

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 05/21/2012
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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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V0000	<p>This visit was a revisit for an ESRD Recertification Survey that resulted in an Immediate Jeopardy that was unremoved at exit. This visit was to determine whether the Immediate Jeopardy had been removed.</p> <p>Survey date: 5-21-12</p> <p>Facility: 005139</p> <p>Medicaid Vendor: 100217180A</p> <p>Surveyor: Vicki Harmon, RN, PHNS</p> <p>An Immediate Jeopardy was identified on 4-27-12. The facility was informed of the Immediate Jeopardy on 4-27-12 at 3:20 PM. The Immediate Jeopardy remained uncorrected at survey exit.</p> <p>This survey identified that the Immediate Jeopardy had been removed on 5-21-12 through interview, observation, inservice attendance, record review, audit reviews, and hepatitis status report review.</p> <p>Upon arrival to the treatment floor at 12:40 PM, observation noted patient number 48 was being dialyzed in the isolation room. Employee N indicated she was assigned to provide care to the</p>	V0000		
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE _____ TITLE _____ (X6) DATE _____

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

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	<p>patient. The employee indicated she was also assigned to patients numbered 56 and 57. The facility's "Hepatitis Vaccine Record" identified the patients were both "immune."</p> <p>Employee Z, a registered nurse, indicated he was assigned to provide care to patient number 48 in the isolation room. The nurse indicated he was also assigned to care for patients numbered 7, 16, 17, 35, 56, 57, 58, 59, and 60. The facility's "Hepatitis Vaccine Record" identified the patients assigned to employee Z were all "immune."</p> <p>The facility's schedule for the Monday, Wednesday, and Friday morning shifts identified "yellow" zones and "green" zones. The Director of Operations, employee O, indicated at 1:30 PM, the color zones maintained a separation between those patients that were "immune" and "susceptible." The director stated, "Patients are not to be moved between the yellow and the green zones."</p> <p>Employee N, a patient care technician, was observed to initiate dialysis on patient number 27 on 5-21-12 at 11:50 AM. The employee maintained compliance with dialysis precautions and infection control procedures with one exception. The employee placed a</p>				

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	<p>syringe filled with heparin on the dialysis chair side table without a barrier. The employee indicated she had attended multiple infection control and hepatitis B inservices and had been observed by facility education coordinators every day.</p> <p>Employee Y, a registered nurse, was observed to complete a pre-dialysis assessment on patient number 27 maintaining compliance with dialysis precautions and infection control procedures. The employee indicated she had attended multiple infection control and hepatitis B inservices and had been observed by facility education coordinators every day.</p> <p>Observation noted a 1:100 and 1:10 bleach solution on either side of the nurse's station. Employee A was unable to articulate how many milliliters of water and bleach were to be used to mix the appropriate strength of solution but was able to locate the appropriate measuring cups with lines to mark the number of milliliters of bleach and water to use. The employee indicated the 1:100 solution was to be used for "small" spills and the 1:10 was to be used for "large" spills.</p> <p>The facility's inservice records identified all staff had received inservice training regarding infection control, care of other</p>						

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	<p>patients concurrently with care of the hepatitis B positive patient, dialysis precautions, and the mixing of appropriate bleach solutions.</p> <p>The facility's audit records evidenced each employee had been monitored every day since 5-2-12 for infection control practices. The audit tools identified areas of concern that had been addressed with appropriate education and re-training.</p> <p>Fresenius Medical Care Indianapolis North continues to be out of compliance with the Condition for Coverage 42 CFR 494.30 Infection Control, 494.90 Patient Plan of Care, 494.110 Quality Assurance and Performance Improvement, and 494.150 Responsibilities of the Medical Director.</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN May 23, 2012</p>				

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V0110	<p>494.30 CFC-INFECTION CONTROL</p> <p>This visit was a revisit for an ESRD Recertification Survey that resulted in an Immediate Jeopardy. This visit was to determine whether the Immediate Jeopardy had been removed.</p> <p>Survey date: 5-21-12</p> <p>Facility: 005139</p> <p>Medicaid Vendor:</p> <p>Surveyor: Vicki Harmon, RN, PHNS</p>	V0110	<p>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:</p> <ul style="list-style-type: none"> ·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. 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 	05/21/2012	

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			<ul style="list-style-type: none"> ·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 <p>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</p>		

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			<p>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. 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</p>	

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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.	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 · 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.	05/21/2012	

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			<p>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. 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</p>	

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			<p>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 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 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.</p>	

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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.	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 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	05/21/2012	

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			<p>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 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</p>	

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			<p>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 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.</p>	

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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.	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 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	05/21/2012	

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			address the findings with the identified staff member. The Clinical Manager's action will be structured to reinforce 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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V0124	<p>494.30(a)(1)(i) IC: HBV: TEST ALL,REV RESULTS/STATUS B4 ADMIT Routine Testing for Hepatitis B</p> <p>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.</p> <p>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.</p>	V0124	<p>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 th upon receipt of the Statement of Deficiencies, the Director of</p>	05/21/2012	

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			<p>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:</p> <ul style="list-style-type: none"> · Reeducation and reinforcement of FMS-CS-IC-11-155-142A Policy Patient Testing and Vaccination for Hepatitis B with emphasis on: Routine testing of all patients, prompt review of results and ensuring that patients are managed appropriately based on their results inclusive of, but not limited to: <ul style="list-style-type: none"> o All new patients o Any existing patients <p>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</p>		

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			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 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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V0126	494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF Hepatitis B Vaccination Vaccinate all susceptible patients and staff members against hepatitis B.	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 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	05/21/2012	

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			<p>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 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 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:</p>		

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			<ul style="list-style-type: none"> ·Reviews patient hepatitis status prior to admission ·Assigns a nurse to initiate patient assessment prior to the first treatment and as part of this assessment the following occurs: <ul style="list-style-type: none"> ·Patient education on the hepatitis virus ·Patient education on the benefit of vaccination to hepatitis virus ·Obtains the patient consent/declination indicated by patient signature on the appropriate form <p>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:</p> <ul style="list-style-type: none"> ·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. <p>The QAI Committee will assess for an opportunity for improvement. If an opportunity for improvement is identified, the</p>	

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			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	<p>494.30(a)(1)(i) IC-HBV-TEST PTS/STAFF POST LAST DOSE Hepatitis B Screening: Patients and Staff</p> <p>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.</p>	V0127	<p>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,</p>	05/21/2012	

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			<p>the Director of Operations further 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 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</p>	

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			<p>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:</p> <ul style="list-style-type: none"> ·Reviews patient hepatitis status prior to admission ·Assigns a nurse to initiate patient assessment prior to the first treatment and as part of this assessment the following occurs: <ul style="list-style-type: none"> ·Patient education on the hepatitis virus ·Patient education on the benefit of vaccination to hepatitis virus ·Obtains the patient consent/declination indicated by patient signature on the appropriate form <p>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:</p> <ul style="list-style-type: none"> ·A summary of patients susceptible to Hepatitis B 		

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			<ul style="list-style-type: none"> ·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 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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V0131	<p>494.30(a)(1)(i) IC-HBV-ISOLATION-STAFFING Isolation of HBV+ Patients</p> <p>Staff members caring for HBsAg positive patients should not care for HBV susceptible patients at the same time, including during the period when dialysis is terminated on one patient and initiated on another.</p>	V0131	<p>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:</p> <ul style="list-style-type: none"> · 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: <ul style="list-style-type: none"> 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 	05/21/2012	

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			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. Additional actions taken: <ul style="list-style-type: none"> · 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: <ul style="list-style-type: none"> 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 	

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			<p>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 documentation are required as part of the patient education:</p> <ul style="list-style-type: none"> · Vaccine information statement (VIS http://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: <ul style="list-style-type: none"> 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 <p>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 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</p>	

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			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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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.	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 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	06/14/2012	

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			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 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		

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			oversight to ensure issues as identified are being addressed and resolution is occurring.	

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V0540	494.90 CFC-PATIENT PLAN OF CARE	V0540	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. 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 (equipment repair log)The Technical Supervisor is responsible to review the	06/18/2012	

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			<p>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 Committee 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 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,</p>		

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			<p>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 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 Manager on 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 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</p>		

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			<p>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 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</p>		

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			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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V0541	<p>494.90 POC-GOALS=COMMUNITY-BASED STANDARDS</p> <p>The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.</p>	V0541	<p>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 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</p>	06/18/2012	

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			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 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		

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			monthly QAI meeting and reported to the Governing	

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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;	V0543	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 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	06/18/2012	

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			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 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 Hepatitis B	

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			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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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.	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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			<p>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</p>		

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			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.	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 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	06/18/2012	

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			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.	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 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	06/18/2012	

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			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.	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. 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.	06/18/2012	

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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.	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: § 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	06/14/2012	

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			<p>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 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</p>		

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			meeting minutes.	

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V0555	<p>494.90(a)(8) POC-REHAB STATUS ADDRESSED</p> <p>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.</p>	V0555	<p>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:</p> <ul style="list-style-type: none"> · 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 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 	06/18/2012

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			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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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).	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. 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	06/18/2012	

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			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 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		

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			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 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	<p>494.90(b)(3) POC-OUTCOME NOT ACHIEVED-ADJUST POC</p> <p>If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must-</p> <p>(i) Adjust the plan of care to reflect the patient's current condition;</p> <p>(ii) Document in the record the reasons why the patient was unable to achieve the goals; and</p> <p>(iii) Implement plan of care changes to address the issues identified in paragraph (b) (3)(ii) of this section.</p>	V0559	<p>The Regional Quality Manager met with the facility's Interdisciplinary Team 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" 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 completed a 100% chart review of all patients Plans of Care by May 14th 2012 focusing on the patient's laboratory results. Any patient found with laboratory results that do not meet their</p>	06/18/2012	

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			<p>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 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</p>	

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			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. 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.	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 patients, including new patients. The Clinic Manager is responsible to enter and update patient's Plan of Care dates upon admission or	06/18/2012	

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			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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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.	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 audit the home patient records, as received, monthly to verify that any issues noted, have been	06/18/2012	

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			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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V0625	494.110 CFC-QAPI	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. 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	06/08/2012	

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			<p>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. 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</p>		

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			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 corrected to ensure ongoing compliance	

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V0626	<p>494.110 QAPI-COVERS SCOPE SERV/EFFECTIVE/IDT INVOL</p> <p>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.</p>	V0626	<p>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 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</p>	06/18/2012

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			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 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	

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			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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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.	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 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	06/18/2012	

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			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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V0637	<p>494.110(a)(2)(ix) QAPI-INDICATOR-INF CONT-TREND/PLAN/ACT The program must include, but not be limited to, the following: (ix) Infection control; with respect to this component the facility must-</p> <p>(A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence; (B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and (C) Take actions to reduce future incidents.</p>	V0637	<p>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 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</p>	06/18/2012

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			<p>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 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.</p>	

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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.	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 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	06/18/2012	

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			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 Medical Director is also responsible to review all 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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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.	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. 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	06/18/2012	

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			<p>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 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.</p>	

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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.	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 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.	05/21/2012

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			<ul style="list-style-type: none"> ·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 on dialysis precautions, Hepatitis B and infection control measures. Emphasis will be placed on proper infection control methods for Hepatitis B in addition to hand hygiene, PPE, mixing bleach, proper methods of disinfection and prevention of cross contamination. ·Formal inservice to be held April 30 th and May 1 st 2012 with the education coordinators to again review and reinforce requirements related to blood borne pathogens and Hepatitis B. 		

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			<ul style="list-style-type: none"> ·Implement immediate infection control audits daily for each shift of patients. Audits will include all areas as defined by policies above and noted in the survey findings including isolation precautions. Any areas of non-compliance will immediately be referred to the Clinical Manager; immediate correction will occur including corrective action as appropriate. ·Any patients with unknown Hepatitis status or documentation of the Hepatitis vaccine that was initiated but not completed as ordered will be referred to their attending physicians for orders to 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 		

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			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 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		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 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 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. 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	06/18/2012	

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			<p>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, 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</p>		

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			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 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.	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 in V 627, V 637, V 638 and V 639 the	06/18/2012

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			<p>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 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</p>		

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			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	