Control Procedures and CDC's guidelines to prevent the transmission of infections in the dialysis setting in the care and services rendered to the Hepatitis B positive antigen patient. To further ensure compliance and to prevent reoccurrence, on April 27, 28 and 30 2012, the facility's management team in conjunction with the Education Coordinator developed and presented the following Infection Control reeducation for the Clinical Manager and facility staff: · Reeducation and reinforcement of FMS-CS-IC-11-155-142A Policy Patient Testing and	

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	6. The hepatitis status report evidenced patient number 47 had received the 6-month vaccine on 11-7-11. The report failed to evidence the patient had been tested for anti-HBs after the series had been completed. 7. Employee O, the Director of Operations, indicated, on 4-27-12 at 10:50 AM, she was unaware post vaccine testing had not been completed as required. 8. The Medical Director stated, on 4-30-12 at 9:10 AM, "We have infection control policies and procedures in place. This was a glaring oversight on our part. I was not aware staff members were taking care of the patients in isolation at the same time as susceptible patients. I rely on the corporate audits and the education people to oversee these things. I am not here all the time. I only see a 'snapshot' when I am here."		Vaccination for Hepatitis B with emphasis on: Routine testing of all patients, prompt review of results and ensuring that patients are managed appropriately based on their results inclusive of, but not limited to: o Retesting after the completion of the Hepatitis B series A copy of the education provided is maintained available at the facility for review. On April 29 2012, all existing patients were tested for Hepatitis B antigens and antibodies. Any patient found to be susceptible will be offered the Hepatitis B vaccine. The acceptance or refusal of the vaccine will be documented on the Consent/Declination form and stored as part of their medical record. It will also be tracked on the Vaccination tracking tool, which will track a series through its completion including when the patient is due for retesting as a part of the QAI program. To ensure compliance, the Clinical Manager reviews the	

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			Hepatitis B detailed report and the Vaccination tool with the Medical Director weekly. Once the condition is lifted the Vaccination tracking tool will be reviewed monthly as part of the facility's routine QAI program during which identified variances are summarized and reported as part of the Infection Control review during the monthly QAI meeting. The Clinical Manager is responsible and the QAI committee monitors for compliance	

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V0131	494.30(a)(1)(i) IC-HBV-ISOLATION-STAFFING Isolation of HBV+ Patients 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. Based on clinical record, facility policy, and administrative record review and interview, the facility failed to ensure staff assigned to care for hepatitis B positive patients (#15 and #49) did not care for hepatitis B susceptible patients at the same time in 13 (#s 12, 18, 22, 33, 36, 43, 44, 46, 49, 50, 51, 52, and 53) of 46 patients known to be susceptible or whose antibody status was unknown creating the potential to affect the facility's 31 current incenter patients who were susceptible or whose antibody status was unknown. The findings include: 1. Clinical record number 15 evidenced the patient was hepatitis B positive. Post treatment run sheets, dated 4-12-12, 4-14-12, 4-17-12, 4-19-12, 4-24-12 and 4-26-12, evidenced employees A, E, H, I, and L had provided care to the patient in the isolation room during the first shift. Post treatment run sheets for the first shift for these dates evidenced the employees	V0131	Upon identification of the Immediate Jeopardy and to ensure that the facility fully complies with the Centers of Disease Control and Prevention guidelines to decrease the transmission of infection within the dialysis facility in regards to the Hepatitis B Virus, the following actions have occurred: · On April 30, 2012 the Governing Body met to review facility policy Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+) with specific focus to "Make patient/staff assignments to reflect patient hepatitis antibody and antigen status, the bullet which states Staff members can be assigned to care for both HBV infected and HBV immune patients on the same shift. As a result of this review, the Governing Body determined:	05/01/2012

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	had also provided care to patients that were hepatitis B susceptible or their antibody status was unknown. A. A post treatment run sheet for patient number 12 dated 4/12, 4/17, 4/19, and 4/24/12 evidenced employee L had provided care to the patient during the first shift. A post treatment sheet dated 4/14 and 4/19/12 evidenced employee I had provided care to the patient during the first shift. The facility's hepatitis status report evidenced the patient's hepatitis B antibody status was unknown. B. A post treatment run sheet for patient number 22 dated 4/12/12, evidenced employees A had provided care to the patient during the first shift. A post treatment run sheet dated 4/12, 4/17, 4/19, and 4/24/12, evidenced employee L had provided care to the patient during the first shift. A post treatment run sheet dated 4/17/12, evidenced employee I had provided care to the patient during the first shift. The facility's hepatitis status report evidenced the patient's hepatitis B antibody status was unknown. C. A post treatment run sheet for patient number 33 dated 4/12, 4/17, 4/19, 4/24, and 4/26/12, evidenced employee L had provided care to the patient during the first shift. A post treatment run sheet		o The policy does not state that a staff member can simultaneously care for the infected patient and susceptible patients o Additional education of facility management and staff was needed to comply with facility infection control policies and CDC guidelines.. · On April 27, 2012 the Regional Vice President directed the Regional Director of Education to develop a detailed educational program utilizing the facility policy, CDC recommendation as adopted into regulation and the additional guidance from the CMS FAQ's version 1.3. Further and to prevent reoccurrence, the Governing Body determined that: Hepatitis Antigen Positive Patients **will not** have medication or care rendered by an employee assigned to Hepatitis susceptible patients. When two nurses are present, one nurse will be dedicated to administer care to the positive patient and not assigned to care for Hepatitis susceptible patients during that patient shift.	

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	dated 4/17, 4/19, and 4/26/12, evidenced employee I had provided care to the patient during the first shift. The facility's hepatitis status report evidenced the patient's hepatitis B antibody status was unknown. D. A post treatment run sheet for patient number 43 dated 4/12 and 4/24/12, evidenced employee L had provided care to the patient during the first shift A post treatment run sheet dated 4/14/12, evidenced employee I had provided care to the patient during the first shift. A post treatment run sheet dated 4/17, 4/19, and 4/26/12, evidenced employees I and L provided care to the patient during the first shift.. The facility's hepatitis status report evidenced the patient's hepatitis antibody value was less than 10 and that the patient was susceptible. E. A post treatment run sheet for patient number 50 dated 4/12, 4/19, 4/24, and 4/26/12, evidenced employee L had provided care to the patient during the first shift. The post treatment run sheet dated 4/12/12, evidenced employee A provided care to the patient during the first shift. A post treatment run sheet dated 4/14, 4/17, 4/19, and 4/26/12, evidenced employee I provided care to the patient during the first shift. The post run		Additional actions taken: · Update the list of all in-center hemodialysis patients of their HBV antigen and antibody status. · The patient seating charts have now been colored coded to reflect the buffer and non buffered areas. · Revise the patient schedule in the following manner: o Hepatitis Antigen Positive Patients will be dialyzed on the same day o A buffer zone is created so that the PCT and nurse caring for the positive patient are only caring for patients with antibodies. · Changes to patient seating assignments may only be changed through approval from the Clinical Manager. · Immune status must be reviewed and patient schedules adjusted each time antibody samples are obtained as titers tend to drop below 10. The Hepatitis B vaccine shall be offered to all susceptible patients inclusive of peritoneal and home hemodialysis patients. The following information and	

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	sheet dated 4/14 and 4/24/12, evidenced employee H provided care during the first shift. The post treatment run sheet dated 4/19/12, evidenced employee E provided care to the patient during the first shift. The facility's hepatitis status report evidenced the patient's hepatitis antibody value was less than 10 and that the patient was susceptible. F. A post treatment run sheet for patient number 51 dated 4/12 and 4/17/12, evidenced employee A had provided care to the patient during the first shift. The post treatment run sheet dated 4/12, 4/17, 4/19, 4/24, and 4/26/12, evidenced employee L had provided care to the patient during the first shift. The post treatment run sheet dated 4/14 and 4/24/12, evidenced employee H had provided care to the patient during the first shift. The post treatment run sheet dated 4/14, 4/19, and 4/26/12, evidenced employee I provided care to the patient during the first shift. The post treatment run sheet dated 4/19/12, evidenced employee E had provided care to the patient during the first shift. The facility's hepatitis status report evidenced the patient's hepatitis antibody value was less than 10 and that the patient was susceptible. G. A post treatment run sheet for		documentation are required as part of the patient education: · Vaccine information statement (VIShttp://www.immunize.org/vis/) will be given to patients prior to administration of each dose of vaccine for Hepatitis B. · Patients shall sign a vaccination consent/declination form · Patients that refuse vaccination will be offered vaccination annually. The Clinical Manager monitors for compliance by: o Review of the patient schedule and observation of staff compliance daily by direct observation and/or treatment sheet review o Direct observation of assigned personnel o Review of audit tools In the event that a staff member is found to not follow the facility procedures, the Clinical Manager will be notified and will address the findings with the identified staff member. The Clinical Manager's action will be to reinforce by further education following through as necessary the application of	

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	patient number 52 dated 4/12 and 4/24/12, evidenced employee L had provided care to the patient during the first shift. The post treatment run sheet dated 4/14/12, evidenced employee I had provided care to the patient during the first shift. The post treatment run sheet dated 4/17, 4/19, and 4/26/12, evidenced employees I and L provided care to the patient during the first shift. The facility's hepatitis status report evidenced the patient's hepatitis antibody value was less than 10 and that the patient was susceptible. H. A post treatment run sheet for patient number 18 dated 4/19 and 4/26/12, evidenced employees I and L had provided care to the patient during the first shift. The post treatment run sheet dated 4/24/12, evidenced employee L had provided care to the patient during the first shift. The facility's hepatitis status report evidenced the patient's hepatitis B antibody status was unknown. I.. A post treatment run sheet for patient number 53 dated 4-19-12 evidenced employees E and I had provided care to the patient during the first shift. The facility's hepatitis status report evidenced the patient's hepatitis B antibody value was less than 10 and that the patient was susceptible.		progressive disciplinary action. To further ensure compliance, the Clinical Manager reports and discrepancies immediately to the Director of Operations and Medical Director. The Director of Operations and Medical Director will discuss applied interventions and direct further corrective action if warranted. The Clinical Manager is responsible and the Governing Body monitors for compliance.	

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	2. Clinical record number 49 evidenced the patient was hepatitis B positive. Post treatment run sheets, dated 4-13-12, 4-16-12, 4-18-12, and 4-20-12, evidenced employees A, F, G, and H had provided care to the patient in the isolation room during the first shift. Post treatment run sheets for the first shift for these dates evidenced the employees had also provided care to patients that were hepatitis B susceptible or their antibody status was unknown. A. A post treatment run sheet for patient number 36 dated 4-13-12 evidenced employees F and G had provided care to the patient during the first shift. The post treatment run sheet dated 4/16, 4/18, and 4/20/12, evidenced employee F had provided care to the patient during the first shift. The facility's hepatitis status report evidenced the antibody status for patient number 36 was unknown. B. A post treatment run sheet for patient number 44 dated 4-13-12 evidenced employee G had provided care to the patient during the first shift. The facility's hepatitis status report for 4-25-11 to 4-25-12 evidenced patient number 44 had an antibody value of less than 10 and was HBV susceptible.			

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	C. A post treatment run sheet for patient number 46 dated 4-13-12 evidenced employees F and G had provided care to the patient during the first shift. The post treatment run sheet dated 4/16, 4/18, and 4/20/12, evidenced employee F provided care to the patient during the first shift. The facility's hepatitis status report evidenced patient number 46 had an antibody value of less than 10 and was HBV susceptible. D. A post treatment run sheet for patient number 49 dated 4/16 and 4/18/12, evidenced employee F had provided care to the patient during the first shift. The facility's hepatitis status report evidenced patient number 50 had an antibody value of less than 10 and was HBV susceptible. 3. Employee L, a registered nurse, stated, on 5-1-12 at 9:15 AM, "I have been assigned to the isolation room [patient number 15]." The employee indicated she had also been assigned to care for patients numbered 12 and 18. The hepatitis status report identifies the hepatitis antibody status is unknown for these patients. 4. Employee O, the Director of Operations, indicated, on 4-27-12 at 10:50 AM, she was unaware employees			

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	were providing care to hepatitis B positive patients at the same time as patients that were susceptible or their status was unknown. 5. The facility's 1-4-12 "Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+)" policy number FMS-CS-IC-II-155-140A states, "Make patient/staff assignments to reflect patient and staff hepatitis antibody and antigen status . . . Staff members can be assigned to care for both HBV infected and HBV immune patients on the same shift." 6. The Medical Director stated, on 4-30-12 at 9:10 AM, "We have infection control policies and procedures in place. This was a glaring oversight on our part. I was not aware staff members were taking care of the patients in isolation at the same time as susceptible patients. I rely on the corporate audits and the education people to oversee these things. I am not here all the time. I only see a 'snapshot' when I am here." These findings at V131 resulted in the determination that an Immediate Jeopardy existed. The immediate jeopardy was identified on 4-27-12. The Director of Operations was notified of the immediate jeopardy on 4-27-12 at 3:20 PM. The Immediate Jeopardy remained unremoved			

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	at the survey exit due to the facility's failure to ensure staff were not assigned to care for hepatitis B positive patients at the same time as susceptible and/or status unknown patients.			

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V0400	494.60 CFC-PHYSICAL ENVIRONMENT Based on the Life Safety Code (LSC) survey, Fresenius Medical Care Indianapolis North was found not in compliance with Requirements for Participation in Medicare/Medicaid, 42 CFR Subpart 494.60(d), Life Safety from Fire and the 2000 edition of the National Fire Protection Association (NFPA) 101, Life Safety Code (LSC), Chapter 20, New Ambulatory Health Care Occupancies. This one story facility with a partial second story over the storage room, water treatment room and administrative offices was determined to be of Type II (000) construction and sprinkled. The facility has a fire alarm system with smoke detection in the corridors and in all treatment areas. The facility had 31 incenter patients at the time of the survey. Based on the deficiencies found at the LSC survey, it was determined the facility failed to ensure sprinkler inspections were conducted by a qualified person (See K 012); failed to ensure 1 of 2 stairwell exit doors was one hour fire rated, self closed, and latched into the door frame (See K 021); failed to provide exterior emergency lighting for 1 of 6 exits (See K 046); failed to provide a complete written plan	V0400	The Governing Body acknowledges its responsibility to ensure that the Fresenius Medical Care Indianapolis North facility is maintained to ensure a safe, functional and comfortable physical environment for all staff and patients including ensuring all requirements as specified by the Life Safety Code 2000 edition of the NFPA, Chapter 20 are met. The Governing Body, on June 8 th 2012, reviewed the SOD and developed the following Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. The following action plans were implemented The Governing Body will meet weekly to monitor the progress of the Plan of Correction until the Condition level deficiencies are lifted, then monthly for an additional three months to ensure that the corrective actions have resulted in resolution of the cited issues. Once this is determined, the Governing Body will return to quarterly or	06/08/2012

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	containing procedures to be followed in the event the fire alarm system has to be placed out of service for 4 hours or more in a 24 hour period (See K 048); failed to document quarterly fire drills for 3 of 3 shifts (See K 050); and failed to ensure 6 of 43 smoke detectors were installed in accordance with with the applicable requirements of NFPA 72, National Fire Alarm Code (See K 051). The cumulative effect of these systemic problems resulted in the facility's inability to ensure the physical environment was safe with the potential to affect all patients, visitors, and staff of the facility and inability to meet the requirements of the Condition for Coverage 494.60: Physical Environment.		as needed meetings. Effective immediately: · The Clinical Manager (CM) will analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee. · A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda. · The QAI Committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution of the issues · The Director of Operations (DO) will present a report on the Plan of Correction data and all actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. · The Governing Body, at its meeting of May 8 th 2012, designated the Regional Quality Manager to serve as	

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			Plan of Correction Monitor and provide additional oversight. She will actively participate in each QAI and Governing Body meeting - either personally or via conference call - and submit a status report at each of the referenced Governing Body meetings with a copy to the RVP. This additional oversight is to ensure the ongoing correction of deficiencies cited in the Statement of Deficiency through to resolution as well as ensure the Governance of the facility is presented the current and complete data, as necessary, to enhance their governance oversight role · Minutes of the Governing Body and QAI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's direction and oversight and the QAI Committee's ongoing monitoring of facility activities. These are available for review at the facility. · The responses provided for V 401 and V 417 in addition to K codes K012, K021, K046, K048, K050 and K051 describe, in detail, the	

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			processes and monitoring steps taken to ensure that all deficiencies as cited within this Condition are corrected to ensure ongoing compliance	

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V0401	494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment. Based on observation and interview, the facility failed to ensure the treatment floor area had been maintained in a cleanly manner in 4 (#s 1, 3, 4, and 7) of 7 days of observation creating the potential to affect all of the facility's 92 current incenter patients. The findings include: 1. On day 1 of the survey, 4-23-12, observation noted at 4:20 PM a plastic drink bottle and lid and 2 pieces of white paper approximately 1/2" by 2" at station 16. There was no patient in the dialysis chair at this time. At 5 PM, observation noted the plastic drink bottle and pieces of paper still on the floor at station 16. 2. On day 3 of the survey, 4-25-12, observation noted at 2:05 PM a pad blue plastic on one side and white on the other on the floor partially under the chair at station 14 (patient number 24). Observation also noted a protein bar wrapper and an unopened 4 x 4 gauze package on the floor near the dialysis	V0401	Effective immediately on May 21 st 2012, the facility was cleaned and an initial in-service was held with all staff members to present the requirements to ensure the facility is kept clean and debris is not dropped on the floors. Any debris, fluids etc. that are noticed are to be immediately cleaned. The Director of Operations met with the liaison for the contracted housekeeping company and scheduled a deep cleaning of the entire facility. This cleaning was completed on May 19 th 2012 The Education Coordinators provided an in-service on May 21 st 2012, to all direct patient care staff to review and reeducate on May 21 st 2012 on the Housekeeping Policy FMS-CS-IC-!!-155-116A with emphasis regarding trash on the floor. The Education Coordinators and Operations team will monitor the	06/14/2012

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	chair. At 5:00 PM, observation noted 2 pieces of white paper approximately 1/2" by 2" on the floor under the dialysis chair at station number 24. 3. On day 4, 4-26-12, observation noted at 8:40 AM, a large amount of clear fluid on the floor between stations 17 and 18 and under the machine at station 18. Observation also noted a small, clear cap; a dried leaf; and 1 white paper strips approximately 1/2" by 2" at station 16. There were no patients in the chairs at stations 16, 17, and 18 at the time of the observations. On 4-26-12 at 9 AM, observation noted 2 pieces of white paper 1/2" by 2" on the floor by the dialysis machine in the isolation room (Patient number 15 was being dialyzed). 4. On day 7, 5-1-12 at 8:30 AM, observation noted an opened small plastic bag with bread on top of the employee lockers in the hallway at the treatment floor entrance. The bag had bread crumbs spilling out and onto an opened package of cover gowns to be donned prior to entering the treatment floor. A. Observation noted 2 pieces of clear		cleanliness of the treatment room daily thru the infection control audits until the facility is resurveyed, then continue daily audits until the QAI Committee determines resolution is occurring based on the audit results. At that time, the QAI Committee will determine when audits can resume as indicated via the QAI Calendar. Any observed noncompliance will be addressed immediately including corrective action as appropriate. The Clinical Manager and the liaison for the contracted housekeeping company will maintain open communication with any housekeeping issues noted daily via the Citywide Maintenance communication book located near the janitor supply closet. The Clinic Manager is responsible to review the communications daily/weekly to ensure appropriate action is being taken and issues noted and resolved. The RVP on June 8 th 2012 directed the ordering/placement of new trash receptacles at each patient station for	

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	plastic approximately 1" by 2" on the floor and a strip of white material approximately 1/4' wide and 3 inches long at station 16. B. A small piece of paper, approximately 1/2 inch in diameter, was noted on the floor at station 6 (patient number 55). C. Employee W, the Regional Quality Manager, also observed the environmental findings with the surveyor on 5-1-12 and indicated the trash and bread should have been cleaned and not allowed to remain on the treatment floor and on top of the lockers next to the clean cover gowns.		non-biohazard waste. The Clinical Manager will ensure that new trash receptacles will be placed at each patient station by June 18 th 2012 in order to maintain cleanliness of the treatment room floor The Clinical Manager is responsible to review and analyze all audit results prior to presenting to the QAI Committee on a monthly basis. The Director of Operations is responsible to ensure that all issues as identified and addressed in this Plan of Correction, are presented to each QAI Committee and to provide follow up to the Governing Body. The QAI Committee is responsible to trend and provide oversight to ensure issues as identified are being addressed and resolution is occurring.	

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V0417	494.60(e)(1) PE-FIRE SAFETY-LIFE SAFETY CODE 2000 (1) Except as provided in paragraph (e)(2) of this section, by February 9, 2009. The dialysis facility must comply with applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference at §403.744 (a)(1)(i) of this chapter). Based on record review, interview, and observation, the facility failed to ensure sprinkler inspections were conducted by a qualified person; failed to ensure 1 of 2 stairwell exit doors was one hour fire rated, self closed, and latched into the door frame ; failed to provide exterior emergency lighting for 1 of 6 exits; failed to provide a complete written plan containing procedures to be followed in the event the fire alarm system had to be placed out of service for 4 hours or more in a 24 hour period; failed to document quarterly fire drills for 3 of 3 shifts; and failed to ensure 6 of 43 smoke detectors were installed in accordance with with the applicable requirements of NFPA 72, National Fire Alarm Code with the potential to affect the safety of all patients visitors, and staff. Findings include: 1. Related to failure to ensure sprinkler inspections were conducted by a qualified	V0417	The Governing Body of Indianapolis North met on 6-8-12 to review and adopt a facility specific plan to ensure that the facility is compliant with 2000 edition of Life Safety Code of the National Fire Protection Association. As documented in the 2567 response to the Life Safety Code survey concluded May 14, 2012: . On 5-25-12 Koorsen Fire and Security completed initial inspection of Automatic Sprinkler System and Fire Alarm System. Record of the work performed is maintained in the facility and documented on the ER-1 (equipment repair record). This inspection has been amended on the Facility Life Safety Equipment Schedule / QAI audit tool and will be performed annually going forward, by a qualified vendor, such as Koorsen Fire and Security, next due in May 2013.	06/22/2012

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	person A. "FMC-Equipment Record ER-1" quarterly sprinkler system inspection records dated 03/29/12 were reviewed with the Technical Operations Manager and the Technical Supervisor from 9:40 a.m. to 11:15 a.m. on 05/14/12. An initial automatic sprinkler system acceptance inspection documentation was not available for review. B. At the time of record review, the Technical Supervisor stated the facility opened in December 2011 and a sprinkler system inspection was performed on 03/29/12 but acknowledged no initial automatic sprinkler system acceptance inspection records were available for review. C. NFPA 13, Standard for the Installation of Sprinkler Systems requires sprinkler systems installed in accordance with this standard shall be properly inspected, tested and maintained in accordance with NFPA 25, 1998 edition, Standard for Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems. At the time of the record review, the Technical Supervisor stated the facility opened in December 2011 and acknowledged one quarterly sprinkler system inspection was		Quarterly inspections of the Automatic Sprinkler System and Fire Alarm System which began on 3-29-12, as per the Facility Life Safety Equipment Schedule / QAI audit tool, will continue as scheduled and will be performed by a certified NFPA-LSC Company (Koorsen) Record of this work will be maintained in the facility and documented in the ER-1 log (equiptment repair log) The Technical Supervisor is responsible to review the quarterly audit results and present/review with the Clinical Manager per the QAI calendar The Clinical Manager is responsible to present the results to the QAI Commitee for review and oversight On 5-25-12 Central Indiana Hardware installed a new 1.5 hour fire rated door, with self-closing device attached to the door frame. Record of this work performed is maintained in the facility and documented on the ER-1 (equipment repair record) 3. On 5-31-12 Resource Construction Inc. installed and tested a temporary exterior emergency battery backup light at the front entrance for means of egress. The permanent fixture, to match	

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	performed on 03/29/12 by facility staff. The Technical Supervisor indicated staff had received training to conduct the sprinkler inspection but did not have a copy of NFPA 25 available. Based on review of the staff training record, there was no indication of training pertaining to the sprinkler system or mention of NFPA 25. 2. Related to failure to ensure 1 of 2 stairwell exit doors was one hour fire rated, self closed, and latched into the door frame A. During a tour of the facility from 11:15 a.m. to 12:55 p.m. on 05/14/12 with the Technical Operations Manager and the Technical Supervisor, the ground floor stairwell exit door by the storage room was observed in the open position, had no fire resistance rating on the door, and the door was not equipped with a self closing device. B. At the time of observation, the Technical Operations Manager acknowledged the ground floor stairwell exit door by the storage room had no fire resistance rating and the door was not equipped with a self closing device. 3. Related to failure to provide exterior		the existing fixtures, has a 3 week lead time, with an estimated installation date of 6-28-12 by Resource Construction Inc., per Purchase Order #4506929653. Record of this work performed is maintained in the facility and documented on the ER-1 (equipment repair record) The lights will be checked per the QAI/LSC checklist monthly to ensure they are in operating condition. The Technical Supervisor is responsible to review the QAI/LSC audit results and present/review with the Clinical Manager per the QAI calendar. The Clinical Manager is responsible to present the results to the QAI Committee for review and oversight. 4. On 5-17-12, the Governing Body met and adopted Fire Watch Policy #FMS-CS-IC-II-130-016A in the event that the fire alarm system is placed out of service for 4 or more hours within a 24 hour period, for the protection of all patients, staff and visitors, in the event of an	

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	emergency lighting for 1 of 6 exits A. During a tour of the facility from 11:15 a.m. to 12:55 p.m. on 05/14/12 with the Technical Operations Manager and the Technical Supervisor, the front entrance was observed as not having any exterior emergency lighting. B. At the time of observation, the Technical Operations Manager stated the facility does not have an emergency generator for emergency lighting. The facility has a night shift concluding at 9:30 p.m. and acknowledged no exterior emergency lighting was provided at the front entrance. 4. Related to failure to provide a complete written plan containing procedures to be followed in the event the fire alarm system had to be placed out of service for 4 hours or more in a 24 hour period A. The "FMC Indianapolis North - Facility Specific Fire Safety Plan" documentation reviewed with the Technical Operations Manager and the Technical Supervisor from 9:40 a.m. to 11:15 a.m. on 05/14/12 failed to evidence a written policy in the event the fire alarm system is out of service for four hours or more in a twenty four hour period. The		emergency. The FMC Indianapolis North – Facility Specific Fire Safety Plan has been updated to reflect this policy. The Clinical Manager Director of Operations, the Technical Supervisor and Biomedical Technician have been designated to perform Fire Watches as trained by the Clinical Manageron 6-14-12. Record of this training will be maintained in personnel files. If a fire watch is required, it will be documented within the QAI with observations as to the efficiency of the fire watch as well as a determination of the default and correction of the sprinkler system requiring the fire watch. If necessary, the Clinical Manager will present the issues to the monthly QAI Committee for review and oversight. 5. On 5-21-12 and 5-22-12, the Clinical Manager provided an in-service to all staff members reviewing the Indianapolis North. The “Facility Specific Fire Safety Plan” Fire/Emergency Drill Observation documentation	

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	facility did not have a written policy in the event the sprinkler system was out of service for four hours or more in a twenty four hour period. B. The Technical Supervisor acknowledged at the time of the review there was no written policy in the event the fire alarm system was out of service for four hours or more in a twenty four hour period. The Technical Supervisor acknowledged there was no written policy in the event the sprinkler system was out of service for four hours or more in a twenty four hour period. 5. Related to failure to document quarterly fire drills for 3 of 3 shifts A. A review of documents with the Technical Operations Manager and the Technical Supervisor from 9:40 a.m. to 11:15 a.m. on 05/14/12 failed to evidence documentation of fire drills conducted on 3 of 3 shifts since the facility opened in December 2011. B. The Technical Supervisor, at the time of the review, stated the facility opened in December 2011 and operates for three shifts per day on Monday, Wednesday, and Friday and two shifts per day Tuesday, Thursday, and Saturday.		and attendance sheet are available at the facility. Fire drills were held on 5-21-12, 3 on 3 shifts and 5-22-12, 2 on 2 shifts, to include activation of the fire alarm and staff members' specific roles. Documentation of the drills is available within the facility. Ongoing, fire drills will be held per the QAI quarterly audit tool. A review/observation of the efficiency of the fire drills was discussed during the May 16 th 2012 QAI Meeting. Any opportunities for improvement were noted and will be addressed with the next quarterly drills. The Clinical Manager or designee is responsible to ensure the drills are conducted quarterly per the QAI Calendar, to include both patients and staff, and documentation will be available within the facility. The Clinical Manager is responsible to present the results of the drill to the monthly QAI Committee, as conducted and the QAI Committee is responsible to	

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	The Technical Supervisor stated fire drills had been conducted, but acknowledged no written documentation of fire drills conducted since the facility opened in December 2011 was available for review. 6. Related to failure to ensure 6 of 43 smoke detectors were installed in accordance with with the applicable requirements of NFPA 72, National Fire Alarm Code A. During a tour of the facility from 11:15 a.m. to 12:55 p.m. on 05/14/12 with the Technical Operations Manager and the Technical Supervisor, the following was noted: 1.) The smoke detector on the ceiling on the second floor at the top of the stairwell by the storage room was located one foot from an air supply vent. 2.) Two of two smoke detectors on the ceiling in the second floor training room were each located one foot from an air supply vent. 3.) The smoke detector on the ceiling in the lobby by the receptionist area was located one and half feet from an air supply vent. 4.) The smoke detector on the		review and provide oversight. 6. On 5-21-12 Resource Construction Inc. relocated 9 of 43 smoke detectors found within 3 feet of air supply vents or return air openings to be in compliance with the applicable requirements of NFPA 72, National Fire Alarm Code. Record of this work performed is maintained in the facility and documented on the ER-1 (equipment repair record). The Clinical Manager is responsible to present all data to the QAI Committee on the appropriate scheduled date. The QAI Committee is responsible for analysis and trending of the data. The Governing Body is responsible to ensure the audits are occurring and document ongoing resolution of the citations.	

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	ceiling in the treatment area by the lobby entrance was located one and a half feet from an air supply vent. 5.) The smoke detector on the ceiling in the treatment isolation room was located one and a half feet from an air supply vent. B. The Technical Operations Manager and the Technical Supervisor acknowledged, at the time of the observations, the aforementioned smoke detectors were each located less than three feet from an air supply diffuser or return air opening.			

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V0540	494.90 CFC-PATIENT PLAN OF CARE Based on clinical record and facility policy review and interview, it was determined the facility failed to ensure plans of care were complete and addressed all identified problems by failing to ensure all members of the interdisciplinary team had participated in the development of the plan of care in 4 of 12 records reviewed and failed to ensure plans of care included goals and estimated timetables in 10 of 12 records reviewed creating the potential to affect all of the facility's 124 current patients (See V 541); by failing to ensure plans of care addressed blood pressure management in 3 of 12 records reviewed creating the potential to affect all of the facility's 124 current patients (See V 543); by failing to ensure to ensure patients achieved the prescribed dose of dialysis by ensuring heparin had been administered as ordered in 3 of 10 hemodialysis records reviewed creating the potential to affect all of the facility's 98 current hemodialysis patients (home and incenter) (See V 544); by failing to ensure ensure patients' albumin was measured monthly in 1 of 12 records reviewed creating the potential to affect all of the facility's 124 current patients (See V 545); by failing to ensure ensure the necessary care was provided to	V0540	The Governing Body acknowledges its responsibility to ensure that Fresenius Medical Care Indianapolis North has implemented a "Comprehensive Interdisciplinary Assessment and Plan of Care" process as defined in #FMS-CS-IC-I-110-125A" to ensure that every patient has a timely, complete and current Comprehensive Assessment and Plan of Care completed by all members of the IDT which is available within their medical record and meets all criteria. The Governing Body, on June 8 th 2012, reviewed the SOD and developed the following Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. The following action steps were implemented The Governing Body will meet weekly to monitor the progress of the Plan of Correction until the Condition level deficiencies are lifted,	06/18/2012

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS NORTH		STREET ADDRESS, CITY, STATE, ZIP CODE 1225 W 86TH ST INDIANAPOLIS, IN 46260	

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	manage renal bone disease in 1 of 12 records reviewed (See V 546); by failing to ensure plans of care included interventions to monitor patients' accesses in 10 of 12 records reviewed creating the potential to affect all of the facility's 124 current patients (See V 551); by failing to ensure of care included patient-specific, individualized interventions to address identified needs and to monitor the patients' psychosocial status in 12 of 12 records reviewed creating the potential to affect all of the facility's 124 current patients (See V 552); by failing to ensure plans of care addressed rehabilitation needs in 9 of 12 records reviewed (See V 555); by failing to ensure plans of care had been updated annually in 1 of 12 records reviewed (See V 558); by failing to ensure plans of care specified reasons why goals had not been achieved in 4 of 12 records reviewed (See V 559); and by failing to ensure plans of care addressed identified educational needs in 7 of 8 records reviewed of patients with plans of care that identified educational needs creating the potential to affect all of the facility's 124 current patients (See V 562). The cumulative effect of these systemic problems resulted in the facility's inability to meet the requirements of this condition, 42 CFR 494.90 Patient Plan of Care.		then monthly for an additional three months to ensure that the corrective actions have resulted in resolution of the cited issues. Once this is determined, the Governing Body will return to quarterly or as needed meetings. Effective immediately: · The Clinical Manager (CM) will analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee. · A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda. · The QAI Committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution of the issues · The Director of Operations (DO) will present a report on the Plan of Correction data and all actions taken toward the resolution of the deficiencies at each Governing Body meeting	

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			through to the sustained resolution of all identified issues. · The Governing Body, at its meeting of June 8 th 2012,, designated the Regional Quality Manager to serve as Plan of Correction Monitor and provide additional oversight. She will actively participate in each QAI and Governing Body meeting - either personally or via conference call - and submit a status report at each of the referenced Governing Body meetings with a copy to the RVP. This additional oversight is to ensure the ongoing correction of deficiencies cited in the Statement of Deficiency through to resolution as well as ensure the Governance oversight role. · Minutes of the Governing Body and QAI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's direction and oversight and the QAI Committee's ongoing monitoring of facility activities. These are available for review at the facility. · The responses provided	

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			for V Tag' s V541, V543, V544, V545, V546, V551, V552, V555, V558, V559, and V 562 describe, in detail, the processes and monitoring steps taken to ensure that all deficiencies as cited within this Condition are corrected to ensure ongoing compliance	

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V0541	494.90 POC-GOALS=COMMUNITY-BASED STANDARDS 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. Based on clinical record review and interview, the facility failed to ensure all members of the interdisciplinary team (IDT) had participated in the development of the plan of care (PoC) in 4 (#s 1, 9, 11, & 12) of 12 records reviewed and failed to ensure plans of care included goals and estimated timetables in 10 (#s 1, 3, 4, 5, 7, 8, 9, 10, 11, & 12) of 12 records reviewed creating the potential to affect all of the facility's 124 current patients. The findings include: Regarding IDT participation: 1. Clinical record number 1 included a PoC dated 7-26-11. The plan failed to evidence the the medical social worker (MSW) and the registered dietitian (RD)	V0541	On May 2 nd 2012, the Regional Quality Manager met with the members of the IDT to emphasize the requirements as defined within the Conditions of Coverage and Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care" that all patients must have a Plan of Care that is specific to address the patient's needs and is based upon that patient's specific Comprehensive Assessment and that all disciplines i.e. members of the IDT must participate in the development. The patient's Plan of Care must include specific measurable outcomes	06/18/2012

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	had participated in the development of the plan. 2. Clinical record number 9 included a PoC dated 6-28-11. The plan failed to evidence the the MSW and the RD had participated in the development of the plan. 3. Clinical record number 11 included a PoC dated 6-28-11. The plan failed to evidence the the MSW and the RD had participated in the development of the plan. 4. Clinical record number 12 included a PoC dated 6-28-11. The plan failed to evidence the the MSW and the RD had participated in the development of the plan. 5. On 5-1-12 at 12:40 PM, these findings were presented to the Director of Operations, employee O; the Regional Quality Manager, employee W; and the Regional Vice President, employee X. No additional documentation and/or information was provided to the surveyor by the time of exit regarding these findings. Regarding outcomes and estimated timetables:		and timetables estimated to obtain each patient's outcomes. Emphasis was placed upon setting timetables for meeting psychosocial and rehabilitation goals, setting goals and timetables for resolving issues with home resources, diabetes education, monitoring the patient's modality status including the outcome and timetable, setting outcomes and meeting goals for blood pressure. The Clinical Manager and Regional Quality Manager completed 100% review of all patients' Plans of Care by May 14 th 2012, to ensure that all Plans of Care include desired outcomes/goals and estimated timetables to achieve those outcomes/goals. Any patients' Plan of Care found to be out of compliance including patients # 1, 3, 4, 5, 7, 8, 9, 10, 11 and 12 will be presented to the IDT for completion by June 18 th 2012 The Clinical Manager will review all Plans of Care monthly to ensure that desired outcomes/goals and estimated timetables have been	

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	1. Clinical record number 1 included a PoC dated 7-26-11. The plan identified "issues" with "coping and adjustment to dialysis." The plan failed to evidence an expected outcome or an estimated timetable to achieve the outcome. 2. Clinical record number 3 included a PoC dated 1-17-12. The plan included a rehabilitation goal of "maximum functional and/or work status." The plan failed to evidence an estimated timetable to achieve the desired outcome. 3. Clinical record number 4 included a PoC dated 3-22-12. The PoC identified a modality goal to "complete CAPD [continuous ambulatory peritoneal dialysis] training then PET/Adq [laboratory test] [then] CCPD [continuous cycling peritoneal dialysis]." The plan failed to evidence an estimated timetable to achieve the desired outcome. 4. Clinical record number 5 included a PoC dated 1-23-12. The PoC identified "issues" with "home resources". The plan failed to evidence any desired outcomes or estimated timetables to achieve the outcomes. A. The plan identified additional education was needed related to diabetes self management. The plan failed to		included. Any POC's found out of compliance will be scheduled for completion within the next 30 days and corrective action will be taken as appropriate. The Clinical Manager is responsible to report a summary of findings monthly to the QAI. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee. The Director of Operations is responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body	

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	evidence any desired outcomes or estimated timetables to achieve the outcomes. B. The plan stated, "Current plan: Continue to dialyze @ home." The plan failed to evidence any desired outcomes or estimated timetables to achieve the desired outcomes. 5. Clinical record number 7 included a PoC dated 11-29-11. The plan included a blood pressure and fluid management goal to achieve estimated dry weight and blood pressure control. The plan failed to evidence what the desired estimated dry weight and blood pressure goals were and failed to evidence an estimated timetable to achieve the desired outcomes. 6. Clinical record number 8 included a PoC dated 12-27-11. The plan states, "Goal: Achieve BP control." The plan failed to evidence what the desired blood pressure was for that patient and failed to evidence an estimated timetable to achieve the desired outcome. The plan identified additional education was needed regarding diabetes self management. The plan failed to include the desired outcome and an estimated timetable to achieve the desired outcome related to the identified			

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	education needs. 7. Clinical record number 9 included a PoC dated 6-28-11. The plan states, "Goal: Achieve BP control." The plan failed to evidence what the desired blood pressure was for that patient and failed to evidence an estimated timetable to achieve the desired outcome. A. The plan identified "issues" with "Coping and adjustment to dialysis." The plan failed to evidence the desired outcome or estimated timetable to achieve the outcome related to the identified psychosocial needs. B. The plan identified additional education was needed regarding diabetes self management. The plan failed to evidence the desired outcomes or estimated timetable to achieve the outcome related to the identified educational needs. 8. Clinical record number 10 included a PoC dated 2-28-12. The plan states, "Goal: Achieve BP control." The plan failed to evidence what the desired blood pressure was for that patient and failed to evidence an estimated timetable to achieve the desired outcome. 9. Clinical record number 11 included a			

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	PoC dated 6-28-11. The plan states, "Goal: Achieve BP control." The plan failed to evidence what the desired blood pressure was for that patient and failed to evidence an estimated timetable to achieve the desired outcome. A. The plan identified an anemia goal of 10-12 g/dL. The plan failed to evidence an estimated timetable to achieve the desired outcome. B. The plan identified the patient had a central venous catheter with the desired goal of a permanent access. The plan failed to evidence an estimated timetable to achieve the desired outcome of a permanent access. C. The plan identified "issues" with "coping and adjustment to dialysis." The plan failed to evidence an expected outcome or an estimated timetable to achieve the outcome. 10. Clinical record number 12 included a PoC dated 6-28-11. The plan states, "Goal: Achieve BP control." The plan failed to evidence what the desired blood pressure was for that patient and failed to evidence an estimated timetable to achieve the desired outcome. A. The plan identified "issues" with			

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	"coping and adjustment to dialysis." The plan failed to evidence an expected outcome or an estimated timetable to achieve the outcome. B. The plan identified educational needs related to diabetes self management. The plan failed to include the desired outcome or estimated timetable to achieve the outcome related to the identified educational needs. 11. On 5-1-12 at 12:40 PM, these findings were presented to the Director of Operations, employee O; the Regional Quality Manager, employee W; and the Regional Vice President, employee X. No additional documentation and/or information was provided to the surveyor by the time of exit regarding these findings.			

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V0543	494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; Based on clinical record review and interview, the facility failed to ensure the necessary care and services had been provided to manage the patients' volume status by failing to ensure plans of care addressed blood pressure management in 3 (#s 8, 9, and 11) of 12 records reviewed creating the potential to affect all of the facility's 124 current patients. The findings include: 1. Clinical record number 8 included a plan of care (PoC) dated 12-27-11. The portion of the PoC that addressed blood pressure control was blank. 2. Clinical record number 9 included a PoC dated 6-28-11. The portion of the PoC that addressed blood pressure control was blank. 3. Clinical record number 11 included a PoC dated 6-28-11. The portion of the PoC that addressed blood pressure control was blank.	V0543	To specifically address inclusion of the patient's volume status to manage blood pressure in the patient care plan, the following has occurred: · Reeducation of the IDT and attending physicians to facility policy on May 2nd 2012 as noted above emphasizing management of the patients' volume status by addressing blood pressure management · Review of 100% of the patient records in relation to blood pressure management · Scheduled several care plan meetings from May 2012 thru June 18 th 2012 for any patients found out of compliance in relation to volume status/ blood pressure management including patients 8, 9 and 11. · Implemented a monthly monitoring process focusing on volume status/blood pressure management as noted above.	06/18/2012

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	4. On 5-1-12 at 12:40 PM, these findings were presented to the Director of Operations, employee O; the Regional Quality Manager, employee W; and the Regional Vice President, employee X. No additional documentation and/or information was provided to the surveyor by the time of exit regarding these findings.		The Clinical Manager is responsible to report a summary of findings monthly to the QAI. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee. The Director of Operations is responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body.	

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V0544	494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. Based on clinical record review and interview, the facility failed to ensure patients achieved the prescribed dose of dialysis by ensuring heparin had been administered as ordered in 3 (#s 5, 9, & 11) of 10 hemodialysis records reviewed creating the potential to affect all of the facility's 98 current hemodialysis patients (home and incenter). The findings include: 1. Clinical record number 5 evidenced the patient was a home hemodialysis patient. The record included physician orders dated 7-1-10 that identified the patient was to receive 3500 units of bolus heparin each treatment. A. Home hemodialysis treatment runs sheets, dated 3-1-2, 3-3-12, 3-5-12, 3-6-12, 3-8-12, 3-9-12, 3-10-12, 3-12-12, 3-14-12, 3-15-12, 3-16-12, 3-17-12, 3-19-12, and 3-20-12, evidenced the patient had received 2800 units of heparin during each treatment.	V0544	A mandatory in-service was scheduled for all staff in both the in-center and home departments, on May 14 2012 with emphasis on ensuring that the patient's heparin is delivered according to the physician's prescription. The Clinical Manager or designee completed a review of all recent treatment sheets to ensure that every patient is receiving their heparin as per physician prescription. Any patient with discrepancies from the physician order will be presented to the patients attending physician and referred to the IDT as necessary for an update review of their orders and POC including patients 5, 9 and 11 Heparin administration will be monitored daily by the nurses during their treatment sheet review and then further reviewed by the Clinical Manager. Frequency of ongoing monitoring will be determined by the QAI Committee upon review of monitoring results and resolution of the issue. Any heparin dosages found out of compliance will be corrected immediately and corrective action will be taken as appropriate. The Home Program Manager will	06/18/2012

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	B. The Home Program Manager, employee U, stated, on 4-25-12 at 11:50 AM, "I called [patient number 5]. The patient states [the patient] has been administering 3500 units of heparin as ordered. The patient states [the patient] does not know why [the patient] wrote down 2800." The manager indicated the home records did not evidence the nurse had reviewed them and noted the discrepancy. 2. Clinical record number 9 included physician orders dated 11-30-10 identified 5000 units of bolus heparin was to be administered prior to the beginning of each hemodialysis treatment. A. Post treatment run sheets, dated 3-26-12, 3-30-12, 4-2-12, 4-4-12, 4-6-12, 4-9-12, 4-11-12, 4-13-12, 4-16-12, 4-18-12, 4-20-12, and 4-23-12, evidenced 10,000 units of bolus heparin had been administered prior to each treatment. B. The Director of Operations, employee O, stated, on 4-30-12 at 2:30 PM, "The order was put into the computer wrong. The order says DH100." 3. Clinical record number 11 included physician orders dated 3-14-12 that state "Heparin 6000 units every sched [scheduled] dialysis trmt [treatment] . . .		monitor this on a monthly basis by reviewing home patient's treatment records. Any home patient's heparin doses found out of compliance will result in immediate education with the patient and review with the patient's attending as indicated.The Clinical Manager will monitor the results of the treatment sheet reviews daily until the facility is resurveyed then weekly. Ongoing monitoring will be determined by the QAI Committee upon review of monitoring results and resolution of the issue The Clinical Manager and Home Program Manager are responsible to report a summary of findings monthly in QAI. If resolution is not evident, the QAI Committee will complete a root cause analysis and the Plan of Correction will be revised as necessary. The Director of Operations is responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body The Regional Quality Manager held an in-service with all members of the IDT team on May 2nd 2012 to review the following:. Comprehensive Interdisciplinary Assessment & Plan of Care Policy – FMS-CS-IC-1-110-125 A. Emphasis was placed that the Plan of Care must include education and training for patient and family members or	

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	Heparin 1500 units every sched dialysis trmt . . . Give 1500 cc heparin 2 hours into dialysis treatment to avoid clotting system." A. Post treatment run sheets, dated 3-29-12, 3-31-12, 4-3-12, 4-5-12, 4-7-12, 4-10-12, 4-12-12, 4-14-12, 4-19-12, 4-21-12, and 4-24-12, evidenced the 1500 units of heparin had been administered at the beginning of the treatment along with the 6000 units. B. A post treatment run sheet dated 4-17-12 evidenced the treatment had been initiated at 10:03 AM and had finished at 2:25 PM. The run sheet evidenced the 1500 units of heparin had been administered at 2:09 PM, 16 minutes before the end of the treatment. 4. On 5-1-12 at 12:40 PM, these findings were presented to the Director of Operations, employee O; the Regional Quality Manager, employee W; and the Regional Vice President, employee X. No additional documentation and/or information was provided to the surveyor by the time of exit regarding these findings.		caregivers or both in the aspects of identified educational needs.	

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V0545	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 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 clinical record and facility policy review and interview, the facility failed to ensure patients' albumin was measured monthly in 1 (#s 2) of 12 records reviewed creating the potential to affect all of the facility's 124 current patients. The findings include: 1. Clinical record number 2 failed to evidence the patient's albumin level had been measured for the month of April 2012. 2. The Director of Operations, employee O, indicated, on 4-24-12 at 5:00 PM, the patient's labs had been drawn twice during the month of April but no results had been received yet. The director stated, on 4-26-12 at 1:15 PM, "The nurse in charge should have followed up and ensured the labs had been drawn. I called Spectra. They did not receive any samples."	V0545	To specifically address inclusion of monitoring albumin level no less often than monthly as part of the patient care plan, the following has occurred: · Reeducation of the IDT and attending physicians to facility policy on May 2, 2012 as noted above Review of 100% of the patient records with emphasis placed on patient's albumin levels in respect to their identified goals. · Any patients found with abnormal levels or not meeting goal will be scheduled for a care plan meeting for May 15 2012 to include patient #2. · Implemented a monthly monitoring process in the QAI tracking tool Additionally the Clinical Manager noted the requirement for every patient to have monthly lab results	06/18/2012

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	3. The facility's 5-18-05 "Timing of Monthly Lab Panel" policy number HP-13-LS-1.02 states, "All Renal Care Group (RCG) clinics will have the monthly laboratory panel drawn on the first treatment day of the week during which the labs are drawn . . . Patients labs that were missed will be drawn on the patient's first treatment of the following week."		available. The Clinic Manager has been assigned the responsibility to ensure all patient's lab results are available. Any patient missing lab for whatever reason will be rescheduled and the lab results will be monitored to ensure they are received. The Clinical Manager is responsible to report a summary of findings monthly to the QAI. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee. The Director of Operations is responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body.	

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V0546	494.90(a)(3) POC-MANAGE MINERAL METABOLISM Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease. Based on clinical record and facility policy review and interview, the facility failed to ensure the necessary care was provided to manage renal bone disease in 1 (# 2) of 12 records reviewed. The findings include: 1. Clinical record number 2 failed to evidence the necessary care had been provided to manage the patient's phosphorous level. A. The record included laboratory results that evidenced the patient's phosphorous levels were above the desired values of 3.5 to 5.5 milligrams per deciliter (mg/dL) according to the Centers for Medicare and Medicaid Services (CMS) Measurement Assessment Tool (MAT). The levels were 5.9 mg/dL on 1-16-12, 7.1 mg/dL on 2-6-12, and 7.5 mg/dL on 3-5-12. B. The record failed to evidence patient's calcium, phosphorous, and PTH levels had been measured for the month of April 2012. C The Director of Operations,	V0546	To specifically address inclusion of monitoring albumin level no less often than monthly as part of the patient care plan, the following has occurred: · Reeducation of the IDT and attending physicians to facility policy on May 2, 2012 as noted above Review of 100% of the patient records with emphasis placed on patient's albumin levels in respect to their identified goals. · Any patients found with abnormal levels or not meeting goal will be scheduled for a care plan meeting for May 15 2012 to include patient #2. · Implemented a monthly monitoring process in the QAI tracking tool Additionally the Clinical Manager noted the requirement for every patient to have monthly lab results available. The Clinic Manager has been assigned the responsibility to ensure all patient's lab results are	06/18/2012

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	employee O, indicated, on 4-24-12 at 5:00 PM, the patient's labs had been drawn twice during the month of April but no results had been received yet. The director stated, on 4-26-12 at 1:15 PM, "The nurse in charge should have followed up and ensured the labs had been drawn. I called Spectra. They did not receive any samples." 2. The facility's 5-18-05 "Timing of Monthly Lab Panel" policy number HP-13-LS-1.02 states, "All Renal Care Group (RCG) clinics will have the monthly laboratory panel drawn on the first treatment day of the week during which the labs are drawn . . . Patients labs that were missed will be drawn on the patient's first treatment of the following week."		available. Any patient missing lab for whatever reason will be rescheduled and the lab results will be monitored to ensure they are received. The Clinical Manager is responsible to report a summary of findings monthly to the QAI. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee. The Director of Operations is responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body.	

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V0551	494.90(a)(5) POC-VA MONITOR/PREVENT FAILURE/STENOSIS The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis. Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care included interventions to monitor patients' accesses in 10 (#s 1, 3, 5, 6, 7, 8, 9, 10, 11, and 12) of 12 records reviewed creating the potential to affect all of the facility's 124 current patients. The findings include: 1. Clinical record number 1 included a plan of care (PoC) dated 7-26-11 that identified the patient had a "straight graft." The plan failed to evidence any interventions to monitor the access to prevent access failure. On 4-23-11 at 4:00 PM, the patient was asked if there had been any problems with the access. The patient replied, "I have had to have it declotted. Three times, I think." 2. Clinical record number 3 included a PoC dated 1-17 12 that identified the patient had a peritoneal dialysis catheter. The plan failed to evidence interventions	V0551	On May 2 nd 2012 the RQM met with all members of the IDT to review the requirements as noted in the Conditions for Coverage that all patient's vascular accesses must be monitored to prevent access failure – including AV grafts and fistula for signs of stenosis. On May 29 th 2012, the Education Coordinator provided an in-service to all patient care staff to review the requirement to monitor each patient's vascular access for symptoms of stenosis The Clinical Manager is responsible to report a summary of audit results monthly to the QAI Committee. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.	06/18/2012

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	to monitor the access for patency and exit site infection. 3. Clinical record number 5 included a PoC dated 1-23-12 that identified the patient had a arteriovenous fistula (AVF) in the right upper arm. The plan failed to evidence interventions to monitor the access to prevent failure. 4. Clinical record number 6 included a PoC dated 1-17-12 that identified the patient had an AVF in the left lower arm. The plan failed to evidence interventions to monitor the access to prevent failure. 5. Clinical record number 7 included a PoC dated 11-29-11 that identified the patient had a "straight graft." The plan failed to evidence interventions to monitor the access to prevent failure. 6. Clinical record number 8 included a PoC dated 12-27-11 that identified the patient had an AVF. The plan failed to include interventions to monitor the access to prevent failure. 7. Clinical record number 9 included a PoC dated 6-28-11 that identified the patient had an AVF. The plan failed to include interventions to monitor the access to prevent failure.		The Director of Operations is responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body.	

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	8. Clinical record number 10 included a PoC dated 2-28-12 that identified the patient had a "curved graft." The plan failed to include interventions to monitor the access to prevent failure. During an interview with patient number 10, on 4-26-12 at 8:40 AM, the patient indicated this was the "second" graft. 9. Clinical record number 11 included a PoC dated 6-28-11 that identified the patient had a double lumen cuffed intravenous catheter. The plan failed to include interventions to monitor the catheter's patency and to monitor the insertion site for signs and symptoms of infection. 10. Clinical record number 12 included a PoC dated 6-28-11 that identified the patient had a double lumen cuffed intravenous catheter. The plan failed to include interventions to monitor the catheter's patency and the insertion site for signs and symptoms of infection. 11. On 5-1-12 at 12:40 PM, these findings were presented to the Director of Operations, employee O; the Regional Quality Manager, employee W; and the Regional Vice President, employee X. No additional documentation and/or			

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	information was provided to the surveyor by the time of exit regarding these findings. 12. The facility's February 2, 2011 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-138-020-091 states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Provide vascular access monitoring . . . Provide PD Catheter access monitoring for patency, catheter, tunnel, or exit site infection."			

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V0552	494.90(a)(6) POC-P/S COUNSELING/REFERRALS/HRQOL TOOL The interdisciplinary team must provide the necessary monitoring and social work interventions. These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis. Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care included patient-specific, individualized interventions to address identified needs and to monitor the patients' psychosocial status in 12 (#s 1 through 12) of 12 records reviewed creating the potential to affect all of the facility's 124 current patients. The findings include: 1. Clinical record number 1 included a plan of care (PoC) dated 7-26-11. The PoC identified "issues" with "coping and adjustment to dialysis." The plan failed to include any interventions to address the identified issues and monitor the patient's psychosocial status. 2. Clinical record number 2 included a PoC dated 8-31-10. The PoC failed to	V0552	On June 7 th 2012 the Clinical Manager and Director of Operations met with the Social Worker to review her job description and the requirement - as a member of the IDT - to ensure every patient is provided the necessary monitoring and social work interventions. On June 14 th 2012, the Social Worker was oriented by the Region Lead Social Worker using an orientation check list to ensure she understands and complies with all requirements as defined within the Conditions for Coverage. The Regional Quality Manager held an in-service with all members of the IDT team on May 2 nd 2012 to review the following:	06/14/2012

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	evidence any interventions to monitor the patient's psychosocial status. 3. Clinical record number 3 included a "Progress Note Report" dated 2-29-12 that states, "[The patient] is seeing outside counselor that [the patient] says is helping." The record included a "Progress Note Report" dated 4-10-12 that states, "Pt continuing with outpt [outpatient] counseling which [the patient] reports to be very helpful." The record included a "Progress Note Report" dated 4-24-12 that states, "Has continued with outpt. counseling." The record included a PoC dated 1-17 12. The PoC failed to evidence any interventions to monitor the patient's psychosocial status. 4. Clinical record number 4 included a PoC dated 3-22-12. The PoC failed to evidence any interventions to monitor the patient's psychosocial status. 5. Clinical record number 5 included a PoC dated 1-23-12 that identified "issues" with "home resources." The plan of care failed to include any interventions to address the identified issue and to monitor the patient's psychosocial status. 6. Clinical record number 6 included a		§ Comprehensive Interdisciplinary Assessment & Plan of Care Policy – FMS-CS-IC-1 -110-125 A § Emphasis was placed that all members of the IDT must participate in providing the necessary monitoring and social work interventions to assist the patient in achieving and sustaining an appropriate psychosocial status. On May 14 th 2012 the Clinic Manager and the Home Therapy Manager completed a review of 100% of all patients' Plan of Care to determine if the patients' psychosocial status was current and included patient-specific, individualized intervention to address identified needs. Any patients without evidence of appropriate psychosocial intervention, including patient # 1 - 12 will have a revised Plan of Care by June 18 th 2012 The Clinical Manager or designee will review all completed POC's monthly x3 to verify the POC contains necessary monitoring and social work interventions. The	

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	PoC dated 1-17-12. The PoC failed to evidence any interventions to monitor the patient's psychosocial status. 7. Clinical record number 7 included a PoC dated 11-29-11. The PoC failed to evidence any interventions to monitor the patient's psychosocial status. 8. Clinical record number 8 included a PoC dated 12-27-11 that identified "issues" related to "education/vocation." The plan failed to evidence any interventions to address the identified need or to monitor the patient's psychosocial status. 9. Clinical record number 9 included a PoC dated 6-28-11 that identified "issues" related to "coping and adjustment to dialysis." The PoC failed to evidence any interventions to address the identified need or to monitor the patient's psychosocial status. 10. Clinical record number 10 included a PoC dated 2-28-12 that identified "issues" related to "insurance or financial resources." The plan failed to evidence any interventions to address the identified need or to monitor the patient's psychosocial status." 11. Clinical record number 11 included a		QAI Committee will determine the frequency of ongoing audits and the return to the QAI medical record audit based on audit results and resolution of the issue. The Director of Operations is responsible to ensure the Clinical Manager has presented all data and monitoring results to the QAI Committee as defined within this Plan of Correction. The QAI Committee is responsible to provide oversight to ensure the citations have been addressed and resolution has occurred and is sustained. A summary of the results and potential interventions will be documented in the monthly quality assurance improvement meeting minutes.	

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	PoC dated 6-28-11 that identified "issues" related to "coping and adjustment to dialysis." The plan failed to evidence any interventions to address the identified need or to monitor the patient's psychosocial status. 12. Clinical record number 12 included a PoC dated 6-28-11 that identified "issues" related to "coping and adjustment to dialysis." The plan failed to evidence any interventions to address the identified need or to monitor the patient's psychosocial status. 13. An interview was conducted with the medical social worker (MSW), employee S, on 4-26-12 at 1:55 PM. The MSW stated, "I see the patients almost every week and talk to them. I am most always available if needed. I do talk to other staff about how the patient is doing." The MSW indicated the interventions are not written on the plans of care. 14. The facility's February 2, 2011, "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-138-020-091 states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Psychosocial Status: Provide necessary monitoring and social work interventions, including			

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	counseling services and appropriate referrals."			

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V0555	494.90(a)(8) POC-REHAB STATUS ADDRESSED The interdisciplinary team must assist the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years), and make rehabilitation and vocational rehabilitation referrals as appropriate. Based on clinical record review and interview, the facility failed to ensure plans of care addressed rehabilitation needs in 9 (#s 1, 4, 5, 7, 8, 9, 10, 11, and 12) of 12 records reviewed. The findings include: 1. Clinical record number 1 included a plan of care dated 7-26-11. The plan of care failed to evidence if any rehabilitation needs had been identified as a result of the comprehensive assessment. The portion of the plan of care that addressed rehabilitation status was blank. 2. Clinical record number 4 included a plan of care dated 3-22-12. The plan failed to evidence in any rehabilitation needs had been identified as a result of the comprehensive assessment. The portion of the plan of care that addressed rehabilitation status was blank. 3. Clinical record number 5 included a plan of care dated 1-23-12 that identified	V0555	On May 2 nd 2012, the Regional Quality Manager reviewed the “Comprehensive Interdisciplinary Assessment and Plan of Care” policy with the Dietitian, Social Worker and Nursing Staff in reference to assessing patients’ level of productive activity including education, rehab and vocational rehab referrals. To ensure inclusion of the patient rehabilitation status in the developed patient care plan, the following has occurred: · Reeducation of the IDT and attending physicians to facility policy on May 2 nd 2012 emphasizing the requirement to address patients’ rehabilitation needs · Review of 100% of the patient records focusing on patient’s rehabilitation status · Any patient found deficient in this area including patients # 1,4,5,7,8,9,10,11	06/18/2012

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	the patient is a home hemodialysis patient. The rehabilitation portion of the plan was blank. The record included a comprehensive interdisciplinary assessment (CIA) dated 1-23-12 that identified the patient's "physical activities are limited." 4. Clinical record number 7 included a plan of care dated 11-29-11 that failed to evidence if any rehabilitation needs had been identified as a result of the comprehensive assessment. The rehabilitation portion of the plan of care was blank. 5. Clinical record number 8 included a psychosocial services note dated 12-21-11 that identified the patient was "interested in returning to school to study counseling." The record included a PoC dated 12-27-11. The rehabilitation portion of the plan of care was blank. 6. Clinical record number 9 included a PoC dated 6-28-11. The plan failed to evidence if any rehabilitation needs had been identified as a result of the comprehensive assessment. The rehabilitation portion of the plan was blank. 7. Clinical record number 10 included a PoC dated 2-28-12 that failed to evidence		and 12, will have scheduled several care plan meetings from May 15 th 2012 thru June 18 th , 2012 · Implemented a monthly monitoring process in the QAI Plan of Care tracking tool. The Clinical Manager is responsible to report a summary of findings monthly to the QAI. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee. The Director of Operations is responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body.	

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	if any rehabilitation needs had been identified as a result of the comprehensive assessment. The rehabilitation portion of the PoC was blank. 8. Clinical record number 11 included a PoC dated 6-28-11 that failed to evidence if any rehabilitation needs had been identified as a result of the comprehensive assessment. The rehabilitation portion of the PoC was blank. 9. Clinical record number 12 included a PoC dated 6-28-11 that failed to evidence if any rehabilitation needs had been identified as a result of the comprehensive assessment. The rehabilitation portion of the PoC was blank. 10. On 5-1-12 at 12:40 PM, these findings were presented to the Director of Operations, employee O; the Regional Quality Manager, employee W; and the Regional Vice President, employee X. No additional documentation and/or information was provided to the surveyor by the time of exit regarding these findings.			

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V0558	494.90(b)(2) POC-IMPLEMENT UPDATE-15 DAYS P PT ASSESS Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments specified in §494.80(d). Based on clinical record review and interview, the facility failed to ensure plans of care had been updated annually in 1 (# 2) of 12 records reviewed. The findings include: 1. Clinical record number 2 included a plan of care dated 8-31-10. The record failed to evidence any further review and update of the entire plan of care since 8-31-10. 2. The Director of Operations, employee O, stated, on 4-24-12 at 5:15 PM, "The plan of care was updated in August of 2011, but I cannot find it."	V0558	A meeting was held with the facility's Interdisciplinary Team on May 2 nd 2012 to review the requirements as stated in the Conditions for Coverage and detailed in Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care" #FMS-CS-IC-I-110-125A." emphasizing the requirement that all newly admitted patients must have their Comprehensive Assessment and Plan of Care completed by all members of the IDT within 30 days or 13 treatments from admission if they do not present with a completed current CIA/POC from a transferring facility. Additionally, all existing stable patients must have 90 day and annual update of their CIA/POC and that implementation of monthly or annual updates of the POC must be performed within 15 days of the completion of a new patient assessment by all members of the IDT.	06/18/2012

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			A Plan of Care tracking tool was initiated on May 2 nd 2012 to ensure all patients' Assessments and Plans of Care are scheduled and completed timely. The Clinic Manager and Home Therapy Manager are responsible to add new patients to the tickler system on admission. The Clinic Manager and Home Therapy Manager are responsible to manage the ticker system on a monthly basis. By June 18 th 2012 100% of the patients' Plans of Care will be reviewed by IDT Team for timely completion. Any newly admitted patient whose Plan of Care was developed later that 30 days or 13 treatments from their admission date or any existing patient's Plan of Care developed longer than 15 days from the time of the completion of the Assessments by all members of the IDT and is not current - will have an update to the Assessments and a POC completed by June 18 th 2012 including patient # 2. The Clinical Manager or designee will review all	

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			completed POC's monthly x 3 to verify the POC was developed within the first 30 days or 13 treatments for new patients and within 15 days of the completion of the re-assessments for monthly, 90 day and annual re-assessments. Any patient whose Plan of Care is non-compliant with these dates, will be rescheduled to be done immediately with the next POC meeting, the Clinical Manager will review the reason for non-compliance and corrective action may be initiated as appropriate. The QAI Committee will determine the frequency of ongoing audits and the return to the QAI medical record audit based on audit results and resolution of the issue. The Clinical Manager is responsible to present to the QAI Committee monthly - the number of CIA/POC's scheduled for completion and the number completed. Any discrepancy will be analyzed and presented for oversight. The Director of Operations or designee is responsible to ensure the Clinical Manager	

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			has presented all monitoring data as required to the QAI Committee for review. The QAI Committee is responsible to review all data, develop a root cause analysis if the CIA/POC's are not occurring timely and provide oversight to ensure the issue is resolved and the resolution is sustained.	

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V0559	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- (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 address the issues identified in paragraph (b)(3)(ii) of this section.			
	Based on clinical record review and interview, the facility failed to ensure plans of care specified reasons why goals had not been achieved in 4 (#s 2, 4, 7, and 8) of 12 records reviewed. The findings include: 1. Clinical record number 2 failed to evidence documentation of reasons for continued elevated phosphorous levels had been identified and addressed. A. The record included laboratory results that evidenced the patient's phosphorous levels were above the desired values of 3.5 to 5.5 milligrams per deciliter (mg/dL) according to the Centers for Medicare and Medicaid Services (CMS) Measurement Assessment Tool (MAT). The levels were 5.9 mg/dL on	V0559	The Regional Quality Manager met with the facility's Interdisciplinary Team on May 2 nd 2012 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care" FMS-CS-I-110-125A, to ensure that every patient will have a timely, complete and current Comprehensive Assessment and Plan of Care available with identified goals/outcomes and that each Plan of Care will be updated if needed, with reasons why an expected goal is not achieved. The Clinical Manager and Home Program Manager	06/18/2012

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	1-16-12, 7.1 mg/dL on 2-6-12, and on 7.5 mg/dL on 3-5-12. B. The record failed to evidence patient's calcium, phosphorous, and PTH (parathyroid hormone) levels had been measured for the month of April 2012. C The Director of Operations, employee O, indicated, on 4-24-12 at 5:00 PM, the patient's labs had been drawn twice during the month of April but no results had been received yet. The director stated, on 4-26-12 at 1:15 PM, "The nurse in charge should have followed up and ensured the labs had been drawn. I called Spectra. They did not receive any samples." 2. Clinical record number 4 failed to evidence documentation of reasons for continued decreased hemoglobin levels had been identified and addressed. A. The record included laboratory results that evidenced the patient's hemoglobin levels were below the desired values of 10-12 g/dL; less than 13 according to the CMS MAT. The levels were 7.8 g/dL on 2-23-12, 8.5 g/dL on 3-14-12, 9.8 g/dL on 3-22-12, 9.2 g/dL on 4-4-12, and 9.6 g/dL on 4-13-12. B. The Home Program Director,		completed a 100% chart review of all patients Plans of Care by May 14 th 2012 focusing on the patient's laboratory results. Any patient found with laboratory results that do not meet their patient specific goals will be presented at the Interdisciplinary Team meeting by June 18 th 2012 including patient's #2, 4, 7 and 8. Patient specific issues as identified will be included in the patient's specific Plan of Care. All members of the IDT, including the Dietitian and Social Worker, will review specific patient issues on a monthly basis. Any patients not meeting any of their specific goals, including laboratory results will be included on a monthly list of patients. The Clinical Manager will include patients on the list on the agenda for review by the Interdisciplinary team at the monthly care plan meeting for the purpose of making an adjustment to the Plan of Care. Recommendations of the IDT and actions taken monthly will be documented in each patient's specific Plan of Care	

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	employee U, was unable to provide any additional documentation and/or information when asked on 4-24-12 at 2:10 PM. 3. Clinical record number 7 failed to evidence documentation of reasons for continued less than desired phosphorous levels had been identified and addressed. The record included laboratory results that evidenced the patient's phosphorous levels were less than the desired 3.5 to 5.5 mg/dL according to the CMS MAT. The levels were 3.0 mg/dL on 3-5-12 and 2.5 mg/dL on 4-2-12. 4. Clinical record number 8 failed to evidence documentation of reasons for continued elevated phosphorous levels had been identified and addressed. The record included laboratory results that evidenced the patient's phosphorous levels were above the desired values of 3.5 to 5.5 mg/dL according to the CMS MAT. The levels were 5.8 mg/dL on 2-6-12, 7.1 mg/dL on 3-5-12, and 7.4 mg/dL on 4-23-12. 5. On 5-1-12 at 12:40 PM, these findings were presented to the Director of Operations, employee O; the Regional Quality Manager, employee W; and the		update/progress note section. Monthly monitoring of all Plans of Care completed that month will be done by the Clinical Manager and Home Program Manager, to ensure that patients not meeting a goal have been identified, are addressed and Plans of Care are being updated timely and appropriately. Any Plan of Care found out of compliance will be scheduled for completion within the next 30 days and corrective action will be taken as appropriate. The Clinical Manager or designee will review Plans of Care monthly until the facility is resurveyed. Frequency of ongoing monitoring will be determined by the QAI Committee based on review of audit findings and resolution of the issues. Ongoing, the Clinical Manager and Home Program Manager will ensure compliance when directed by the QAI Committee by auditing 25% of all medical records monthly for a period of 3 months focusing on all patients meeting goals and interventions when that does not occur.	

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	Regional Vice President, employee X. No additional documentation and/or information was provided to the surveyor by the time of exit regarding these findings.		The Clinical Manager (CM) is responsible to analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee for oversight and review. The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to analyze the results and determine a root cause analysis then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee	

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V0562	494.90(d) POC-PT/FAMILY EDUCATION & TRAINING The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types. Based on clinical record review and interview, the facility failed to ensure plans of care addressed identified educational needs in 7 (#s 1, 5, 7, 8, 9, 11, and 12) of 8 records reviewed of patients with plans of care that identified educational needs creating the potential to affect all of the facility's 124 current patients. The findings included: 1. Clinical record number 1 included a plan of care (PoC) dated 7-26-11. The PoC identified additional education was needed related to "diabetes self-management, diet, exercise." The plan failed to evidence interventions to address these identified educational needs. 2. Clinical record number 5 included a PoC dated 1-23-12 that identified additional education was needed related to "diabetes self-management, diet,	V0562	The Regional Quality Manager held an in-service with all members of the IDT team on May 2 nd 2012 to review the following: Comprehensive Interdisciplinary Assessment & Plan of Care Policy – FMS-CS-IC-1 -110-125 A Emphasis was placed that the Plan of Care must include education and training for patient and family members or caregivers or both - in the aspects of identified educational needs. On May 2 nd 2012 the Director of Operations started a review of 100% of all patients' Plans of Care to determine if every patient's Plan of Care included education and training. Any patients without evidence of this, including patient # 1, 5, 7, 8, 9, 11and 12 will be scheduled to have a revised Plan of Care by June 18 th 2012 The Clinical Manger has implemented a Plan of Care tracking tool system to track the dates for the POC for all	06/18/2012

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	exercise, foot checks, dental care, blood glucose monitoring, and diabetes meds." The plan failed to evidence interventions to address these identified educational needs. 3. Clinical record number 7 included a PoC dated 11-29-11 that identified additional education was needed related to "diabetes self-management, diet, exercise, foot checks, dental care, blood glucose monitoring." The plan failed to evidence interventions to address these identified educational needs. 4. Clinical record number 8 included a PoC dated 12-27-11 that identified additional education was needed related to "medication regime adherence . . . quality of life . . . "diabetes self-management, diet, exercise, foot checks, dental care, blood glucose monitoring, and diabetes meds." The plan failed to evidence interventions to address these identified educational needs. 5. Clinical record number 9 included a PoC dated 6-28-11 that identified additional education was needed related to "diabetes . . . diet, exercise, foot checks, dental care, blood glucose monitoring, and diabetes meds." The plan failed to evidence interventions to address these identified educational needs.		patients, including new patients. The Clinic Manager is responsible to enter and update patient's Plan of Care dates upon admission or status change. The Clinical Manager or designee will review all completed POC's monthly x3 to verify the POC contains education and training. The QAI Committee will determine the frequency of ongoing audits and the return to the QAI medical record audit based on audit results and resolution of the issue. The CM is responsible to monitor the completion of Plan of Care monthly through tracking Plans of Care due vs. Plans of Care completed and presenting to the QAI Committee for review. Any Plan of Care missed will be reviewed for determination of a root cause, the Plan of Care will be scheduled immediately for completion and an action plan developed to address the overall issue. The Director of Operations is responsible to ensure the Clinical Manager has presented all data and monitoring results to the QAI Committee as defined within this Plan of Correction. The QAI Committee is responsible to provide oversight to ensure the citations have been addressed and resolution has occurred and is sustained. A summary of the results and potential interventions will be documented in the monthly quality assurance improvement meeting minutes.	

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	6. Clinical record number 11 included a PoC dated 6-28-11 that identified additional education was needed related to "diabetes self management, diet, exercise, foot checks, blood glucose monitoring, diabetes meds." The plan failed to evidence interventions to address these identified educational needs. 7. Clinical record number 12 included a PoC dated 6-28-11 that identified additional education was needed related to "diabetes . . . diet, exercise, foot checks, dental care, blood glucose monitoring, diabetes meds." The plan failed to evidence interventions to address these identified educational needs. 8. On 5-1-12 at 12:40 PM, these findings were presented to the Director of Operations, employee O; the Regional Quality Manager, employee W; and the Regional Vice President, employee X. No additional documentation and/or information was provided to the surveyor by the time of exit regarding these findings.			

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V0587	494.100(b)(2),(3) H-FAC RECEIVE/REVIEW PT RECORDS Q 2 MONTHS The dialysis facility must - (2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and (3) Maintain this information in the patient ' s medical record. Based on clinical record and facility policy review and interview, the facility failed to ensure patient home records had been reviewed in 4 (#s 3, 4, 5, and 6) of 4 home dialysis records reviewed creating the potential to affect all of the facility's 32 home dialysis patients. The findings include: 1. The facility's 10-21-09 "Patient Home Record Keeping" policy number FMS-CS-HT-200-010A states, "Patient must bring Home Treatment log to each monthly clinic visit. Home records will be reviewed by Home Program nursing staff during patient monthly clinic visits to identify trends or omissions. Copies of the Home Treatment log will be kept in the patient medical record." The facility's 7-14-08 "Home Hemodialysis Treatment Record Policy" number FMS-CS-HT-II-300-020A states, "The home hemodialysis patient and/or caregiver will be trained in the	V0587	The Regional Quality Manager met with the facility's patient care staff on May 2nd 2012, to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care", to ensure that every home patients home record sheets will be reviewed at least every two months with documentation showing the review was completed timely upon receipt of the records and any deficiencies were addressed. The Home Therapy Manager will complete 100% chart audit of all patient's monthly visit sheets by May 14 th 2012 to ensure that all patients have documentation showing that their home record sheets have been reviewed at a minimum of every two months. Any patient found out of compliance, including patient's # 3, 4, 5 and 6 will be reviewed at the monthly clinic visits by June 18 th 2012 The Home Therapy Manager will	06/18/2012

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	completion of the Home Hemodialysis Treatment Record . . . Instruct the patient to bring all copies of treatment records and any other logs since the last clinic visit. Review patient's treatment records and address any concerns during the clinic visit. Maintain copies of the patient's treatment records and logs in the patients Home Program medical records. 2. Clinical record number 3 evidenced the patient was a home peritoneal dialysis patient. The record included a "Patient's Weight/Blood Pressure/Solutions Report" for 2-1-12 to 2-20-12. The report failed to evidence daily blood pressures had been recorded. A. The report failed to evidence the nursing staff had reviewed the records and noted the lack of blood pressure recordings. B. The Home Program Manager, employee U, stated, on 4-24-12 at 9:55 AM, "The blood pressures are not there. There is no documentation the nurse reviewed the records." 3. Clinical record number 4 evidenced the patient was a home peritoneal dialysis patient. The record included "Treatment Data Sheets" for 3-9-12 to 4-23-12.		audit the home patient records, as received, monthly to verify that any issues noted, have been addressed including notification to the patient's attending physician if required - as evidenced by available documentation within the medical record. The Home Program Manager is responsible to review the audit results monthly and discuss the results with the Clinical Manager. The Home Program Manager is also responsible to report a summary of findings monthly utilizing the medical record audit tool to the QAI committee. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.	

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	A. The data sheets failed to evidence the blood pressure or estimated dry weights had been recorded. The data sheets failed to evidence the nursing staff had reviewed and noted the lack of blood pressure and estimated dry weight recordings. B. The record included physician orders dated 2-27-12 and 3-30-12 that evidenced the patient was to self administer 20,000 units of Epogen three times per week. The record included a home calendar, dated 3-8-12 to 4-11-12, that identified when the patient had self administered Epogen. 1). The calendar evidenced the patient had self administered Epogen only 2 times the weeks of 3-8-12, 3-19-12, and 3-22-12. 2.) The record failed to evidence the nursing staff had reviewed the Epogen calendar and noted the patient had not self administered the medication per the physician's orders. 4. Clinical record number 5 evidenced the patient was a home hemodialysis patient. The record included physician orders dated 7-1-10 that identified the patient was to receive 3500 units of bolus heparin each treatment.			

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	A. Home hemodialysis treatment runs sheets, dated 3-1-2, 3-3-12, 3-5-12, 3-6-12, 3-8-12, 3-9-12, 3-10-12, 3-12-12, 3-14-12, 3-15-12, 3-16-12, 3-17-12, 3-19-12, and 3-20-12, evidenced the patient had received 2800 units of heparin during each treatment. B. The runs sheets failed to evidence the nursing staff had reviewed and noted the heparin dose discrepancy. C. The Home Program Manager, employee U, indicated, on 4-25-12 at 11:50 AM, the home records did not evidence the nurse had reviewed them and noted the discrepancy. 5. Clinical record number 6 evidenced the patient was a home hemodialysis patient. The record included "Home Hemodialysis Treatment Record Forms" dated 3-19-12, 3-21-12, 3-23-12, 3-26-12, 3-28-12, 3-30-12, 4-2-12, 4-4-12, 4-6-12, 4-9-12, 4-11-12, 4-13-12, and 4-16-12. The record failed to evidence the nursing staff had reviewed the home forms.			

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V0625	494.110 CFC-QAPI Based on administrative record and facility policy review and interview, the facility failed to ensure a quality assessment and performance improvement program was in place that addressed infection control practices and hepatitis B status of all patients creating the potential to affect all of the facility's 124 current patients (V 626); failed to ensure a quality assessment and performance improvement program was in place that included the identification and resolution of infection control practice noncompliance and the management of patients with regards to their hepatitis B status resulting in the continued noncompliance with infection control policies and procedures and the mismanagement of hepatitis B susceptible patients creating the potential to affect all of the facility's 124 current patients (See V 627); failed to ensure a quality assessment and performance improvement program was in place that identified noncompliant infection control practices and the hepatitis B status of all patients to prevent staff from caring for both hepatitis B positive and susceptible patients at the same time creating the potential to affect all of the facility's 124 current patients (See V 637); failed to ensure a quality assessment and	V0625	The Governing Body acknowledges its responsibility to ensure that FMC Indianapolis North facility has an effective, data driven Comprehensive Quality Assessment and Performance Improvement program in place that addresses infection control practices and the hepatitis B status of all patients. The Governing Body, on June 8 th 2012 reviewed the SOD and developed the following Plan of Correction ensuring that the deficiencies are addressed, both immediately and with long term resolution. The following action steps were implemented The Governing Body will meet weekly to monitor the progress of the Plan of Correction until the Condition level deficiencies are lifted, then monthly for an additional three months to ensure that the corrective actions have resulted in resolution of the cited issues. Once this is determined, the Governing Body will return to quarterly or as needed meetings.	06/08/2012

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	performance improvement program was in place that systematically monitored infection control practices and the hepatitis B status of all patients resulting in noncompliance with infection control policies and procedures and staff caring for hepatitis B positive patients and susceptible patients at the same time creating the potential to affect all of the facility's 124 current patients (See V 638); failed to ensure a quality assessment and performance improvement program was in place that identified the severity of noncompliant infection control practices creating the potential to affect all of the facility's 124 current patients (See V 639); and failed to ensure a quality assessment and performance improvement program was in place to identify and correct noncompliant infection control practices and the hepatitis B status of all patients to prevent staff from caring for both hepatitis B positive and susceptible patients at the same time creating the potential to affect all of the facility's 124 current patients (See V 640). The cumulative effect of these systemic problems resulted in the facility's inability to meet the requirements of the Condition for Coverage 42 CFR 494.110 Quality Assurrance and Performance Improvement.		Effective immediately: · The Clinical Manager (CM) will analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee. · A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda. · The QAI Committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution. · The Director of Operations will present a report on the Plan of Correction data and all actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. · The Governing Body, at its meeting of June 8 th 2012, designated the Regional Quality Manager to serve as Plan of Correction Monitor and provide additional oversight.	

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			She will actively participate in each QAI and Governing Body meeting - either personally or via conference call - and submit a formal status report at each of the referenced Governing Body meetings with a copy to the RVP. This additional oversight is to ensure the ongoing correction of deficiencies - as cited in the Statement of Deficiency - through to resolution as well as ensure the Governance of the facility is presented current and complete data to enhance their governance oversight role · Minutes of the Governing Body and QAI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's direction and oversight and the QAI Committee's ongoing monitoring of facility activities. These are available for review at the facility. · The responses provided for V626, V627, V637, V638, V639 and V640 describe, in detail, the processes and monitoring steps taken to ensure that all deficiencies as cited within this Condition are	

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			corrected to ensure ongoing compliance	

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V0626	494.110 QAPI-COVERS SCOPE SERV/EFFECTIVE/IDT INVOL The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.			
	Based on administrative record and facility policy review and interview, the facility failed to ensure a quality assessment and performance improvement (QAPI) program was in place that addressed infection control practices and hepatitis B status of all patients creating the potential to affect all of the facility's 124 current patients. The findings include: 1. The facility's administrative records failed to evidence documentation all patients' hepatitis status was tracked and monitored. The facility's QAPI documentation failed to evidence the facility tracked and monitored the	V0626	The Governing Body will ensure that the dialysis facility identifies issues and develops action plans for areas where the facility does not reach its expected goals. On May 9 th , 2012 the Director of Operations contacted the Regional Quality Manager and scheduled a meeting with all participants of the QAI Committee for the purpose of reeducation on the QAI process. This education included but was not limited to the following: · Review of the 2012 QAPI Program including the required outcomes, QAI	06/18/2012

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	hepatitis B antibody and antigen status of all patients. A. The facility's "Hepatitis Status - Detail" failed to evidence the antibody and/or antigen status was known for all patients. The Regional Quality Manager, employee W, stated, on 4-26-12 at 3:30 PM, "The status report is used to track all the patients' hepatitis status and vaccines. I can tell you it is incomplete." B. The facility's QAPI meeting minutes dated 9-14-2011, 10-19-2011, 11-16-2011, 12-28-2011, and 1-18-2012 all identify 33 HBV susceptible patients with 64% of the susceptible patients completing the vaccination series. The minutes all state, "All new admits were offered the vaccaine [sic] continue series on existing patients." C. The facility's QAPI meeting minutes dated 2-22-2012 failed to identify the number of susceptible patients and the percentage of patients completing the vaccination series. The only documentation included in the vaccination outcomes portion of the minutes states the hepatitis vaccination trends are "improving." D. The Medical Director indicated, on 4-30-12 at 9:10 AM, he was unaware the		Calendar, use of the Minutes template · Review of the process to identify, evaluate, trend, develop plans of correction and monitor results as related to all outcomes. · Outcomes and requirements specific to infection control and patients' hepatitis status. The QAI Committee acknowledges it has been deficient with infection control tracking in the past. The facility has appointed a new Clinical Manager and will analyze the information available within the facility for infection control tracking and hepatitis results at the QAI Meeting of May16th 2012 to update the Minutes with the current status as evidenced by trends and log reports. The Clinical Manager will also perform an audit of the QAI minutes from 2012 to ensure that there are no other areas in need of improvement and to recognize any negative trends of any outcomes. The Governing Body will ensure that a root cause analysis of these trends is	

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	facility had not tracked and monitored all patients' hepatitis status. He stated, "This was a glaring oversight on our part. I did not notice the QAPI meeting minutes all said the same thing. We do make sure our positive patients are dialyzed in isolation." 2. The facility's QAPI meeting minutes dated 9-14-2011, 10-19-2011, and 11-16-2011 failed to evidence any infection control observation audit results were reviewed. The infection control observation portion of the meeting minutes are blank except for "trend analysis" which is marked "improving." 3. The 12-28-2011 and 1-18-2012 QAPI meeting minutes failed to evidence any infection control observation audit results were reviewed. The infection control observation portion of the meeting minutes are blank except for "trend analysis" which is marked "improving" and a comment that "All observation up to date with no action plan required." 4. The 2-22-2012 QAPI meeting minutes failed to evidence any infection control observation audit results were reviewed. The infection control observation portion of the meeting minutes are blank. 5. The Director of Operations, employee		completed and an action plan developed. Focus will be placed on infection control, patient hepatitis status and any other identified issue. The Clinical Manager is responsible to report a summary of trending and analysis of infection control and hepatitis tracking monthly to the QAI and Medical Director. The Director of Operations is responsible monitor the QAI data monthly to ensure the Clinical Manager is presenting all trending and documentation as required. The QAI Committee and Medical Director are responsible to analyze the data, determine a root cause analysis if trending identifies infection control non-compliance and hepatitis B susceptibility that is outside of target and ensure action plans are in place and resolution is occurring. The Governing Body is responsible to provide oversight to the QAI Committee to ensure the Committee is fulfilling its role	

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	O, stated, on 4-27-12 at 10:50 AM, "We cannot find the infection control audits done by the former facility manager." The director offered to provide audits she had completed but none were received. 6. The Director of Operations, employee O, stated, on 4-27-12 at 1:00 PM, "Infection control audits are done quarterly and therefore there is nothing to discuss at some QAPI meetings because there were no audits done. 7. The Medical Director stated, on 4-30-12 at 9:10 AM, "I rely on corporate audits and the education people to make sure these things are done. I did not notice the blanks in the QAPI meeting minutes." 8. The facility's "HD Quality Assessment Improvement Program" calendar states infection control observation audits are to be done "bimonthly." 9. The facility's 1-4-12 "Infection Control Overview" policy number FMS-CS-IC-155-060A states, "The facility will monitor the effectiveness of the infection control program through the Quality Assessment and Performance Program."		in the identification, analysis, development of actions plans and monitoring improvement for all desired outcomes particularly infection control and patient's hepatitis B status.	

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V0627	494.110(a)(1) QAPI-ONGOING;USES INDICATORS=IMPROVEMENT The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.			
	Based on administrative record and facility policy review and interview, the facility failed to ensure a quality assessment and performance improvement (QAPI) program was in place that included the identification and resolution of infection control practice noncompliance and the management of patients with regards to their hepatitis B status resulting in the continued noncompliance with infection control policies and procedures and the mismanagement of hepatitis B susceptible patients creating the potential to affect all of the facility's 124 current patients. The findings include: 1. The facility's administrative records failed to evidence documentation all patients' hepatitis status was tracked and monitored. The facility's QAPI documentation failed to evidence the facility tracked and monitored the hepatitis B antibody and antigen status of	V0627	As noted in detail in V 626 above, the QAI Committee has instituted processes to ensure that all indicators including infection control and patient hepatitis status, will be closed monitored and non-compliance resolved through the facility's QAI program. The QAI Committee will also focus on improving health outcomes by the identification and reduction of medical errors including the recognition and resolution of infection control non-compliance and the management of patients with regards to their hepatitis B status. The Clinical Manager is responsible to report a summary of trending and analysis of infection control and hepatitis tracking as noted	06/18/2012

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152525	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING	(X3) DATE SURVEY COMPLETED 05/01/2012
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS NORTH		STREET ADDRESS, CITY, STATE, ZIP CODE 1225 W 86TH ST INDIANAPOLIS, IN 46260	

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	all patients. A. The facility's "Hepatitis Status - Detail" failed to evidence the antibody and/or antigen status was known for all patients. The Regional Quality Manager, employee W, stated, on 4-26-12 at 3:30 PM, "The status report is used to track all the patients' hepatitis status and vaccines. I can tell you it is incomplete." B. The facility's QAPI meeting minutes dated 9-14-2011, 10-19-2011, 11-16-2011, 12-28-2011, and 1-18-2012 all identify 33 HBV susceptible patients with 64% of the susceptible patients completing the vaccination series. The minutes all state, "All new admits were offered the vaccaine [sic] continue series on existing patients." C. The facility's QAPI meeting minutes dated 2-22-2012 failed to identify the number of susceptible patients and the percentage of patients completing the vaccination series. The only documentation included in the vaccination outcomes portion of the minutes states the hepatitis vaccination trends are "improving." D. The Medical Director indicated, on 4-30-12 at 9:10 AM, he was unaware the facility had not tracked and monitored all		through the adverse event reporting - monthly to the QAI and Medical Director. The Director of Operations is responsible monitor the QAI data monthly to ensure the Clinical Manager is presenting all trending and documentation as required. The QAI Committee and Medical Director are responsible to analyze the data, determine a root cause analysis if trending identifies infection control non-compliance and hepatitis B susceptibility that is outside of target and ensure action plans are in place and resolution is occurring. The Governing Body is responsible to provide oversight to the QAI Committee to ensure the Committee is fulfilling its role in the identification, analysis, development of actions plans and monitoring improvement for all desired outcomes particularly infection control and patient's hepatitis B status.	

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	patients' hepatitis status. He stated, "This was a glaring oversight on our part. I did not notice the QAPI meeting minutes all said the same thing. We do make sure our positive patients are dialyzed in isolation." 2. The facility's QAPI meeting minutes dated 9-14-2011, 10-19-2011, and 11-16-2011 failed to evidence any infection control observation audit results were reviewed. The infection control observation portion of the meeting minutes are blank except for "trend analysis" which is marked "improving." 3. The 12-28-2011 and 1-18-2012 QAPI meeting minutes failed to evidence any infection control observation audit results were reviewed. The infection control observation portion of the meeting minutes are blank except for "trend analysis" which is marked "improving" and a comment that "All observation up to date with no action plan required." 4. The 2-22-2012 QAPI meeting minutes failed to evidence any infection control observation audit results were reviewed. The infection control observation portion of the meeting minutes are blank. 5. The Director of Operations, employee O, stated, on 4-27-12 at 10:50 AM, "We			

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	cannot find the infection control audits done by the former facility manager." The director offered to provide audits she had completed but none were received. 6. The Director of Operations, employee O, stated, on 4-27-12 at 1:00 PM, "Infection control audits are done quarterly and therefore there is nothing to discuss at some QAPI meetings because there were no audits done. 7. The Medical Director stated, on 4-30-12 at 9:10 AM, "I rely on corporate audits and the education people to make sure these things are done. I did not notice the blanks in the QAPI meeting minutes." 8. The facility's "HD Quality Assessment Improvement Program" calendar states infection control observation audits are to be done "bimonthly." 9. The facility's 1-4-12 "Infection Control Overview" policy number FMS-CS-IC-155-060A states, "The facility will monitor the effectiveness of the infection control program through the Quality Assessment and Performance Program."			

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V0637	494.110(a)(2)(ix) QAPI-INDICATOR-INF CONT-TREND/PLAN/ACT The program must include, but not be limited to, the following: (ix) Infection control; with respect to this component the facility must- (A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence; (B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and (C) Take actions to reduce future incidents. Based on administrative record and facility policy review and interview, the facility failed to ensure a quality assessment and performance improvement (QAPI) program was in place that identified noncompliant infection control practices and the hepatitis B status of all patients to prevent staff from caring for both hepatitis B positive and susceptible patients at the same time creating the potential to affect all of the facility's 124 current patients. The findings include: 1. The facility's administrative records failed to evidence documentation all patients' hepatitis status was tracked and monitored. The facility's QAPI documentation failed to evidence the facility tracked and monitored the hepatitis B antibody and antigen status of	V0637	As noted in detail in V 626 and 627, the Governing Body has implemented processes to ensure that the facility's QAPI Program and systems in place to analyze and document the incidence of infection to identify trends and establish baselines as well as to develop recommendations and action plans to minimize infection transmission and promote patient immunization and to prevent future incidents. These processes are discussed in detail in V 124, V126, V127, and V131. As noted throughout the development of processes and subsequent monitoring tools, the Clinical Manager is responsible to report a	06/18/2012

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	all patients. A. The facility's "Hepatitis Status - Detail" failed to evidence the antibody and/or antigen status was known for all patients. The Regional Quality Manager, employee W, stated, on 4-26-12 at 3:30 PM, "The status report is used to track all the patients' hepatitis status and vaccines. I can tell you it is incomplete." B. The facility's QAPI meeting minutes dated 9-14-2011, 10-19-2011, 11-16-2011, 12-28-2011, and 1-18-2012 all identify 33 HBV susceptible patients with 64% of the susceptible patients completing the vaccination series. The minutes all state, "All new admits were offered the vaccaine [sic] continue series on existing patients." C. The facility's QAPI meeting minutes dated 2-22-2012 failed to identify the number of susceptible patients and the percentage of patients completing the vaccination series. The only documentation included in the vaccination outcomes portion of the minutes states the hepatitis vaccination trends are "improving." D. The Medical Director indicated, on 4-30-12 at 9:10 AM, he was unaware the facility had not tracked and monitored all		summary of trending and analysis of infections, infection control issues and hepatitis tracking as noted including the number of susceptible patients, percentages of immunization rates and staffing related to the buffer zone - monthly to the QAI and Medical Director. The Director of Operations is responsible monitor the QAI data monthly to ensure the Clinical Manager is presenting all trending and documentation as required. The QAI Committee and Medical Director are responsible to analyze the data, determine a root cause, analysis if trending identifies infection control non-compliance and hepatitis B susceptibility that is outside of target and ensure action plans are in place and resolution is occurring. The Governing As noted in detail in V 626 and 627, the Governing Body has implemented processes to ensure that the facility's QAPI Program and systems in place to analyze and document the incidence of infection to	

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	patients' hepatitis status. He stated, "This was a glaring oversight on our part. I did not notice the QAPI meeting minutes all said the same thing. We do make sure our positive patients are dialyzed in isolation." 2. The facility's QAPI meeting minutes dated 9-14-2011, 10-19-2011, and 11-16-2011 failed to evidence any infection control observation audit results were reviewed. The infection control observation portion of the meeting minutes are blank except for "trend analysis" which is marked "improving." 3. The 12-28-2011 and 1-18-2012 QAPI meeting minutes failed to evidence any infection control observation audit results were reviewed. The infection control observation portion of the meeting minutes are blank except for "trend analysis" which is marked "improving" and a comment that "All observation up to date with no action plan required." 4. The 2-22-2012 QAPI meeting minutes failed to evidence any infection control observation audit results were reviewed. The infection control observation portion of the meeting minutes are blank. 5. The Director of Operations, employee O, stated, on 4-27-12 at 10:50 AM, "We		identify trends and establish baselines as well as to develop recommendations and action plans to minimize infection transmission and promote patient immunization and to prevent future incidents.	

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	cannot find the infection control audits done by the former facility manager." The director offered to provide audits she had completed but none were received. 6. The Director of Operations, employee O, stated, on 4-27-12 at 1:00 PM, "Infection control audits are done quarterly and therefore there is nothing to discuss at some QAPI meetings because there were no audits done. 7. The Medical Director stated, on 4-30-12 at 9:10 AM, "I rely on corporate audits and the education people to make sure these things are done. I did not notice the blanks in the QAPI meeting minutes." 8. The facility's "HD Quality Assessment Improvement Program" calendar states infection control observation audits are to be done "bimonthly." 9. The facility's 1-4-12 "Infection Control Overview" policy number FMS-CS-IC-155-060A states, "The facility will monitor the effectiveness of the infection control program through the Quality Assessment and Performance Program."			

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V0638	494.110(b) QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time. Based on administrative record and facility policy review and interview, the facility failed to ensure a quality assessment and performance improvement (QAPI) program was in place that systematically monitored infection control practices and the hepatitis B status of all patients resulting in noncompliance with infection control policies and procedures and staff caring for hepatitis B positive patients and susceptible patients at the same time creating the potential to affect all the the facility's 124 current incenter patients. The findings include: 1. The facility's administrative records failed to evidence documentation all patients' hepatitis status was tracked and monitored. The facility's QAPI documentation failed to evidence the facility tracked and monitored the hepatitis B antibody and antigen status of all patients. A. The facility's "Hepatitis Status -	V0638	As noted in detail in V 626 and 627, the Governing Body has implemented processes to ensure that the facility's QAPI Program and systems in place to analyze and document the incidence of infection to identify trends and establish baselines as well as to develop recommendations and action plans to minimize infection transmission and promote patient immunization and to prevent future incidents. These processes are discussed in detail in V 124, V126, V127, and V131. The facility has also developed processes to continuously monitor its performance, tack actions and track performance to ensure resolution of the issues is occurring. As noted throughout this POC in regards to infection control and hepatitis B monitoring tools, the Clinical Manager is responsible to report a	06/18/2012

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V0639	494.110(c) QAPI-PRIORITIZING IMPROVEMENT ACTIVITIES The dialysis facility must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety. Based on administrative record and facility policy review and interview, the facility failed to ensure a quality assessment and performance improvement (QAPI) program was in place that identified the severity of noncompliant infection control practices creating the potential to affect all of the facility's 124 current patients. The findings include: 1. The facility's administrative records failed to evidence documentation all patients' hepatitis status was tracked and monitored. The facility's QAPI documentation failed to evidence the facility tracked and monitored the hepatitis B antibody and antigen status of all patients. A. The facility's "Hepatitis Status - Detail" failed to evidence the antibody and/or antigen status was known for all patients. The Regional Quality Manager, employee W, stated, on 4-26-12 at 3:30	V0639	As noted in detail in V 626 and 627, the Governing Body has implemented processes to ensure that the facility's QAPI Program and systems in place to analyze and document the incidence of infection to identify trends and establish baselines as well as to develop recommendations and action plans to minimize infection transmission and promote patient immunization and to prevent future incidents. These processes are discussed in detail in V 124, V126, V127, and V131. The QAI Committee, under the direction of the Medical Director, has also developed processes to ensure prioritization of all issues identified by the QAI Committee according to the severity of identified problems – giving the priority to those issues that would affect patient safety and/or clinical outcomes.	06/18/2012

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	PM, "The status report is used to track all the patients' hepatitis status and vaccines. I can tell you it is incomplete." B. The facility's QAPI meeting minutes dated 9-14-2011, 10-19-2011, 11-16-2011, 12-28-2011, and 1-18-2012 all identify 33 HBV susceptible patients with 64% of the susceptible patients completing the vaccination series. The minutes all state, "All new admits were offered the vaccaine [sic] continue series on existing patients." C. The facility's QAPI meeting minutes dated 2-22-2012 failed to identify the number of susceptible patients and the percentage of patients completing the vaccination series. The only documentation included in the vaccination outcomes portion of the minutes states the hepatitis vaccination trends are "improving." D. The Medical Director indicated, on 4-30-12 at 9:10 AM, he was unaware the facility had not tracked and monitored all patients' hepatitis status. He stated, "This was a glaring oversight on our part. I did not notice the QAPI meeting minutes all said the same thing. We do make sure our positive patients are dialyzed in isolation."		As noted throughout this POC in regards to infection control and hepatitis B monitoring tools, the Clinical Manager is responsible to report a summary of trending and analysis of infections, infection control issues and hepatitis tracking as noted including the number of susceptible patients, percentages of immunization rates and staffing related to the buffer zone - monthly to the QAI and Medical Director. The Director of Operations is responsible monitor the QAI data monthly to ensure the Clinical Manager is presenting all trending and documentation as required. The QAI Committee and Medical Director are responsible to analyze and prioritize the data, determine a root cause analysis if trending identifies infection control non-compliance and hepatitis B susceptibility that is outside of target and ensure action plans are in place and resolution is occurring. The Medical Director is responsible to review all	

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	2. The facility's QAPI meeting minutes dated 9-14-2011, 10-19-2011, and 11-16-2011 failed to evidence any infection control observation audit results were reviewed. The infection control observation portion of the meeting minutes are blank except for "trend analysis" which is marked "improving." 3. The 12-28-2011 and 1-18-2012 QAPI meeting minutes failed to evidence any infection control observation audit results were reviewed. The infection control observation portion of the meeting minutes are blank except for "trend analysis" which is marked "improving" and a comment that "All observation up to date with no action plan required." 4. The 2-22-2012 QAPI meeting minutes failed to evidence any infection control observation audit results were reviewed. The infection control observation portion of the meeting minutes are blank. 5. The Director of Operations, employee O, stated, on 4-27-12 at 10:50 AM, "We cannot find the infection control audits done by the former facility manager." The director offered to provide audits she had completed but none were received. 6. The Director of Operations, employee O, stated, on 4-27-12 at 1:00 PM,		Minutes to ensure they are complete and accurately document actions taken in all areas including infection control and hepatitis B. The Governing Body is responsible to provide oversight to the QAI Committee to ensure the Committee is fulfilling its role in the identification, analysis, development of actions plans and monitoring improvement for all desired outcomes particularly infection control and patient's hepatitis B status.	

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	"Infection control audits are done quarterly and, therefore, there is nothing to discuss at some QAPI meetings because there were no audits done. 7. The Medical Director stated, on 4-30-12 at 9:10 AM, "I rely on corporate audits and the education people to make sure these things are done. I did not notice the blanks in the QAPI meeting minutes." 8. The facility's "HD Quality Assessment Improvement Program" calendar states infection control observation audits are to be done "bimonthly." 9. The facility's 1-4-12 "Infection Control Overview" policy number FMS-CS-IC-155-060A states, "The facility will monitor the effectiveness of the infection control program through the Quality Assessment and Performance Program."			

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V0640	494.110(c) QAPI-QAPI-IMMEDIATELY CORRECT ANY IJ ISSUES The facility must immediately correct any identified problems that threaten the health and safety of patients. Based on administrative record and facility policy review and interview, the facility failed to ensure a quality assessment and performance improvement (QAPI) program was in place to identify and correct noncompliant infection control practices and the hepatitis B status of all patients to prevent staff from caring for both hepatitis B positive and susceptible patients at the same time creating the potential to affect all of the facility's 124 current patients. The findings include: 1. The facility's administrative records failed to evidence documentation all patients' hepatitis status was tracked and monitored. The facility's QAPI documentation failed to evidence the facility tracked and monitored the hepatitis B antibody and antigen status of all patients. A. The facility's "Hepatitis Status - Detail" failed to evidence the antibody and/or antigen status was known for all patients. The Regional Quality Manager, employee W, stated, on 4-26-12 at 3:30	V0640	As noted throughout multiple V tags above i.e. V 124, V126, V127, V131, V 627, V 637, V 638 and V 639 the facility has develop and implemented multiple processes related to the immediate correction of infection control noncompliance and patient's hepatitis B status. As submitted to CMS on April 27, 2012, the following Plan was submitted in response to the immediate jeopardy: ·Call meeting of Governing Body to address issues related to Immediate Jeopardy situation and develop Plan of Correction as noted below ·Review all patient records to determine antibody and antigen status of each patient as well as any patient who was scheduled to received the Hepatitis vaccination and either did not or received an incomplete dose. Any patient without known status will be scheduled for testing as noted below ·Review all staff immunization records to	05/01/2012

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	PM, "The status report is used to track all the patients' hepatitis status and vaccines. I can tell you it is incomplete." B. The facility's QAPI meeting minutes dated 9-14-2011, 10-19-2011, 11-16-2011, 12-28-2011, and 1-18-2012 all identify 33 HBV susceptible patients with 64% of the susceptible patients completing the vaccination series. The minutes all state, "All new admits were offered the vaccaine [sic] continue series on existing patients." C. The facility's QAPI meeting minutes dated 2-22-2012 failed to identify the number of susceptible patients and the percentage of patients completing the vaccination series. The only documentation included in the vaccination outcomes portion of the minutes states the hepatitis vaccination trends are "improving." D. The Medical Director indicated, on 4-30-12 at 9:10 AM, he was unaware the facility had not tracked and monitored all patients' hepatitis status. He stated, "This was a glaring oversight on our part. I did not notice the QAPI meeting minutes all said the same thing. We do make sure our positive patients are dialyzed in isolation."		determine antibody status for each staff members. Any staff member without a known status will be testing. Any staff members without antibodies will be offered the Hepatitis B vaccine. ·Revise all patient seating charts based on antibody/antigen status to ensure buffer zone is comprised of AB+ patients only. ·Dedicate primary care giver for all Hepatitis B + patients and ensure only Hepatitis AB+ patients on the daily staffing schedule are assigned to the dedicated primary care giver. This care giver as well as the RN administering medications will be Hepatitis antibody + ·Dedicate primary nurse to provide IV medications to only Hepatitis B antigen+ patient and Hepatitis AB+ patients ·Include in revised patient seating charts a second area for all patients with “unknown status.” These patients will be treated by separate staff members including RN who are Hepatitis B antibody positive until the patient status is known. ·Hold immediate staff in-service with **all** direct patient care staff to educate	

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	"Infection control audits are done quarterly and therefore there is nothing to discuss at some QAPI meetings because there were no audits done. 7. The Medical Director stated, on 4-30-12 at 9:10 AM, "I rely on corporate audits and the education people to make sure these things are done. I did not notice the blanks in the QAPI meeting minutes." 8. The facility's "HD Quality Assessment Improvement Program" calendar states infection control observation audits are to be done "bimonthly." 9. The facility's 1-4-12 "Infection Control Overview" policy number FMS-CS-IC-155-060A states, "The facility will monitor the effectiveness of the infection control program through the Quality Assessment and Performance Program."		immediately draw Hepatitis Panels and offer the Hepatitis vaccine upon negative results. Documentation will be in the patient's medical records including declination if the patients' decline. The Clinical Manager is responsible to review all lab results, notify the attending physicians and ensure the information is documented in the patients' Plan of Care. ·Update Vaccination tracking tools with most current information and monitor weekly. The Clinic Manager is responsible to add all new patients to the tracking tool. The Clinic Manager is responsible to obtain orders on all new patients to ensure their hepatitis status is known and the Hepatitis vaccination offered. ·Inform each patient regarding seating changes and reasons for drawing blood if required. Documentation of discussions of patients is available in the patient's medical record ·All infection control audits as well as specifics as related to this Plan of Correction will be presented to the QAI Committee monthly to review for trends. If resolution is not	

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			occurring, the QAI Committee will review to determine the root cause, implement a revised action plan and follow through to resolution. This will be evidenced through documentation in the QAI Minutes.	

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V0710	Based on observation, interview, and administrative record review, it was determined the medical director failed to ensure a quality assessment and performance improvement program was in place that addressed infection control and the hepatitis B status of all patients creating the potential to affect all of the facility's 124 current patients (See V 712). The cumulative effect of this systemic problem resulted in the facility being out of Compliance with the Conditions for Coverage 494.150: Responsibilities of the Medical Director.	V0710	The Medical Director acknowledges his responsibility to ensure that FMC Indianapolis North facility has an effective Quality Assessment and Performance Improvement program that addresses infection control and the hepatitis B status of all patients. The Governing Body, including the Medical Director on June 8 th 2012reviewed the SOD and developed the following Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. The following action steps were implemented The Medical Director as a member of Governing Body will meet weekly to monitor the progress of the Plan of Correction until the Condition level deficiencies are lifted, then monthly for an additional three months to ensure that the corrective actions have resulted in resolution of the cited issues. Once this is determined, the Medical Director will return to quarterly or as needed Governing Body meetings.	06/18/2012

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			Effective immediately: · The Clinical Manager (CM) will analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the Medical Director as responsible for the QAI Committee. · A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda. · The Medical Director as chairperson of the QAI Committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution of the issues · The Director of Operations (DO) will present a report to the Medical Director on the Plan of Correction and all actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. · The Governing Body, at its meeting of June 8 th 2012,	

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			designated the Regional Quality Manager to serve as Plan of Correction Monitor and provide additional oversight. She will actively participate in each QAI and Governing Body meeting - either personally or via conference call - and submit a formal status report at each of the referenced Governing Body meetings and provide a copy to the RVP. This additional oversight is to ensure the ongoing correction of deficiencies cited in the Statement of Deficiency through to resolution as well as ensure the Governance of the Facility is presented current and complete data to enhance their governance oversight role · Minutes of the Governing Body and QAI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's direction and oversight and the QAI Committee's ongoing monitoring of facility activities. These are available for review at the facility. · The responses provided for V712 describe, in detail, the processes and monitoring	

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			steps taken to ensure that all deficiencies as cited within this Condition are corrected to ensure ongoing compliance	

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V0712	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. Based on observation, interview, and administrative record review, the medical director failed to ensure a quality assessment and performance improvement program was in place that addressed infection control and the hepatitis B status of all patients creating the potential to affect all of the facility's 124 current patients. The findings include: 1. The facility's administrative records failed to evidence documentation all patients' hepatitis status was tracked and monitored. The facility's QAPI documentation failed to evidence the facility tracked and monitored the hepatitis B antibody and antigen status of all patients. A. The facility's "Hepatitis Status - Detail" failed to evidence the antibody and/or antigen status was known for all patients. The Regional Quality Manager, employee W, stated, on 4-26-12 at 3:30 PM, "The status report is used to track all the patients' hepatitis status and vaccines. I can tell you it is incomplete."	V0712	The Director of Operations met with the Medical Director on May 9 th 2012 to review the Medical Director's responsibility as defined in the "Conditions for Coverage", the "Fresenius Medical Staff Bylaws", the "Fresenius Medical Director's Responsibilities" and the "Fresenius Governing Body Bylaws" as Chairperson providing the operational responsibility for the facility's QAI program. This responsibility includes review of quality indicators including infection control issues and patient hepatitis B status as related to improved patient health outcomes and monitoring this data on a continual basis; education of facility and medical staff in the QAI objectives; reviewing the method of prioritizing the importance of improvement projects; inclusion/encouragement of all staff in participating towards achievement of QAI goals; communication with the Governing Body regarding the needs identified; and participating in the evaluation of the effectiveness of performance improvement plans/activities. As detailed above and defined	06/18/2012

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	B. The facility's QAPI meeting minutes dated 9-14-2011, 10-19-2011, 11-16-2011, 12-28-2011, and 1-18-2012 all identify 33 HBV susceptible patients with 64% of the susceptible patients completing the vaccination series. The minutes all state, "All new admits were offered the vaccaine [sic] continue series on existing patients." C. The facility's QAPI meeting minutes dated 2-22-2012 failed to identify the number of susceptible patients and the percentage of patients completing the vaccination series. The only documentation included in the vaccination outcomes portion of the minutes states the hepatitis vaccination trends are "improving." D. The Medical Director indicated, on 4-30-12 at 9:10 AM, he was unaware the facility had not tracked and monitored all patients' hepatitis status. He stated, "This was a glaring oversight on our part. I did not notice the QAPI meeting minutes all said the same thing. We do make sure our positive patients are dialyzed in isolation." 2. The facility's QAPI meeting minutes dated 9-14-2011, 10-19-2011, and 11-16-2011 failed to evidence any		in V 627, V 637, V 638 and V 639 the Medical Director will ensure that the QAI Committee identifies, tracks/trends, completes an analysis of, prioritizes and develops action plans for any infection control issues including patients' hepatitis B status as well as any other facility indicator not meeting goals. Per the Medical Director's direction – the QAI Committee is re-evaluating all QAI infection control data available for the last few months and developing action plans to address trends. This includes but is not limited to infection rates and patient's hepatitis B status. Any indicators identified as not meeting goal, will be evaluated, action plans will be developed as appropriate and the Medical Director will ensure follow up occurs until the issues are resolved and resolution is sustained. The Clinical Manager, per the Medical Director and QAI Committee direction, will conduct audits/monitoring as required by the outcomes being evaluated. Frequency of ongoing audits will be	

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	infection control observation audit results were reviewed. The infection control observation portion of the meeting minutes are blank except for "trend analysis" which is marked "improving." 3. The 12-28-2011 and 1-18-2012 QAPI meeting minutes failed to evidence any infection control observation audit results were reviewed. The infection control observation portion of the meeting minutes are blank except for "trend analysis" which is marked "improving" and a comment that "All observation up to date with no action plan required." 4. The 2-22-2012 QAPI meeting minutes failed to evidence any infection control observation audit results were reviewed. The infection control observation portion of the meeting minutes are blank. 5. The Director of Operations, employee O, stated, on 4-27-12 at 10:50 AM, "We cannot find the infection control audits done by the former facility manager." The director offered to provide audits she had completed but none were received. 6. The Director of Operations, employee O, stated, on 4-27-12 at 1:00 PM, "Infection control audits are done quarterly and therefore there is nothing to discuss at some QAPI meetings because		determined by the Medical Director/QAI Committee. The Clinical Manager is responsible to report a summary of trending and analysis monthly to the Medical Director and the QAI Committee. The Director of Operations is responsible monitor the QAI data monthly to ensure the Clinical Manager is presenting all trending and documentation as required. The Medical Director as operationally responsible for the QAI Committee is responsible to analyze the data, determine a root cause analysis if trending identifies outcomes that are outside of target and ensure action plans are in place and resolution is occurring	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152525	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING	(X3) DATE SURVEY COMPLETED 05/01/2012
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	there were no audits done. 7. The Medical Director stated, on 4-30-12 at 9:10 AM, "I rely on corporate audits and the education people to make sure these things are done. I did not notice the blanks in the QAPI meeting minutes." 8. The facility's "HD Quality Assessment Improvement Program" calendar states infection control observation audits are to be done "bimonthly." 9. The facility's 1-4-12 "Infection Control Overview" policy number FMS-CS-IC-155-060A states, "The facility will monitor the effectiveness of the infection control program through the Quality Assessment and Performance Program."			