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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152534 | X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____ | X3) DATE SURVEY COMPLETED 11/29/2012 |
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| NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS SOUTH | STREET ADDRESS, CITY, STATE, ZIP CODE 1350 E COUNTY LINE RD STE L INDIANAPOLIS, IN 46227 |
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| V0000 | <p>This was a federal ESRD recertification survey and survey for the addition of peritoneal dialysis services, including home training for peritoneal dialysis and support.</p> <p>Survey Dates: 11/26/12 - 11/29/12</p> <p>Facility #: 008874</p> <p>Medicaid Vendor #: 200062560A</p> <p>Surveyors: Kelly Ennis, RN, BSN, Public Health Nurse Surveyor, Team Leader Dawn Snider, RN, BSN, Public Health Nurse Surveyor</p> <p>Census by Service Type:</p> <p>Number of In-Center Hemodialysis Patients: 54 Number of Home Hemodialysis Patients: 0 Number of Peritoneal Dialysis Patients: 1</p> <p>Total: 55</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN December 5, 2012</p> | V0000 | | |

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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| V0113 | <p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.</p> <p>Based on observation, staff interview, and policy and procedure review, the facility failed to ensure 1 of 3 Patient Care Technicians (PCT) (employee J) observed followed infection control policies creating the potential for the transmission of disease causing organisms among staff and all of the facility's 54 current in-center hemodialysis patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> On 11/26/12 at 10:48 AM, employee J, PCT, was at station #12. With gloves on, the PCT reached into the patient's bag and obtained a pillow to place behind the patient's back. The PCT then proceeded to apply an alcohol swab to the patient's arm and inserted needle #1. No glove change was completed prior to needle insertion. On 11/28/12 at 6:45 PM, during the daily exit conference, employee N, clinical manager, indicated the PCT should have changed gloves | V0113 | <p>On December 13, 2012 the Governing Body met to review the statement of deficiencies and to make certain that all identified deficiencies are being addressed both immediately and with long term resolution.</p> <p>The Clinical Manager is responsible to ensure that all staff members follow "Hand Hygiene, Personal Protective Equipment and Infection Control Overview" policies to ensure a safe treatment environment that prevents cross contamination of patients and equipment.</p> <p>The Clinical Manager met with the facility Education Coordinator to arrange and schedule staff in-services to re-educate all staff members on the following policies "Hand Hygiene" FMS-CS-IC-II-155-090A, "Personal Protective Equipment" FMS-CS-IC-II-155-080A and "Infection Control with emphasis placed on appropriate glove usage, glove changes and hand hygiene using hand sanitizer. Training will be completed by January 18, 2013 and an in-service attendance sheet will be available in the facility for</p> | 01/18/2013 |

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| | <p>prior to initiating treatment.</p> <p>3. Facility policy titled "Hand Hygiene" document number FMS-CS-IC-II-155-090A, revision date 1/04/2012, states, "Hands will be decontaminated using alcohol based hand rub or by washing hands with antimicrobial soap and water ... before performing any invasive procedure such as vascular access cannulation or administration."</p> | | <p>review in addition an audit with skills checks will be completed by January 18 th 2013</p> | |

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| V0121 | <p>494.30(a)(4)(i) IC-HANDLING INFECTIOUS WASTE [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- (i) Handling, storage and disposal of potentially infectious waste;</p> <p>Based on observation and staff interview, the facility failed to ensure proper disposal of potentially infectious waste during discontinuation of treatment for 2 of 3 patient care technicians (PCT) observed (J and B) creating the potential to spread infectious and communicable disease to all staff and 54 in-center hemodialysis patients of the facility.</p> <p>The findings include:</p> <p>1. On 11/26/12 at 10:58 AM, employee J, PCT, was at station #11 to discontinue treatment on the patient. The PCT removed needle #2 from the patient's arm and placed it on the chair side table. The PCT applied gauze and tape to the access site. The PCT placed a clamp on the patient's arm. The PCT then picked up the used needle from the chair side table and placed it in the sharps</p> | V0121 | <p>The Clinic Manager will meet with all direct patient care staff on January 11 th 2013 to discuss the findings of the recent survey and to review policy # FMS-CS-IC-II-115-01C "Post Treatment Fistula Needle Removal" with emphasis placed on discarding needles. After the in-service, all staff will be able to acknowledge understanding that any potentially infectious waste should be discarded in the appropriate marked waste container. Agenda and attendance sheet will be available within the facility.</p> <p>The Clinical manager or designee will conduct audits daily times two weeks then weekly for 4 weeks. Upon resolution, this will be audited ongoing by adding it to the QAI Infection Control audit and be monitored per the QAI calendar audit schedule.</p> <p>The Clinical Manager is responsible to review, analyze and trend all reports and present them monthly to the QAI</p> | 01/11/2013 | | | |

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| | <p>container.</p> <p>2. On 11/26/12 at 11:05 AM, employee B, PCT, was at station #8 to discontinue treatment on the patient. The PCT removed needle #1 from the patient's arm and placed it on the chair side table. The PCT applied gauze and tape to the access site. The PCT placed a clamp on the patient's arm. The PCT then picked up the used needle from the chair side table and placed it in the sharps container.</p> <p>3. On 11/26/12 at 11:12 AM, employee B, PCT, returned to station #8 to remove needle #2. The PCT removed needle #2 and placed it on the chair side table. The PCT applied gauze and tape to the access site. The PCT placed a clamp on the patient's arm. The PCT then picked up the used needle from the chair side table and placed it in the sharps container.</p> <p>4. On 11/26/12 at 11:15 AM, employee B, PCT, was at station #9 to discontinue treatment on the patient. The PCT removed needle #1 from the patient's arm and placed it on the chair side table. The PCT applied gauze and tape to the access site. The PCT placed a clamp on the</p> | | <p>Committee for review.</p> <p>The QAI Committee is responsible to provide oversight until ongoing resolution has been determined.</p> | |

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| | <p>patient's arm. The PCT then picked up the used needle from the chair side table and placed it in the sharps container</p> <p>5. On 11/28/12 at 6:55 PM, during the daily exit conference, employee N, clinical manager, indicated the PCT should have placed the safety needle into the sharps container immediately after removing it from the patient's arm.</p> | | | |

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| V0126 | <p>494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF Hepatitis B Vaccination</p> <p>Vaccinate all susceptible patients and staff members against hepatitis B.</p> | V0126 | <p>The Director of Operations met with the Practice Manager for the Indiana Nephrology and Internal Medicine Group to discuss the need for documentation of Hepatitis B vaccination and or serologic immune status of all medical staff including the Medical Director of the FMC Indianapolis South Facility Documentation of Hepatitis B Vaccination and or serologic immune status of all FMC Indianapolis South facility staff will be obtained by January 11 th 2013 including the Medical Director.</p> <p>The Clinical Manager is responsible to update the personnel tracking tool in the QAI Calendar on January 11 th 2013 .</p> <p>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 ·A summary of any patients who have missed a dose or the vaccination has not been initiated as ordered ·Any patients that have specific, | 01/11/2013 |

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| | <p>Based on personnel file review and staff interview, the facility failed to ensure all patient care staff had evidence of being vaccinated for Hepatitis B and or the serologic immune status in 1 (file P) of 6 personnel staff files reviewed of employees providing patient care with the potential to affect all of the facility's 54 current In-center hemodialysis patients.</p> <p>The findings include:</p> <p>1. Personnel file F, the Medical Director, failed to evidence documentation of being</p> | | <p>documented reasons for not receiving scheduled doses of Hepatitis B vaccine.</p> <p>· In addition, An Annual summary of all facility staff and the evidence of Hepatitis B Vaccination and or serologic immune status including the Medical Director</p> <p>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.</p> <p>The Clinical Manager is responsible for documenting and reporting data to the QAI Committee and the QAI Committee monitors for compliance</p> | | |

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| | <p>vaccinated for Hepatitis B.</p> <p>2. On 11/29/12 at 5:15 PM the clinical manager, employee N, indicated the medical director did not have any evidence of serologic testing or the vaccination.</p> | | | |

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| V0146 | <p>494.30(c)(2) IC-CATHETERS:GENERAL (2) The "Guidelines for the Prevention of Intravascular Catheter-Related Infections" entitled "Recommendations for Placement of Intravascular Catheters in Adults and Children" parts I - IV; and "Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients," Morbidity and Mortality Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection as the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html</p> <p>Based on observation, staff interview, and policy review, the facility failed to ensure 2 of 3 Patient Care Technicians (PCT) (employees B and J) observed treating a patient with a central venous catheter (CVC) provided care in compliance with central venous catheter policy creating the potential to spread infectious and communicable disease which could affect all patients with a</p> | V0146 | <p>The Clinical Manager is responsible to ensure that all staff members follow the " Changing the Catheter Dressing" policy to ensure a safe treatment environment that prevents cross contamination of patients and equipment.</p> <p>The Clinical Manager met with the facility Education Coordinator to arrange and schedule staff in-services to re-educate all staff members on the following policy "Changing the Catheter Dressing"</p> | 01/18/2013 | |

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| | <p>CVC.</p> <p>The findings include:</p> <ol style="list-style-type: none"> On 11/27/12 at 11:25 AM, employee J, (PCT), was at station #4 performing a dressing change on a patient with a catheter. The PCT removed the old dressing and cleansed around the catheter site. The PCT then walked away to dispose of gloves, apply hand gel, and obtain new gloves. While away, the patient's shirt collar was touching the exposed catheter site. On 11/27/12 at 11:30 AM, employee B, PCT, was at station #2 performing a dressing change on a patient with a catheter. The PCT removed the old dressing and cleansed around the catheter site. The PCT then walked away to dispose of gloves, apply hand gel, and obtain new gloves. While away, the patient's shirt collar was touching the exposed catheter site. On 11/28/12 at 6:50 PM, during the daily exit conference, employee N, clinical manager, indicated the PCT should have used hemostats or tape to hold the patient's shirt collar back while performing the dressing change. | | <p>FMS-CS-IC-II-105-032C with emphasis placed on dressing changes.</p> <p>Training will be completed by January 18 th 2013 and an in-service attendance sheet is available in the facility for review in addition an audit with skills checks will be completed by January 18 th 2013</p> <p>The Clinical Manager held a counseling session for Employee J and B on December 14 th 2012 to discuss policy violations on November 27, 2012 as noted in the SOD. Expectations for improvement were discussed and documented.</p> <p>The Clinical manager or designee will conduct audits daily times two weeks then weekly for 4 weeks.</p> | | |

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| | 4. Facility policy titled "Changing the Catheter Dressing" document number FMS-CS-IC-I-105-032A, with an effective date of 4/4/12 states, "Catheter related infections are one of the leading causes of death and reasons for catheter removal in dialysis patients. Strict infection control practices and adherence to the catheter dressing change procedure is essential to prevent serious complications." | | | |

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| V0410 | 494.60(d)(1) PE-PT CARE STAFF-CURRENT CPR CERT Staff training must be provided and evaluated at least annually and include the following: Ensuring that, at a minimum, patient care staff maintain current CPR certification | V0410 | The Director of Operations met with the facility's staff on December 13 th 2012 to review their requirements as stated in the Conditions for Coverage, to ensure that every staff member has a current CPR certification in their education file and to emphasize their responsibility to ensure the CPR certification remains current and documentation is provided to the Clinical Manager on a timely basis. On December 13 th 2012 the Clinical Manager performed a 100% audit of all personnel files to ensure a current CPR certification is on file. Any staff missing their CPR will be immediately placed in the next available CPR class; all will be current on December 13 th 2012 The Clinical Manager will utilize the Personnel file tracking tool in the QAI for all staff quarterly to ensure that all staff maintain a current CPR certification. The Clinical Manager is responsible to review the personnel tracking tool quarterly | 12/13/2012 | |

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| | Based on personnel file review and staff interview, the facility failed to ensure all patient care staff were CPR (Cardiopulmonary Resuscitation) certified in 1 (file F) of 6 personnel files reviewed of patient care staff with the potential to affect all of the facility's 54 current | | <p>identifying any opportunities for improvement and ensuring that all staff members remain current in CPR. This review is to be presented to the QAI Committee quarterly.</p> <p>The Director of Operations is responsible to ensure all documentation required as part of personnel tracking process and review is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans if needed.</p> <p>Medical Directors are not considered part of the direct patient care staff and are therefore not required to maintain a current CPR certification.</p> <p>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.</p> | | |

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| | <p>In-center hemodialysis patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Personnel file F, the Medical Director, failed to evidence documentation of CPR certification. 2. On 11/29/12 at 5:15 PM, the clinical manager, employee N, indicated the medical director had not been certified in CPR. | | | |

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| V0412 | 494.60(d)(2) PE-ER PREP-PTS ORIENTED/TRAINED The facility must provide appropriate orientation and training to patients, including the areas specified in paragraphs (d)(1)(i) of this section. | V0412 | <p>The Clinic Manager met with the facility's staff on December 13 th 2012 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy "Fire Drill Policy" FMS-CS-IC-II-130-013A, to ensure that every patient will be oriented and educated on emergency preparedness.</p> <p>As part of the admission process, each new patient will also be given this education. Quarterly, each patient will be invited to participate in the facility's fire drill with participation documented on the "Patient Participation in Fire and Disaster Drill Form", this form will also be used to document review of the information if a patient was absent on the day of the facility's fire drill, which will be available within the patients chart.</p> <p>The Clinical Manager will complete 100% review of all patients' Participation in Fire and Disaster Drill Form by December 31 st 2012 to ensure that all patients were given the opportunity to participate in the facility's quarterly Fire Drill, as evidenced by having each patient sign the participation form after</p> | 12/31/2012 |

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| | | | <p>each Fire Drill. Any patient without a form or lacking a signature, including patient #4, will have the emergency preparedness information reviewed and form signed by December 31 st 2012.</p> <p>The Clinical Manager will utilize the QAI tool for Fire Drill Observation tracking of all patients quarterly to ensure that all patients participated in the facility's fire drill as evidenced by their participation form and timely signature. New patients will be tracked utilizing the medical record audit form for all new patients monthly to ensure that they have been educated and trained on emergency preparedness.</p> <p>The Clinical Manager is responsible to report a summary of findings monthly utilizing the tracking tool as noted above to the QAI. Any patient without evidence of review and/or participation in the facility's fire drill will be scheduled for completion the following month and corrective action will be taken as appropriate.</p> <p>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</p> | | |

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| | <p>Based on clinical record review, staff and patient interview, and policy review, the facility failed to ensure patients and/or caregivers had been provided with appropriate orientation and training in emergency preparedness for 1 (#4) of 5 records reviewed with the potential to affect all of the facility's 54 current in-center hemodialysis patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record #4 evidenced the patient's first date of dialysis at the facility was 9/10/12. The record failed to evidence documentation the patient had received education and training in emergency preparedness. 2. During an interview on 11/28/12 at 4:45 PM, patient #4 indicated the facility had not provided any education regarding how to disconnect from the machine in | | <p>appropriate with the subsequent development of action plans.</p> <p>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.</p> | | |

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| | <p>the event of an emergency or disaster.</p> <p>3. On 11/29/12 at 5:30 PM, employee N, the clinical manager, was unable to provide any documentation patient #4 had received education and training in emergency preparedness.</p> <p>4. Facility policy titled "Patient Education" document number FMS-CS-IC-I-101-007A, with an effective date of 4/4/12 states, "Patient Education must be documented in the Patient's Medical Record as follows: New Patients-Education should be documented in the Education Record for New Patients ... It is the responsibility of the interdisciplinary team (RN, SW, RD, and, if available, the RightStart Case Manager, RSCM) to provide education on <u><i>all topics listed on the Education Record for New patients.</i></u>"</p> | | | |

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| V0413 | 494.60(d)(3) PE-ER EQUIP ON PREMISES-02, AED, SUCTION Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available. | V0413 | V 413 The Clinic Manager will meet with the facility's staff on January 10th 2013 to review their requirements detailed in Fresenius policy "Emergency Equipment/Supplies" to ensure that emergency supplies and medications are maintained at the dialysis facility as determined by the Governing Body under the guidance of the Medical Director. The Clinic Manager under the guidance of the Medical Director will obtain the medications and equipment that is to be kept at the facility for use in the emergency box by January 18 th 2013. The Clinic Manager will create a checklist by January 11 th 2013 containing all medications and supplies that are kept in the facility. The supplies and equipment will be checked daily by the clinic staff for expiration dates, quantities and that the medications and supplies are covered and locked. | 01/10/2013 | |

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| | Based on observation, facility document review, policy review, and interview, the facility failed to ensure emergency drugs had not expired and were available for emergency use with the potential to affect all of the facility's 54 current In-center hemodialysis patients. | | <p>The Clinic Manager is responsible to review the checklist of the medications and supplies monthly to ensure they audits are occurring.</p> <p>The Clinic Manager is responsible to report a summary of findings monthly and analyze the data and report to the QAI Committee on a monthly basis.</p> <p>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.</p> <p>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.</p> | | |

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| | <p>The findings include:</p> <ol style="list-style-type: none"> On 11/27/12 at 2:05 PM, employee N, the clinical manager, performed a review of the emergency kit with the surveyor. The label on the kit indicated expiration 10/12/12. The Dextrose 50% 50 cc (cubic centimeters) syringe and epinephrine 1:10,000 10 ml (milliliter) syringe expired on 10/12/12. The document titled "AED / Emergency Cart Daily Checklist" contained a category titled "Emergency kit lock intact. Kit within expiration date." A check mark in this category was marked to indicate it had been monitored for each day the facility was open, November 1st through November 27, 2012. On 11/27/12 at 2:05 PM, employee N, the clinical manager, indicated the emergency drugs inside the kit had passed the expiration date. The facility policy titled "Emergency Medications, Equipment and Supplies" document number FMS-CS-IC-II-130-007A with an effective date 10/3/12 states, "FMC Pharmacy Services will monitor | | | |

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| | expiration dates on any medication they distribute. Sixty days prior to expiration, a representative from FMS Pharmacy Services will contact the facility to notify them of an impending expired medication. The facility can then reorder the medication(s) due to expire." | | | |

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| V0502 | <p>494.80(a)(1) PA-ASSESS CURRENT HEALTH STATUS/COMORBIDS The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>(1) Evaluation of current health status and medical condition, including co-morbid conditions.</p> | V0502 | <p>The Clinic Manager will meet with the facilities interdisciplinary team on January 3 rd 2013 to review the requirements for the facility's Interdisciplinary Team 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 that includes a review of comorbid conditions.</p> <p>The Clinical Manager will complete 100% review of all patients' Comprehensive Assessments by January 18 th 2013 to ensure that all Assessments evidence the review of any comorbid conditions. Any patient's Assessment found to be out of compliance including patient # 4 will be presented to the IDT for completion by January 28 th 2013</p> <p>The Clinical Manager will utilize the QAI tool for Assessment and</p> | 01/28/2013 | |

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| | Based on clinical record review, staff interview, and policy review, the facility failed to ensure the comprehensive assessment included co-morbid conditions utilizing the facility's updated | | <p>Care-Plan tracking of all patients monthly to ensure that a review of all comorbid conditions was completed.</p> <p>The Clinical Manager is responsible to report a summary of findings monthly utilizing the tracking tool as noted above to include the number of Assessments due, completed and missed to the QAI. Any patient missing any component of the Assessment will be scheduled for completion the following month and corrective action will be taken as appropriate.</p> <p>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.</p> <p>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.</p> | | |

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| | <p>comprehensive assessment form in 1 (#4) of 1 clinical records reviewed of unstable patients with the potential to affect all of the facility's newly admitted patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical Record #4 included a comprehensive assessment completed by the registered nurse, employee N, on 9/10/12 that failed to evidence documentation of the patient's co-morbid conditions. 2. On 11/29/12 at 5:30 PM, employee N, the clinical manager, indicated the comprehensive assessment did not list the co-morbid conditions for patient #4 as a result of instituting a new computer system form which does not have an area for the co-morbid conditions. 3. The facility policy titled "Comorbid Review and Reconciliation (Applies to In-center and Home Patients)" document number FMS-CS-IC-II-150-021A with an effective date 1/4/12 states, "The purpose of this policy is to provide guidance to all in-center and home programs on obtaining, documenting, and maintaining the patient's current comorbid conditions to give the interdisciplinary team the necessary information to provide appropriate clinical care." | | | |

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| V0520 | <p>494.80(d)(2) PA-FREQUENCY REASSESSMENT-UNSTABLE Q MO In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted-</p> <p>At least monthly for unstable patients including, but not limited to, patients with the following: (i) Extended or frequent hospitalizations; (ii) Marked deterioration in health status; (iii) Significant change in psychosocial needs; or (iv) Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis.</p> | V0520 | <p>On January 3 rd 2013 the Clinic Manager will review the "Comprehensive Interdisciplinary Assessment and Plan of Care" policy with all members of the IDT in reference to patients who should be considered unstable with emphasis on those patients with frequent hospitalizations.</p> <p>The Clinical Manager will review 100% of all patients' Comprehensive Assessments by January 18 th 2013 to ensure that any patient, who meets the criteria for being unstable, has been identified and monthly Assessments and Plans of Care are occurring. Any patient identified as unstable, who has not been seen on a monthly basis, will be scheduled for initiation of monthly reviews by January 28 th 2013.</p> | 01/28/2013 | |

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| | | | <p>Ongoing, all members of the IDT will review patient status monthly to identify any patient who is not meeting their patient specific goal. Any patient deemed unstable will then be reassessed and a new Plan of Care developed for the purpose of making an adjustment to the Plan of Care.</p> <p>The Clinical Manager with the assistance of the facility secretary will utilize the QAI tool for hospitalizations, in addition to all members of the IDT reviewing all patients's to identify any patient who meets the unstable criteria for Assessment and Care-Plan tracking of all patients monthly to ensure the timely monthly completion of any unstable patient's Comprehensive Re-Assessment.</p> <p>The Clinical Manager is responsible to report a summary of findings monthly utilizing the audit to include the number of unstable Assessments due, completed and missed to the QAI. Any unstable patient that was missed will be scheduled for completion the following month and corrective action will be taken as appropriate.</p> <p>The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented,</p> | | |

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| | <p>Based on clinical record review, staff interview, and policy review, the facility failed to ensure the interdisciplinary team (IDT) conducted a comprehensive assessment at least monthly for a patient classified as unstable for 1 of 1 clinical records reviewed of unstable patients. (#4)</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record #4, start of care 9/10/12, evidenced an IDT care plan dated 10/1/12 that was marked as unstable. The record failed to evidence the patient had been reassessed within one month. 2. On 11/29/12 at 5:15 PM, employee N, the clinical manager, indicated the patient should have been reassessed within one | | <p>current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans.</p> <p>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</p> | | |

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| | <p>month if unstable.</p> <p>3. The facility policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care" document number of FMS-CS-IC-1-110-125A, with an effective date of 7/4/12 states, "The frequency of the Comprehensive Interdisciplinary Assessment and Plan of Care are determined by the findings of the comprehensive assessment and whether the patient is determined by the physician, with input from the interdisciplinary team (IDT), to be stable or unstable. Each facility will establish a process by which each patient is reviewed monthly for the status of stability to ensure appropriate frequency of reassessment and modification of the Plan of Care ... Unstable patients must be reassessed by the IDT and a new comprehensive assessment and Plan of Care completed monthly until the patient is determined by the IDT to be stable."</p> | | | |

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| V0543 | <p>494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status;</p> <p>Based on clinical record review, staff interview, and policy review, the facility failed to ensure patients' blood pressures and safety checks were monitored as directed in the facility's policy in 4 of 4 in-center clinical records reviewed. (#2, 3, 4, and 5)</p> <p>Findings:</p> <p>1. Clinical record number 2 revealed the patient's blood pressure and safety checks were not monitored every 30 minutes in 10 of 13 hemodialysis treatment flow sheets reviewed. The hemodialysis flow sheets that failed to monitor blood pressure every 30 minutes were dated 10/26/12, 10/29/12, 10/31/12, 11/2/12, 11/7/12, 11/9/12, 11/12/12, 11/16/12, 11/18/12, and 11/26/12.</p> <p>2. Clinical record number 3 revealed the patient's blood pressure and safety checks were not monitored every 30 minutes in 13 of 13 hemodialysis treatment flow sheets</p> | V0543 | <p>V543 The Clinical Manager/Education Coordinator will educate and review with all staff "Patient Monitoring During Patient Treatment" FMC-CS-IC-I-110-133A and the requirements for receiving machine data electronically through the chairside system by January 4th 2013with emphasis and focus on monitoring the patient's blood pressure every 30 minutes and verifying that machine data has been received in chairside. The Clinical Manager or designee will review treatment sheets daily for 2 weeks, weekly for 2 weeks, monthly times 2, then quarterly to ensure that all blood pressure checks are being done and documented. Any issues of noncompliance will be referred to the Clinical Manager immediately, the patient situation addressed, the Medical Director and/or attending physician notified as appropriate and corrective action taken as appropriate. The Clinical Manager is</p> | 01/03/2013 | | | |

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| | <p>reviewed. The hemodialysis flow sheets that failed to monitor blood pressure every 30 minutes were dated 10/26/12, 10/29/12, 10/31/12, 11/2/12, 11/5/12, 11/7/12, 11/9/12, 11/12/12, 11/14/12, 11/16/12, 11/18/12, 11/23/12, and 11/26/12.</p> <p>3. Clinical record number 5 revealed the patient's blood pressure and safety checks were not monitored every 30 minutes in 13 of 14 hemodialysis treatment flow sheets reviewed. The hemodialysis flow sheets that failed to monitor blood pressure every 30 minutes were dated 10/27/12, 10/30/12, 11/1/12, 11/3/12, 11/6/12, 11/8/12, 11/10/12, 11/13/12, 11/15/12, 11/17/12, 11/19/12, 11/21/12, and 11/27/12.</p> <p>4. On 11/29/12 at 5:35 PM, employee N, clinical manager, indicated safety checks and vital signs are supposed to be taken every 30 minutes.</p> <p>5. A policy titled "Patient Monitoring During Patient Treatment" document number FMS-CS-IC-I-110-133A, effective date 7/4/12 states, "Monitor the patient at the initiation of treatment and every 30 minutes, or more frequently as necessary ... Vital signs shall be monitored at the</p> | | responsible to report a summary of findings monthly in QAI and compliance will be monitored by the QAI committee. | |

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| | <p>initiation of dialysis and every 30 minutes, or more frequently, as needed ... Observe and document at the initiation of dialysis and at every safety check that all connections are secure and visible ... Check machine settings and measurements and document at the initiation of dialysis and at every safety check ... Documentation of monitoring will be completed on the treatment record."</p> <p>6. A policy titled "Patient Safety Checks" document number FMS-CS-IC-I-110-141A, effective date 7/4/12 states, "Safety checks will be performed pre treatment and every 30 minutes or more frequently as needed once treatment has begun."</p> <p>7. Clinical record #4 revealed the patient's blood pressure and safety checks were not monitored every 30 minutes in 5 of 13 hemodialysis treatment flow sheets reviewed. The hemodialysis flow sheets that failed to monitor blood pressure every 30 minutes were dated 10/26/12, 11/2/12, 11/9/12, 11/12/12, and 11/26/12.</p> | | | |

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| V0552 | <p>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.</p> <p>Based on clinical record review, policy review, and interview, the facility failed to ensure the interdisciplinary team provided the necessary monitoring and social work interventions in 1 (#4) of 5 records reviewed with the potential to affect all of the facility's 54 current In-center hemodialysis patients.</p> <p>The findings include:</p> <p>1. Clinical record #4 included a document titled "Kidney Disease Quality of Life 36 (KDQOL-36) Scores Report" dated 11/16/12. The document states, "Discuss responses to the survey with the patient. If any one of the five scores is below the average range or has declined by 10 or more points since the last survey administration, review responses to questions for that particular scale to</p> | V0552 | <p>V 552 On December 19 th 2012 the Regional Lead Masters of Social Worker reviewed the "Comprehensive Interdisciplinary Assessment and Plan of Care" policy with the Social Worker assigned to the FMC Indianapolis South facility in reference to the requirement to include interventions in each patient's Plan of Care for identified psychosocial needs.</p> <p>The Clinical Manager, will ensure each patient has had an evaluation of their psychosocial status and any identified psychosocial need has been addressed by the IDT. Any patient/Plan of Care missing evidence of social work interactions will be presented at the Interdisciplinary Team meeting by January 18 th 2013 including patient's # 4. Patient</p> | 12/19/2012 | | | |

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| | <p>determine if there is an issue or concern that is not already being addressed by the team. Discuss KDQOL scores and any patient identified issues with the interdisciplinary team (IDT) and determine if changes to the plan of care are indicated." The report evidenced 4 of the 5 scores were below the average range. The record failed to evidence the report had been reviewed or signed by the Social Worker.</p> <p>2. The facility policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care" document number FMS-CS-IC-I-110-125A with an effective date of 7/4/12 states, "The comprehensive interdisciplinary assessment must include the following: Evaluation of psychosocial needs by a qualified social worker."</p> <p>3. On 11/28/12 at 5:40 PM, employee N, the clinical manager, indicated there had been a problem with transition of social workers. The KDQOL scores report had not been reviewed due to the transition of social worker staff.</p> | | <p>specific issues as identified will be included in the patient's specific Plan of Care.</p> <p>Monthly monitoring of all Plans of Care completed that month will be done by the Clinical Manager, to ensure the patients' psychosocial needs have been identified, are addressed and Plans of Care are being updated timely and appropriately. This monitoring will continue monthly via the QAI Calendar for Medical Record Audits. Any POCs found out of compliance will be scheduled for completion within the next 30 days and corrective action will be taken as appropriate.</p> <p>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.</p> <p>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.</p> <p>The QAI Committee is responsible to analyze the results and determine a root cause</p> | | |

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| | | | 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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| V0558 | <p>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).</p> <p>Based on clinical record review, staff interview, and policy review, the facility failed to ensure the interdisciplinary team (IDT) conducted a plan of care at least monthly for a patient classified as unstable for 1 of 1 clinical records reviewed of unstable patients. (#4)</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record #4, start of care 9/10/12, evidenced an IDT care plan dated 10/1/12. The IDT plan of care was marked as unstable. The record failed to evidence an additional plan of care was completed within one month of the initial plan of care. 2. On 11/29/12 at 5:15 PM, employee N, the clinical manager, indicated another plan of care should have been completed within one month of the original plan of care if the patient was unstable. 3. The facility policy titled "Comprehensive Interdisciplinary | V0558 | <p>The Clinical Manager met with the facility's Interdisciplinary Team on January 3rd 2013 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 (based on the patient's status), complete and current Comprehensive Re-assessment and New Plan of Care whether monthly for unstable patients, 90 day or annual reassessment for stable patients, available within their medical record that includes implementation of the Plan of Care within 15 days of reassessment.</p> <p>The Clinical Manager will utilize the QAI tool for Care-Plan tracking of all patients monthly to ensure that all Comprehensive Assessments and Plans of Care are completed timely.</p> <p>The Clinical Manager will complete chart audits of all patients' Plans of Care via the QAI calendar Medical Records</p> | 01/03/2013 | |

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| | <p>Assessment and Plan of Care" document number of FMS-CS-IC-1-110-125A, with an effective date of 7/4/12 states, "The frequency of the Comprehensive Interdisciplinary Assessment and Plan of Care are determined by the findings of the comprehensive assessment and whether the patient is determined by the physician, with input from the interdisciplinary team (IDT), to be stable or unstable. Each facility will establish a process by which each patient is reviewed monthly for the status of stability to ensure appropriate frequency of reassessment and modification of the Plan of Care ... Unstable patients must be reassessed by the IDT and a new comprehensive assessment and Plan of Care completed monthly until the patient is determined by the IDT to be stable."</p> | | <p>Audits to ensure all Plans of Care who require reassessments, are current. Any patient's Plan of Care found out of compliance including patient # 4, will be presented at the Interdisciplinary Team meeting conducted on Jan 3 rd 2013</p> <p>The Clinical Manager is responsible to report a summary of findings monthly utilizing the tracking tool as noted above to include the number of Plans of Care due, completed and missed to the QAI.</p> <p>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.</p> | | |

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| V0562 | <p>494.90(d) POC-PT/FAMILY EDUCATION & TRAINING</p> <p>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.</p> | V0562 | <p>V 562</p> <p>The Clinic Manager will meet with the facility's Interdisciplinary Team on January 3 rd 2013 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy titled Patient Education, FMS-CS-IC-I-101-007A to ensure that every new patient will receive education on the dialysis experience, infection prevention, personal care, self care option and rehabilitation education and training for the patient and family members or caregivers in a timely, manner. This education will be completed and available within their medical record that meets all criteria for patient education.</p> <p>The Clinical Manager will or designee will complete medical record audits via the QAI calendar to ensure that new patients' education records are</p> | 01/03/2013 |

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| | | | <p>complete, current and that educational needs are identified with appropriate interventions provided. Any patient's education record found incomplete will be presented to the IDT for completion on January 18 th 2013 including patient #4.</p> <p>Ongoing, the Clinical Manager or designee will ensure compliance by auditing 10% of all medical records monthly and all new patients via the QAI calendar focusing on all patients' educational needs..</p> <p>The Clinical Manager is responsible to report a summary of findings monthly utilizing the tracking tool in the QAI calendar to identify any issues found in the patient's medical record related to patient education. 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.</p> <p>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.</p> <p>The QAI Committee is</p> | | |

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| | <p>Based on staff interview, clinical record review, and policy review, the facility failed to ensure all patients had been provided with education and training in 1 (#4) of 5 records reviewed with the potential to affect all of the facility's 54 current in-center hemodialysis patients.</p> <p>The findings include:</p> <p>1. Clinical record #4 included a plan of care dated 10/1/12 that failed to address and provide for education and training on the dialysis experience, infection prevention / personal care, self care options, and rehabilitation education and training for the patient and family members or caregivers. The record failed to evidence any education and training on these subjects had been provided.</p> | | <p>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</p> <p>Ongoing compliance will be monitored by the Governing Body.</p> | | |

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| | <p>2. On 11/29/12 at 5: 30 PM, employee N, the clinical manager, was unable to provide any documentation patient #4 had received education and training in dialysis experience, infection prevention/personal care, self care options, and rehabilitation education and training.</p> <p>3. Facility policy titled "Patient Education" document number FMS-CS-IC-I-101-007A, with an effective date of 4/4/12 states, "Patient Education must be documented in the Patient's Medical Record as follows: New Patients-Education should be documented in the Education Record for New Patients ... It is the responsibility of the interdisciplinary team (RN, SW, RD, and, if available, the RightStart Case Manager, RSCM) to provide education on <u><i>all topics listed on the Education Record for New patients.</i></u>"</p> | | | |

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| V0626 | <p>494.110 QAPI-COVERS SCOPE SERV/EFFECTIVE/IDT INVOL The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.</p> <p>Based on quality assurance document review, staff interview, and policy review, the facility failed to develop and implement a quality assessment and performance improvement (QAPI) program with participation by all members of the interdisciplinary team for 1 of 1 QAPI program reviewed with the potential to affect all the facility's patients.</p> <p>The findings include:</p> <p>1. The facility's "2011 Facility Quality Assessment and Performance Improvement (QAI) Incenter Hemodialysis Meeting Minutes", dated 1/12/2012, failed to evidence</p> | V0626 | <p>V 626 ·On December 13 th 2012 The Director of Operations met with the QAI committee members for the purpose of reeducation on the necessity of having all members present for each monthly QAI meetings sign the attendance form as documentation of participation in the monthly</p> <p>The Clinical Manager will review all attendance sheets monthly after each QAI meeting to ensure all signatures are present.</p> <p>The Director of Operations is responsible to audit the attendance forms quarterly to ensure compliance with all signatures on the attendance</p> | 01/17/2013 | | | |

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| | <p>the clinical manager, social worker, or technical services participated in the QAPI meeting.</p> <p>2. The facility's "2011 Facility Quality Assessment and Performance Improvement (QAI) Incenter Hemodialysis Meeting Minutes", dated 9/20/2012, failed to evidence the dietician participated in the QAPI meeting.</p> <p>3. The facility's "2011 Facility Quality Assessment and Performance Improvement (QAI) Incenter Hemodialysis Meeting Minutes", dated 10/18/2012, failed to evidence the clinical manager participated in the QAPI meeting.</p> <p>4. On 11/29/12 at 5:30 PM, employee Q, Director of Operations, indicated there were no signatures to prove all members attended the QAPI meetings.</p> <p>5. Review of policy titled "Quality Assessment and Performance Improvement Program (QAPI)", document number FMS-CS-IC-I-101-001A with an effective date of 4/4/12 states, "QAI Committee members include, but are not limited to, Medical Director, Director of Operations (or designee),</p> | | <p>forms</p> <p>. The QAI Committee is responsible to analyze the results of these audits to ensure compliance is occurring.</p> <p>Ongoing compliance will be monitored by the QAI committee.</p> | | |

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| | Area Manager, Clinical Manager, Dietitian, Social Worker, Home Therapies representative, if applicable, and Technical Services representative." | | | |

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| V0715 | <p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must-</p> <p>(2) Ensure that-</p> <p>(i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers;</p> <p>Based on facility policy and procedure review, the medical director failed to ensure the facility had provided services in accordance with its own policies with the potential to affect all the agency's patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The medical director failed to ensure the facility policy titled "Hand Hygiene" document number FMS-CS-IC-II-155-090A, revision date 1/04/2012, was followed. (See V 113) 2. The medical director failed to ensure the facility policy titled "Changing the Catheter Dressing" document number FMS-CS-IC-I-105-032A, with an effective date of 4/4/12, was followed. (See V 146) 3. The medical director failed to | V0715 | <p>The Director of Operations will meet with the Medical Director before December 27 th 2012 to review her requirements as defined in the Condition for Coverage and Staff Bylaws to ensure that all policies and procedures relative to patient admission, patient care, infection control and patient safety are adhered to by all individual who treat patients in the facility emphasizing adherence to hand hygiene, changing of the catheter dressing, patient education, emergency medications, co-morbid review and reconciliation, interdisciplinary assessment and plan of care, patient monitoring during patient treatment and quality assessment and performance improvement program.</p> <p>The Director of Operations will also review the Plan of Correction that is instituted to correct these issues.</p> <p>The Medical Director will then approve and direct the implementation of the plan as noted below.</p> | 01/18/2013 | | | |

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| | <p>ensure the facility policy titled "Patient Education" document number FMS-CS-IC-I-101-007A, with an effective date of 4/4/12, was followed. (See V 412 and V 562)</p> <p>4. The medical director failed to ensure the facility policy titled "Emergency Medications, Equipment and Supplies" document number FMS-CS-IC-II-130-007A, with an effective date 10/3/12, was followed. (See V 413)</p> <p>5. The medical director failed to ensure the facility policy titled ""Comorbid Review and Reconciliation (Applies to In-center and Home Patients)" document number FMS-CS-IC-II-150-021A, with an effective date 1/4/12, was followed. (See V 502)</p> <p>6. The medical director failed to ensure the facility policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care" document number of FMS-CS-IC-1-110-125A, with an effective date of 7/4/12, was followed. (See V 520, V 552, and V 558)</p> <p>7. The medical director failed to ensure the the facility policy titled "Patient Monitoring During Patient</p> | | <p>The facility's patient care staff will be in-serviced on the following policies, "Hand Hygiene", "Personal Protective Equipment" and "Patient Monitoring During Patient Treatment" "Changing of the Catheter Dressing" "Patient Education" "Emergency Medications Equipment and Supplies" "Co-morbid Review and Reconciliation , "Comprehensive Assessments and Plans of Care" "Patient Safety Checks" and Quality Assessment and Performance Improvement Program" and "Post Treatment Fistula Needle Removal by January 18 th 2013 by education or designee with a record of training reviewed by the QAI committee.</p> <p>The Clinical Manager (CM) is responsible to present all data and monitoring/audit results as related to this Plan of Correction to the Medical Director at the QAI Meeting for oversight and review.</p> <p>The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented to the Medical Director during the monthly QAI Committee Meeting.</p> <p>The Medical Director as Chairperson of the QAI Committee is responsible to analyze the results and direct a</p> | | |

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| | <p>Treatment" document number FMS-CS-IC-I-110-133A, effective date 7/4/12, was followed. (See V 543)</p> <p>8. The medical director failed to ensure the the facility policy titled "Patient Safety Checks" document number FMS-CS-IC-I-110-141A, effective date 7/4/12, was followed. (See V 543)</p> <p>9. The medical director failed to ensure the the facility policy titled "Quality Assessment and Performance Improvement Program (QAPI)", document number FMS-CS-IC-I-101-001A, with an effective date of 4/4/12, was followed. (See V 626)</p> | | <p>root cause analysis with the development of a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee</p> | |