

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152542	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 04/24/2013
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY BLACKTHORN	STREET ADDRESS, CITY, STATE, ZIP CODE 6201 NIMTZ PKWY SOUTH BEND, IN 46628
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V000000	<p>This was a federal ESRD recertification survey.</p> <p>Survey Dates: 4/22/13 - 4/25/13</p> <p>Facility #: 009879</p> <p>Medicaid Vendor #: 200032320C</p> <p>Surveyors: Ingrid Miller, RN, Public Health Nurse Surveyor Dawn Snider, RN, Public Health Nurse Surveyor Janet Brandt, RN, Public Health Nurse Surveyor</p> <p>Number of In-Center Hemodialysis Patients: 138</p> <p>Fresenius Medical Care Nephrology Blackthorn was found to be out of compliance with the Condition for Coverage 494.30: Infection control.</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN May 2, 2013</p>	V000000		

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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V000110	<p>494.30 CFC-INFECTION CONTROL</p> <p>Based on observation, interview, and facility policy and procedure, it was determined the facility failed to ensure staff followed infection control policies during the provision of care in 3 of 5 observations creating the potential to affect all of the facility's 138 current patients (see V 111), failed to ensure staff performed hand hygiene appropriately after removing gloves in 3 of 5 observations of care on the treatment floor creating the potential to affect all of the facility's 138 patients (See V 113), failed to ensure surfaces were not contaminated with blood for 1 of 1 trash can by the north wing handwashing sink with the potential to affect all 138 patients of the dialysis clinic and any staff or visitors who would come in contact with the waste can (See V 122), failed to ensure HBsAG+ (Positive Hepatitis B Antigen) patients were separated from other stations by a space at least equivalent to the width of one hemodialysis station for 1 of 2 HBsAg+ positive patients observed receiving hemodialysis with the potential to affect all the patients susceptible to hepatitis B (See V 128), and failed to ensure staff followed infection control policies during the provision of catheter care in 1 of 5 observations creating the potential to</p>	V000110	<p>The Governing Body acknowledges its responsibility to ensure that Fresenius Medical Care Nephrology Blackthorn provides and monitors a sanitary environment to minimize transmission of infectious agents, ensure staff wear gloves and complete hand sanitizing appropriately including following policy on catheter care, surfaces are not contaminated with blood, HBsAg+ patients are in an area removed from the mainstream of activity and are separated one station width from adjacent station. The Governing Body, on 5/6/13 reviewed the SOD and developed the following Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. The following action steps were implemented: The Governing Body will meet weekly to monitor the progress of the Plan of Correction until the Condition level deficiencies are lifted, 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</p>	05/16/2013

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	<p>affect all of the facility's patients with a catheter(See V 146).</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to meet the requirements of the Condition for Coverage 494.30: Infection control.</p>		<p>presenting the monthly data to the QAI Committee. · A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda. · The QAI Committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution of the issues · The Director of Operations (DO) will present a report on the Plan of Correction data and all actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. · The Governing Body, at its meeting on 5/6/13, 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 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</p>		

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			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 V111, V113, V122, V128, V146 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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V000111	<p>494.30 IC-SANITARY ENVIRONMENT The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas. Based on observation, interview, and review of facility policy and procedure, the facility failed to ensure staff followed infection control policies during the provision of care in 3 of 5 observations (observation #1 and #2 on the north wing and observation #1 on the east wing) creating the potential to affect all of the facility's 138 current patients.</p> <p>Findings</p> <ol style="list-style-type: none"> 1. During observation #1 on the north wing on April 22, 2013, at 2:40 PM, Employee K, patient care technician (PCT), was observed at station #7 to change a catheter exit site dressing on patient #9's right upper chest. After removing the catheter dressing, the PCT did not wash hands prior to donning clean gloves. She then administered a heparin 5000 units bolus. 2. During observation #2 on the north wing on April 23, 2013, at 4:35 PM, Employee K was observed to not change gloves while touching the computer screens on four patient machines and also 	V000111	<p>On 5/3/13 the Operations Manager and Clinic Manager met with the staff present to discuss the findings of the State Survey conducted 4/22/13 through 4/25/13. The staff was notified that there were many infection control deficiencies noted leading to a Condition level. The staff was specifically instructed to sign up for mandatory rein-services on infection control on May 8 th , May 15 th and May 16 th to review the following policies: Infection Control Overview (FMS-CS-IC-II-155-060A), Personal Protective Equipment (FMS-CS-IC-II-155-080A), Hand Hygiene Policy (FMS-CS-IC-II-155-090A), Hand Hygiene Procedure (FMS-CS-IC-II-155-090C), Initiation of Treatment Using an External Catheter and Optiflux Hollow Fiber Dialyzer Procedure & Procedure (FMS-CS-IC-I-105-002A & C), Changing the Catheter Dressing Policy (FMS-CS-IC-I-105-032A), Changing the Catheter Dressing Procedure (FMS-CS-IC-I-105-032C) Cleaning and Disinfection Policy (FMS-CS-IC-II-155-110A), Work Surface Cleaning and Disinfection</p>	05/16/2013			

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	<p>touching the arm of one patient. Employee K was observed to complete an arteriovenous fistula dressing prior to completion of hemodialysis treatment on Patient #16 at station #5 on machine #27. Employee K was wearing gloves. She then moved the red biohazard container that was on rollers out of the station. She removed the gloves, washed her hands, and donned clean gloves before entering station #4 with patient #17 and touched machine #24's computer screen in station #4. She left that station and proceeded to station #6 and touched Patient #18's computer screen on machine #16. She did not remove her gloves and proceeded to station #2 and touched Patient #19's computer screen on machine #3. She then touched the patient's left arm near the patient's arteriovenous fistula site above the elbow. She did not remove her gloves. She proceeded to station #1 and touched patient #20's computer screen on machine #5. She removed the gloves and washed her hands.</p> <p>3. On 4/23/13 at 4:45 PM, Employee G, Registered Nurse, indicated that direct care staff should discard gloves after touching a patient or the patient's computer screen on a machine before entering another station and touching other equipment and other patients.</p>		<p>with Visible Blood < 10mls and OPIM using Bleach Solutions (FMS-CS-IC-II-155-110C2), Work Surface Cleaning and Disinfection with Visible Blood > 10mls and OPIM using Bleach Solutions (FMS-CS-IC-II-155-110C3), and Housekeeping Policy (FMS-CS-IC-II-155-116A),.</p> <p>Starting on May 6 th , Clinic Manager or designee will conduct an audit daily including observation of proper glove usage, hand hygiene, proper catheter dressing procedures and policies. Audit will be completed daily until Condition is lifted then continue weekly until reviewed by QAI. Frequency of ongoing audits will be determined through the QAI Committee upon review of audit findings and resolution of the issues. The results of the audit will be documented and reported in the weekly Governing Body meetings and at QAI.</p> <p>Any evidence of non-compliance will be immediately brought to the attention of the Director of Operations by the Clinical Manager. Appropriate intervention and corrective action will be taken for infraction of the policy. The CM is responsible. Any corrective action given can be found in the employee file.</p> <p>Employees K and L were moved to disciplinary action for violations of policies specific to infection control.</p>				

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	<p>4. On 4/25/13 at 10:30 AM, Employee D, Clinical Manager, indicated handwashing should be completed after gloves are removed after patient care including touching the computer screens on the dialysis machines and any time gloves are removed.</p> <p>5. The agency policy titled "FMS Clinical Services Personal Protective Equipment" with an effective date of March 20, 2013, stated, "Disposable gloves must be used ... when touching any part of the dialysis machine or equipment ... Gloves must be worn appropriately. Change gloves and practice hand hygiene between each patient and / or station to prevent cross - contamination. Remove gloves and practice hand hygiene between each patient contact ... hand hygiene must be performed after glove removal. Avoid touching surfaces with gloved hands that will be touched with ungloved hands (for ex. [example] patient charts and computers."</p> <p>6. The agency procedure titled "FMS Changing the Catheter dressing procedure" with an effective date of April 4, 2012, stated, "Follow the steps below to remove a catheter dressing and inspect the exit site: ... Discard dressing and remove gloves. Perform hand hygiene."</p>		<p>The CM is responsible to review and analyze all monitoring data prior to the QAI Meeting and present monthly to the QAI Committee.</p> <p>The Director of Operations is responsible to ensure that the CM presents all data, as required and defined within the POC, to the QAI Committee.</p> <p>The QAI Committee is responsible to provide oversight and ensure resolution is occurring.</p>				

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	<p>7. The agency policy titled "Hand Hygiene" with an effective date of January 4, 2012, stated, "Hands will be decontaminated using alcohol based hand rub or by washing hands with antimicrobial soap and water ... immediately after removing gloves."</p> <p>8. During observation #1 on the east wing on April 22, 2013, at 2:12 PM, Employee L, PCT, was observed to not change gloves after touching machine #3 at station #16. He then entered station #18 and touched patient #1's taped access site on the patient's left arm without changing his gloves and washing his hands.</p>			

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V000113	<p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.</p> <p>Based on observation, procedure and policy review, and interview, the facility failed to ensure staff performed hand hygiene appropriately after removing gloves in 3 of 5 observations of care (observation #1 and #2 on the north wing and observation #1 on the east wing) on the treatment floor creating the potential to affect all of the facility's 138 patients.</p> <p>Findings</p> <p>1. During observation #1 on the north wing on April 22, 2013, at 2:40 PM, Employee K, patient care technician (PCT), was observed at station #7 to change a catheter exit site dressing on patient #9's right upper chest. After removing the catheter dressing, the PCT did not wash hands prior to donning clean gloves. She then administered a heparin 5000 units bolus.</p> <p>2. During observation #2 on the north wing on April 23, 2013, at 4:35 PM, Employee K was observed to not change gloves while touching the computer</p>	V000113	<p>On 5/3/13 the Operations Manager and Clinic Manager met with the staff present to discuss the findings of the State Survey conducted 4/22/13 through 4/25/13. The staff was notified that there were many infection control deficiencies noted leading to a Condition level. The staff was specifically instructed to sign up for mandatory rein-services on infection control on May 8 th , May 15 th and May 16 th to review the following policies; Infection Control Overview (FMS-CS-IC-II-155-060A), Personal Protective Equipment (FMS-CS-IC-II-155-080A), Hand Hygiene Policy (FMS-CS-IC-II-155-090A), Hand Hygiene Procedure (FMS-CS-IC-II-155-090C), Changing the Catheter Dressing Policy (FMS-CS-IC-I-105-032A), Initiation of Treatment Using an External Catheter and Optiflux Hollow Fiber Dialyzer Procedure & Procedure (FMS-CS-IC-I-105-002A & C), Changing the Catheter Dressing Procedure (FMS-CS-IC-I-105-032C) Cleaning and Disinfection Policy (FMS-CS-IC-II-155-110A), Work Surface Cleaning and Disinfection</p>	05/16/2013

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	<p>screens on four patient machines and also touching the arm of one patient.</p> <p>Employee K was observed to complete an arteriovenous fistula dressing prior to completion of hemodialysis treatment on Patient #16 at station #5 on machine #27. Employee K was wearing gloves. She then moved the red biohazard container that was on rollers out of the station. She removed the gloves, washed her hands, and donned clean gloves before entering station #4 with patient #17 and touched machine #24's computer screen in station #4. She left that station and proceeded to station #6 and touched Patient #18's computer screen on machine #16. She did not remove her gloves and proceeded to station #2 and touched Patient #19's computer screen on machine #3. She then touched the patient's left arm near the patient's arteriovenous fistula site above the elbow. She did not remove her gloves. She proceeded to station #1 and touched patient #20's computer screen on machine #5. She removed the gloves and washed her hands.</p> <p>3. On 4/23/13 at 4:45 PM, Employee G, Registered Nurse, indicated that direct care staff should discard gloves after touching a patient or the patient's computer screen on a machine before entering another station and touching other equipment and other patients.</p>		<p>with Visible Blood < 10mls and OPIM using Bleach Solutions (FMS-CS-IC-II-155-110C2), Work Surface Cleaning and Disinfection with Visible Blood > 10mls and OPIM using Bleach Solutions (FMS-CS-IC-II-155-110C3), and Housekeeping Policy (FMS-CS-IC-II-155-116A).</p> <p>Starting on May 6 th , Clinic Manager or designee will conduct an audit daily including observation of proper glove usage, hand hygiene, initiation of treatment using a CVC, proper catheter dressing procedures and procedures. Audit will be completed daily until Condition is lifted then continue weekly until reviewed by QAI. Frequency of ongoing audits will be determined through the QAI Committee upon review of audit findings and resolution of the issues. The results of the audit will be documented and reported in the weekly Governing Body meetings and at QAI.</p> <p>Any evidence of non-compliance will be immediately brought to the attention of the Director of Operations by the Clinical Manager. Appropriate intervention and corrective action will be taken for infraction of the policy. The CM is responsible. Any corrective action given can be found in the employee file.</p> <p>Employees K and L were moved to disciplinary action for violations</p>	

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	<p>4. On 4/25/13 at 10:30 AM, Employee D, Clinical Manager, indicated handwashing should be completed after gloves are removed after patient care including touching the computer screens on the dialysis machines and any time gloves are removed.</p> <p>5. The agency policy titled "FMS Clinical Services Personal Protective Equipment" with an effective date of March 20, 2013, stated, "Disposable gloves must be used ... when touching any part of the dialysis machine or equipment ... Gloves must be worn appropriately. Change gloves and practice hand hygiene between each patient and / or station to prevent cross - contamination. Remove gloves and practice hand hygiene between each patient contact ... hand hygiene must be performed after glove removal. Avoid touching surfaces with gloved hands that will be touched with ungloved hands (for ex. [example] patient charts and computers."</p> <p>6. The agency procedure titled "FMS Changing the Catheter dressing procedure" with an effective date of April 4, 2012, stated, "Follow the steps below to remove a catheter dressing and inspect the exit site: ... Discard dressing and remove gloves. Perform hand hygiene."</p>		<p>of policies specific to infection control.</p> <p>The CM is responsible to review and analyze all monitoring data prior to the QAI Meeting and present monthly to the QAI Committee.</p> <p>The Director of Operations is responsible to ensure that the CM presents all data, as required and defined within the POC, to the QAI Committee.</p> <p>The QAI Committee is responsible to provide oversight and ensure resolution is occurring.</p>				

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V000122	<p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing-</p> <p>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]</p> <p>(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.</p> <p>Based on observation and interview, the facility failed to ensure surfaces were not contaminated with blood for 1 of 1 trash can by the north wing handwashing sink with the potential to affect all 138 patients of the dialysis clinic and any staff or visitors who would come in contact with the waste can.</p> <p>Findings</p> <ol style="list-style-type: none"> On 4/25/13 at 10:30 AM, a small amount of blood was observed running down the lid of a large waste can by the north wing handwashing sink. There were several pair of disposable gloves noted in the waste can and a disposable towel with visible blood. On 4/25/13 at 10:30 AM, the clinical manager indicated blood should not be on the trash can lid or in the trash of the waste can. 	V000122	<p>On 5/3/13 the Operations Manager and Clinic Manager met with the staff present to discuss the findings of the State Survey conducted 4/22/13 through 4/25/13. The staff was notified that there were many infection control deficiencies noted leading to a Condition level. The staff was specifically instructed to sign up for mandatory rein-services on infection control on May 8 th and May 15 th and May 16 th to review the following policies; Infection Control Overview (FMS-CS-IC-II-155-060A), Personal Protective Equipment (FMS-CS-IC-II-155-080A), Hand Hygiene Policy (FMS-CS-IC-II-155-090A), Hand Hygiene Procedure (FMS-CS-IC-II-155-090C), Initiation of Treatment Using an External Catheter and Optiflux Hollow Fiber Dialyzer Procedure & Procedure (FMS-CS-IC-I-105-002A & C), Changing the Catheter Dressing Policy (FMS-CS-IC-I-105-032A),</p>	05/16/2013			

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			<p>Changing the Catheter Dressing Procedure (FMS-CS-IC-I-105-032C) Cleaning and Disinfection Policy (FMS-CS-IC-II-155-110A), Work Surface Cleaning and Disinfection with Visible Blood < 10mls and OPIM using Bleach Solutions (FMS-CS-IC-II-155-110C2), Work Surface Cleaning and Disinfection with Visible Blood > 10mls and OPIM using Bleach Solutions (FMS-CS-IC-II-155-110C3), and Housekeeping Policy (FMS-CS-IC-II-155-116A).</p> <p>Starting on May 6 th , Clinic Manager or designee will conduct an audit daily inspecting surfaces and equipment to ensure areas are not contaminated with blood along with adherence of staff with cleaning and disinfection of work surfaces and equipment of blood spills </> 10mls along with proper discarding of any soiled equipment. Audit will be completed daily until Condition is lifted then continue weekly until reviewed by QAI. Frequency of ongoing audits will be determined through the QAI Committee upon review of audit findings and resolution of the issues. The results of the audit will be documented and reported in the weekly Governing Body meetings and at QAI.</p> <p>Any evidence of non-compliance will be immediately brought to the attention of the Director of</p>	

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			<p>Operations by the Clinical Manager. Appropriate intervention and corrective action will be taken for infraction of the policy. The CM is responsible. Any corrective action given can be found in the employee file.</p> <p>The CM is responsible to review and analyze all monitoring data prior to the QAI Meeting and present monthly to the QAI Committee.</p> <p>The Director of Operations is responsible to ensure that the CM presents all data, as required and defined within the POC, to the QAI Committee.</p> <p>The QAI Committee is responsible to provide oversight and ensure resolution is occurring.</p>		

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V000128	<p>494.30(a)(1)(i) IC-HBV-ISOLATION (EXISTING FACILITY) Isolation of HBV+ Patients</p> <p>To isolate HBsAg positive patients, designate a separate room for their treatment.</p> <p>For existing units in which a separate room is not possible, HBsAg positive patients should be separated from HBsAg susceptible patients in an area removed from the mainstream of activity.</p> <p>Based on observation, policy review, and interview, the facility failed to ensure HBsAG+ (Positive Hepatitis B Antigen) patients were separated from other stations by a space at least equivalent to the width of one hemodialysis station for 1 of 2 (#5) HBsAg+ positive patients observed receiving hemodialysis with the potential to affect all the patients susceptible to hepatitis B.</p> <p>The findings include:</p> <p>1. During observation #2 on the east wing on 4/24/13 at 12:20 PM, HBsAG+ patient # 5 at Station #24, Machine #1, was placed on dialysis by employee S, the patient care technician, in the designated isolation area. Patient #6 was receiving hemodialysis at the next station #23. The isolation stations #24 and station #23 were next to each other and not separated</p>	V000128	<p>On 5/6/13 the Director of Operations reviewed with the Governing Body the policy "Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+)" document number FMS-CS-IC-II-155-140A describing the need to isolate HBsAg positive patients from HBsAg susceptible patients in an area removed from the mainstream of activity by a space at least equivalent to the width of one hemodialysis station.</p> <p>On 5/15/13, during a staff meeting, the Clinic Manger and Education Coordinator will review policy "Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+)" document number FMS-CS-IC-II-155-140A with the staff. Additionally, the CM reviewed and clarified that patient/staff assignments must reflect patient and staff hepatitis antibody and antigen status as outlined in this policy.</p>	05/16/2013	

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	<p>by a space equivalent to the width of one hemodialysis station.</p> <p>2. The Facility policy titled "Dialyzing Patients with Positive Hepatitis B Antigen(HBsAG+)" document number FMS-CS-IC-II-155-140A, revision date 3/20/13, states, "The area used for HBsAG positive patients must be separated from other stations by a space at least equivalent to the width of one hemodialysis station."</p> <p>3. Employee C, the operation manager, was present during the observation on 4/24/14 at 12:20 PM and indicated the stations were not separated by a space equivalent to the width of one hemodialysis station.</p>		<p>As of 5/13/13, there is a space equal to one hemodialysis station between HBsAg+ patients dialyzing and HBsAg susceptible patients until a separate isolation room exists in the clinic (targeted by 3 rd qtr 2013).</p> <p>The CM is responsible to ensure that the isolation area remain in compliance and report monthly to the QAI Committee.</p> <p>The Director of Operations is responsible to ensure that the CM presents all data, as required and defined within the POC, to the QAI Committee.</p> <p>The QAI Committee is responsible to provide oversight and ensure resolution is occurring.</p>		

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V000146	<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, interview, and review of facility policy and procedure, the facility failed to ensure staff followed infection control policies during the provision of catheter care in 1 of 5 observations (observation #1 on the north wing) creating the potential to affect all of the facility's patients with a catheter.</p> <p>Findings</p>	V000146	On 5/3/13 the Operations Manager and Clinic Manager met with the staff present to discuss the findings of the State Survey conducted 4/22/13 through 4/25/13. The staff was notified that there were many infection control deficiencies noted leading to a Condition level. The staff was specifically instructed to sign up for mandatory rein-services on infection control on May 8 th , May 15 th and May 16 th to review the following policies; Infection Control Overview	05/16/2013			

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	<p>1. During observation #1 on the north wing on April 22, 2013, at 2:40 PM, Employee K, patient care technician, was observed at station #7 to change a catheter exit site dressing on patient #9's right upper chest. After removing the catheter dressing, she did not wash hands prior to donning clean gloves. She then administered a heparin 5000 units bolus.</p> <p>2. On 4/25/13 at 10:30 AM, Employee D, Clinical Manager, indicated handwashing should be completed after gloves are removed.</p> <p>3. The agency policy titled "Hand Hygiene" with an effective date of January 4, 2012, stated, "Hands will be decontaminated using alcohol based hand rub or by washing hands with antimicrobial soap and water ... immediately after removing gloves."</p> <p>4. The agency procedure titled "FMS Changing the Catheter dressing procedure" with an effective date of April 4, 2012, stated, "Follow the steps below to remove a catheter dressing and inspect the exit site: ... Discard dressing and remove gloves. Perform hand hygiene."</p> <p>5. The agency policy titled "FMS Clinical Services Personal Protective Equipment" with an effective date of March 20, 2013</p>		<p>(FMS-CS-IC-II-155-060A), Personal Protective Equipment (FMS-CS-IC-II-155-080A), Hand Hygiene Policy (FMS-CS-IC-II-155-090A), Hand Hygiene Procedure (FMS-CS-IC-II-155-090C), Initiation of Treatment Using an External Catheter and Optiflux Hollow Fiber Dialyzer Policy & Procedure (FMS-CS-IC-I-105-002A & C), Changing the Catheter Dressing Policy (FMS-CS-IC-I-105-032A), Changing the Catheter Dressing Procedure (FMS-CS-IC-I-105-032C) Cleaning and Disinfection Policy (FMS-CS-IC-II-155-110A), Work Surface Cleaning and Disinfection with Visible Blood < 10mls and OPIM using Bleach Solutions (FMS-CS-IC-II-155-110C2), Work Surface Cleaning and Disinfection with Visible Blood > 10mls and OPIM using Bleach Solutions (FMS-CS-IC-II-155-110C3), and Housekeeping Policy (FMS-CS-IC-II-155-116A).</p> <p>Starting on May 6 th , Clinic Manager or designee will conduct an audit daily including observation of proper glove usage, hand hygiene, initiation of dialysis treatment on patient with CVC per policy/procedure and completion of catheter dressing per procedure/policy. Audit will be completed daily until Condition is lifted then continue weekly until reviewed by QAI. Frequency of</p>				

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	stated, "Hand hygiene must be performed after glove removal."		<p>ongoing audits will be determined through the QAI Committee upon review of audit findings and resolution of the issues. The results of the audit will be documented and reported in the weekly Governing Body meetings and at QAI.</p> <p>Any evidence of non-compliance will be immediately brought to the attention of the Director of Operations by the Clinical Manager. Appropriate intervention and corrective action will be taken for infraction of the policy. The CM is responsible. Any corrective action given can be found in the employee file.</p> <p>Employees K and L were moved to disciplinary action for violations of policies specific to infection control.</p> <p>The CM is responsible to review and analyze all monitoring data prior to the QAI Meeting and present monthly to the QAI Committee.</p> <p>The Director of Operations is responsible to ensure that the CM presents all data, as required and defined within the POC, to the QAI Committee.</p> <p>The QAI Committee is responsible to provide oversight and ensure resolution is occurring.</p>		

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V000516	<p>494.80(b)(1) PA-FREQUENCY-INITIAL-30 DAYS/13 TX An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure an initial assessments had been completed within 30 calendar days in 11 of 15 records reviewed (#1, 2, 4, 5, 6, 8, 9, 10, 11, 12, and 15) creating the potential to affect all new admissions to the facility.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record #1 evidenced a start of hemodialysis as November 11, 2009. The record failed to evidence the initial assessment had been completed within 30 days. 2. Clinical record #2 evidenced a start of hemodialysis as February 4, 2012. The record failed to evidence the initial assessment had been completed within 30 days. 3. Clinical record #4 evidenced a start of hemodialysis as March 6, 2013. The 	V000516	<p>The Director of Operations met with the facility's Interdisciplinary Team on 5/6/13 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy i.e. "Comprehensive Interdisciplinary Assessment and Plan of Care" #FMS-CS-IC-I-110-125A." for the purpose of ensuring that every patient will have a timely, complete and current Comprehensive Assessment available within their medical record that meets all criteria. The Clinic Manager and Education Coordinator will meet with the RNs to review the above policy on 5/8/13.</p> <p>The Clinical Manager or designee will complete an audit of 100% of the current Patient Assessments, including patients # 1, 2, 4, 5, 6, 8, 9, 10, 11, 12 and 15 by 5/20/13. Each patient's Comprehensive Assessment will be reviewed to verify the completeness and timeliness of the initial assessment. Assessments found incomplete or outside of the timeframe, will be reviewed with the patient's attending physician and other</p>	08/07/2013	

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	<p>record failed to evidence the initial assessment had been completed within 30 days.</p> <p>4. Clinical record # 5 evidenced a start of hemodialysis as July 27, 2009. The record failed to evidence the initial assessment had been completed within 30 days.</p> <p>5. Clinical record #6 evidenced a start of hemodialysis as September 24, 2002. The record failed to evidence the initial assessment had been completed within 30 days.</p> <p>6. The facility policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care" document # FMS-CS-IC-I-110-125A revision date 7/4/12 states, "An initial comprehensive interdisciplinary assessment must be conducted on all new[SIC] patients and a Plan of Care developed and implemented within the later of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session."</p> <p>7. On 4/23/13 at 4:15 PM, the clinical manager, employee D, indicated the initial comprehensive assessment, subsequent assessments, and plans of care were thinned from the patient charts and sent to storage off the premises.</p>		<p>members of the IDT and revised up to 30 patient assessments each month until all are in compliance to be completed no later than 8/7/13 to reflect the patient's status and condition. The Clinical Manager is responsible.</p> <p>The Renal Dietitian has developed a tracking tool which will be used on a monthly basis to determine those Assessments and Plans of Care that are due. The Renal Dietitian is responsible to add all new patients, and patients returning from hospitalizations to the tracking tool. This tracking tool will be shared with the entire IDT a month in advance of scheduled Assessment/Plan of Care due dates.</p> <p>The Clinical Manager or designee will review each Patient Assessment monthly for three months to ensure each new patient Comprehensive Assessment is completed by all IDT members within designated timeframe. Frequency of ongoing audits will be determined by the QAI Committee upon review of audit data and resolution of the issue.</p> <p>The Clinical Manager has formalized a Patient Comprehensive Assessment Report for the monthly QAI meeting detailing compliance</p>				

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			<p>gaps between scheduled and completed Assessments and/or Plans of Care and corrective actions implemented to correct any identified deficiencies. The Committee reviews areas of noncompliance, interventions taken and evaluates to determine if further action is required. The QAI meeting minutes document this activity and are available for review at the facility.</p> <p>The Director of Operations as the CEO and member of the QAI team is responsible to ensure that all data, including the medical record audits are presented to QAI, are completed, reviewed and trended during the QAI meetings.</p> <p>The QAI Committee is responsible to provide oversight to ensure the Assessments/Plan of Care, as written to address the deficiencies identified with the SOD, is effective and is providing resolution of the issues.</p> <p>Governing Body will review the analysis as provided by the QAI including the trending of the issues. If any deficiencies are noted they will work with the QAI Committee to determine the root cause and amend the Plan of Correction to ensure resolution of the deficiency.</p> <p>The Minutes of the QAI Committee and Governing Body</p>		

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	<p>8. Clinical record #8 evidenced the patient's first date of dialysis was 9/14/12. The record evidenced the initial assessment had not been completed within 30 days.</p> <p>9. Clinical record #9 evidenced the patient's first date of dialysis was 10/20/12. The record failed to evidence the initial assessment had been completed within 30 days.</p> <p>10. Clinical record #10 evidenced the patient's first date of dialysis was 3/7/12. The record failed to evidence the initial assessment had been completed within 30 days.</p> <p>11. Clinical record #11 evidenced the patient's first date of dialysis was 9/14/12. The record evidenced the initial assessment had not been completed within 30 days.</p> <p>12. Clinical record #12 evidenced the patient's first date of dialysis was 10/20/12. The record failed to evidence the initial assessment had been completed within 30 days.</p> <p>13. Clinical Record #15, start of care</p>		are available within the facility for review.				

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	<p>1-9-10, failed to evidence the assessment was completed within 30 days or 13 treatments.</p> <p>14. On 4-25-13 at 4:30 PM, Person T, the FMC Laporte Clinical Manager, indicated the Initial Comprehensive Assessment for patient #15 was not completed within the required time frame or had been "thinned" from the chart and there was no initial comprehensive assessment documentation available.</p> <p>15. On 4-25-13 at 4:00 PM, Employee A, the director of operations, indicated the Initial Comprehensive Assessment for patient #15 may have been thinned from the chart against policy and stored at an alternate facility. The documentation was not available at the time of survey.</p>			

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY BLACKTHORN	STREET ADDRESS, CITY, STATE, ZIP CODE 6201 NIMTZ PKWY SOUTH BEND, IN 46628
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V000517	<p>494.80(b)(2) PA-F/U REASSESSMENT-WITHIN 3 MO OF INITIAL A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in §494.90.</p> <p>Based on review of clinical records and facility policy and interview, the facility failed to ensure a comprehensive reassessment had been completed ninety (90) days after the initial assessment in 9 of 15 records (#1, 5, 6, 8, 9, 10, 11, 12, and 15) reviewed creating the potential to affect all the patients of the facility.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record #1 evidenced a start of hemodialysis as November 11, 2009. The record failed to evidence an assessment had been completed 90 days after the initial assessment. 2. Clinical record # 5 evidenced a start of hemodialysis as July 27, 2009. The record failed to evidence an assessment had been completed 90 days after the initial assessment. 3. Clinical record #6 evidenced a start of hemodialysis as September 24, 2002. The record failed to evidence an assessment 	V000517	<p>The Director of Operations met with the facility's Interdisciplinary Team on 5/6/13 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy i.e. "Comprehensive Interdisciplinary Assessment and Plan of Care" #FMS-CS-IC-I-110-125A." for the purpose of ensuring that every patient will have a complete, current and timely Comprehensive Assessment available within their medical record that meets all criteria. The Clinic Manager and Education Coordinator will meet with the RNs to review the above policy on 5/8/13.</p> <p>The Clinical Manager or designee will complete an audit of 100% of the current Patient Comprehensive Reassessments, including patients # 1, 5, 6, 8, 9, 10, 11, 12, and 15 by 5/20/13. All Comprehensive Patient Assessments will be reviewed to verify completion of reassessment within 3 months following the completion of the initial assessment. Any Reassessments found incomplete or outside of the designated</p>	08/07/2013

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	<p>had been completed 90 days after the initial assessment.</p> <p>4. The facility policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care" document # FMS-CS-IC-I-110-125A revision date 7/4/12 states, " A follow up comprehensive interdisciplinary assessment must occur on all new patients within 3 months after the completion of the initial assessment to adjust the patient's Plan of Care as appropriate or if necessary."</p> <p>5. On 4/23/13 at 4:15 PM, the clinical manager, employee D, indicated the initial comprehensive assessment, subsequent assessments, and plans of care were thinned from the patient charts and sent to storage off the premises.</p>		<p>timeframe for completion will be reviewed with the patient's attending physician and revised up to 30 each month until all are in compliance to be completed no later than 8/7/13 to reflect the patient's status and condition. The Clinical Manager is responsible.</p> <p>The Renal Dietitian has developed a tracking tool which will be used on a monthly basis to determine those Assessments and Plans of Care that are due. The Renal Dietitian is responsible to add all new patients, and patients returning from hospitalizations to the tracking tool. This tracking tool will be shared with the entire IDT a month in advance of scheduled Assessment/Plan of Care due dates.</p> <p>The Clinical Manager or designee will perform monthly audits for three months of the Patient Assessments to ensure the Comprehensive Reassessments are completed within designated timeframe. Frequency of ongoing audits will be determined by the QAI Committee upon review of audit data and resolution of the issue.</p> <p>The Clinical Manager has formalized a Patient Comprehensive Assessment Report for the monthly QAI meeting detailing compliance</p>		

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			<p>gaps between scheduled and completed Assessments and/or Plans of Care and corrective actions implemented to correct any identified deficiencies. The Committee reviews areas of noncompliance, interventions taken and evaluates to determine if further action is required. The QAI meeting minutes document this activity and are available for review at the facility.</p> <p>The Director of Operations as the CEO and member of the QAI team is responsible to ensure that all data, including the medical record audits are presented to QAI, are completed, reviewed and trended during the QAI meetings.</p> <p>The QAI Committee is responsible to provide oversight to ensure the Assessments/Plan of Care, as written to address the deficiencies identified with the SOD, is effective and is providing resolution of the issues.</p> <p>Governing Body will review the analysis as provided by the QAI including the trending of the issues. If any deficiencies are noted they will work with the QAI Committee to determine the root cause and amend the Plan of Correction to ensure resolution of the deficiency.</p> <p>The Minutes of the QAI Committee and Governing Body</p>		

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	<p>6. Clinical record #8 evidenced the patient's first date of dialysis at this facility was 9/14/12. The record failed to evidence an assessment had been completed 90 days after the initial assessment.</p> <p>7. Clinical record #9 evidenced the patient's first date of dialysis at this facility was 10/20/12. The record failed to evidence an assessment had been completed 90 days after the initial assessment.</p> <p>8. Clinical record #10 evidenced the patient's first date of dialysis at this facility was 3/7/12. The record failed to evidence an assessment had been completed 90 days after the initial assessment.</p> <p>9. Clinical record #11 evidenced the patient's first date of dialysis at this facility was 9/14/12. The record failed to evidence an assessment had been completed 90 days after the initial assessment.</p> <p>10. Clinical record #12 evidenced the patient's first date of dialysis at this facility was 10/20/12. The record failed</p>		are available within the facility for review.				

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	<p>to evidence an assessment had been completed 90 days after the initial assessment.</p> <p>11. Clinical Record #15, start of care 1-9-10, failed to evidence a follow up comprehensive assessment was completed within 3 months after the completion of the initial comprehensive assessment.</p> <p>12. On 4-25-13 at 4:30 PM, Person T, the FMC Laporte Clinical Manager, indicated the follow up comprehensive assessment for patient #15 that was to follow within three (3) months of the initial assessment was not completed within the required time frame or had been "thinned" from the chart against policy. There was no follow up assessment documentation available.</p> <p>13. On 4-25-13 at 4:00 PM, Employee A, operations manager, indicated the follow up comprehensive assessment for patient #15 may have been thinned from the chart against policy and stored at an alternate facility, and the documentation was not available.</p>			

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V000518	<p>494.80(c) PA-ASSESS HD ADEQ Q MO;PD ADEQ Q 4 MO</p> <p>The adequacy of the patient's dialysis prescription, as described in §494.90(a)(1), must be assessed on an ongoing basis as follows:</p> <p>(1) Hemodialysis patients. At least monthly by calculating delivered Kt/V or an equivalent measure.</p> <p>(2) Peritoneal dialysis patients. At least every 4 months by calculating delivered weekly Kt/V or an equivalent measure.</p> <p>Based clinical record and facility policy review and interview, the facility failed to ensure the Kt/V was assessed monthly for 1 of 15 clinical records reviewed (#2) creating the potential to affect all the patients of the facility.</p> <p>The findings include:</p> <p>1. Clinical record #2 evidenced a 90 day Patient Plan of Care Report that states, "Maintain Kt/V greater than 1.2, and to monitor monthly." The record evidenced a lab result with a Kt/V value of 1.54 on 2/28/13. The record failed to evidence any subsequent Kt/V results.</p> <p>The treatment sheet for 4/18/13 evidenced documentation by employee K, the patient care technician, at 8:58 PM, that states, "I was unaware of a lab order. There weren't any in the drawer."</p>	V000518	<p>The Director of Operations met with the facility's Interdisciplinary Team on 5/6/13 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy i.e. "Comprehensive Interdisciplinary Assessment and Plan of Care" #FMS-CS-IC-I-110-125A." for the purpose of ensuring that every patient will have adequacy of the dialysis prescription assessed on a monthly basis. The Clinic Manager and Education Coordinator will meet with the RNs to review the above policy on 5/8/13.</p> <p>Each patient's April lab results were reviewed by the Center Manager or designee to identify patients with missing adequacy data for that month. Patients identified as not having adequacy testing completed in April are scheduled to have labs drawn by May 17, 2013. Lab and Adequacy Champions have been identified within the clinic and will</p>	05/17/2013	

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	<p>2. The facility policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care" document # FMS-CS-IC-I-110-125A revision date 7/4/12 states, "The adequacy of the patient's dialysis prescription must be assessed on an ongoing basis as follows: HD patients at least monthly"</p> <p>3. On 4/24/13 at 5:40 PM, the clinical manager, employee D, and the operation manager, employee C, indicated the order had inadvertently been discontinued and no other Kt/V results were available.</p>		<p>be responsible to ensure that each patient has ordered labs collected monthly. The Clinical Manager is responsible.</p> <p>The Operations Manager has developed a Plan of Care Update tracking tool which will be used on a monthly basis by the IDT to ensure patient dialysis prescription is addressed timely.</p> <p>The Clinical Manager or designee will perform monthly audits for three months ensure that each patient has adequacy testing completed at a minimum of an every four week basis. Frequency of ongoing audits will be determined by the QAI Committee upon review of audit data and resolution of the issue.</p> <p>The Clinical Manager has formalized a Patient Comprehensive Assessment Report for the monthly QAI meeting detailing compliance gaps between scheduled and completed adequacy testing and actions implemented to correct any identified deficiencies. The Committee reviews areas of noncompliance, interventions taken and evaluates to determine if further action is required. The QAI meeting minutes document this activity and are available for review at the facility.</p> <p>The Director of Operations as the</p>		

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			<p>CEO and member of the QAI team is responsible to ensure that all data, including the adequacy completion audits are presented to QAI, are completed, reviewed and trended during the QAI meetings.</p> <p>The QAI Committee is responsible to provide oversight to ensure the plan for monitoring completion of adequacy testing on all patients at four week intervals as written to address the deficiencies identified with the SOD, is effective and is providing resolution of the issues.</p> <p>Governing Body will review the analysis as provided by the QAI including the trending of the issues. If any deficiencies are noted they will work with the QAI Committee to determine the root cause and amend the Plan of Correction to ensure resolution of the deficiency.</p> <p>The Minutes of the QAI Committee and Governing Body are available within the facility for review.</p>		

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V000519	<p>494.80(d)(1) PA-FREQUENCY REASSESSMENT-STABLE 1X/YR 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>(1) At least annually for stable patients;</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure a comprehensive reassessment had been completed and the plan of care had been revised annually in 6 of 15 records (# 5, 10, 12, 13, 14, and 15) reviewed with the potential to affect all the patients of the facility.</p> <p>The findings include:</p> <p>1. Clinical record #5, admission date of 11/26/08, failed to evidence a comprehensive assessment and the plan of care were completed annually.</p> <p>2. The facility policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care" document # FMS-CS-IC-I-110-125A revision date 7/4/12 states, "Comprehensive interdisciplinary assessments and modifications to the Plan of Care must be conducted 12 months after the completion of the 3 month assessment and then reassessed annually thereafter on all</p>	V000519	<p>The Director of Operations met with the facility's Interdisciplinary Team on 5/6/13 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy i.e. "Comprehensive Interdisciplinary Assessment and Plan of Care" #FMS-CS-IC-I-110-125A." for the purpose of ensuring that every patient will have a complete, timely and current Annual Comprehensive Assessment available within their medical record that meets all criteria. The Clinic Manager and Education Coordinator will meet with the RNs to review the above policy on 5/8/13.</p> <p>The Clinical Manager or designee will complete an audit of 100% of the current Patient Assessments and Plan of Care, including patients # 5, 10, 12, 13, 14, and 15 by 5/20/13. Each patient's medical record will be reviewed to verify the completeness and timeliness of the annual comprehensive assessment. Incomplete and/or late annual comprehensive assessments will be reviewed with the patient's</p>	08/07/2013			

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	<p>stable patients."</p> <p>3. On 4/23/13 at 4:15 PM, the clinical manager, employee D, indicated assessments and plans of care were thinned from the patient charts and sent to storage off the premises.</p>		<p>attending physician and revised up to 30 patients each month until all are in compliance to be completed no later than 8/7/13 to reflect the patient's status and condition. The Clinical Manager is responsible.</p> <p>The Renal Dietitian has developed a tracking tool which will be used on a monthly basis to determine those Assessments and Plans of Care that are due. The Renal Dietitian is responsible to add all new patients, and patients returning from hospitalizations to the tracking tool. This tracking tool will be shared with the entire IDT a month in advance of scheduled Assessment/Plan of Care due dates.</p> <p>The Clinical Manager or designee will perform monthly audits for three months of the Patient Assessments/Plan of Care to ensure the Assessments/Plan of Care are complete and timely. Frequency of ongoing audits will be determined by the QAI Committee upon review of audit data and resolution of the issue.</p> <p>The Clinical Manager has formalized a Patient Comprehensive Assessment/Plan of Care Report for the monthly QAI meeting detailing compliance gaps between scheduled and completed Assessments and/or Plans of Care and corrective</p>		

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			<p>actions implemented to correct any identified deficiencies. The Committee reviews areas of noncompliance, interventions taken and evaluates to determine if further action is required. The QAI meeting minutes document this activity and are available for review at the facility.</p> <p>The Director of Operations as the CEO and member of the QAI team is responsible to ensure that all data, including the medical record audits are presented to QAI, are completed, reviewed and trended during the QAI meetings.</p> <p>The QAI Committee is responsible to provide oversight to ensure the Assessments/Plan of Care, as written to address the deficiencies identified with the SOD, is effective and is providing resolution of the issues.</p> <p>Governing Body will review the analysis as provided by the QAI including the trending of the issues. If any deficiencies are noted they will work with the QAI Committee to determine the root cause and amend the Assessments/Plan of Correction to ensure resolution of the deficiency.</p> <p>The Minutes of the QAI Committee and Governing Body are available within the facility for review.</p>		

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	<p>4. Clinical record #10 evidenced the patient's first date of dialysis was 3/7/12. The record failed to evidence an annual reassessment had been completed.</p> <p>5. Clinical record #12 evidenced the patient's first date of dialysis was 7/27/11. The record failed to evidence an annual reassessment had been completed.</p> <p>6. Clinical record #13 evidenced the patient's first date of dialysis was 2/19/08. The record failed to evidence an annual reassessment had been completed.</p> <p>7. Clinical record #14 evidenced the first date of dialysis was 5/10/1990. The record failed to evidence an annual reassessment had been completed.</p> <p>8. Clinical Record #15, start of care 1-9-10, failed to evidence an annual comprehensive assessment had been completed.</p> <p>9. On 4-25-13 at 4:30 PM, Person T, indicated the annual reassessment was not completed within the required time frame or had been "thinned" from the chart against policy.</p> <p>10. On 4-25-13 at 4:00 PM, Employee A,</p>			

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	the director of operations, indicated the annual comprehensive evaluations may have been thinned from the chart against policy and stored at an alternate facility, and the documentation was not available.			

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V000542	<p>494.90(a) POC-IDT DEVELOPS PLAN OF CARE The interdisciplinary team must develop a plan of care for each patient. Based on clinical record review, policy review, and interview, the facility failed to ensure an initial plan of care was developed by the interdisciplinary team (IDT) for 10 of 15 records (1, 2, 4, 5, 6, 8, 9, 10, 11, and 12) reviewed with the potential to affect any new patients of the dialysis.</p> <p>Findings</p> <p>1. Clinical record #8 evidenced the patient's first date of dialysis was 9/14/12. The record failed to evidence an initial plan of care had been developed by the IDT.</p> <p>2. Clinical record #9 evidenced the patient's first date of dialysis was 10/20/12. The record failed to evidence an initial plan of care had been developed by the IDT.</p> <p>3. Clinical record #10 evidenced the patient's first date of dialysis was 3/7/12. The record failed to evidence an initial plan of care had been developed by the IDT.</p> <p>4. Clinical record #11 evidenced the patient's first date of dialysis was 9/14/12.</p>	V000542	<p>The Director of Operations met with the facility's Interdisciplinary Team on 5/6/13 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy i.e. "Comprehensive Interdisciplinary Assessment and Plan of Care" #FMS-CS-IC-I-110-125A." for the purpose of ensuring that every patient will have a complete, timely and current Plan of Care available within their medical record that meets all criteria. The Clinic Manager and Education Coordinator will meet with the RNs to review the above policy on 5/8/13.</p> <p>The Clinical Manager or designee will complete an audit of 100% of the current Plan of Care, including patients # 1, 2, 4, 5, 6, 8, 9, 10, 11, 12 and 15 by 5/20/13. All patients' Plan of Care will be reviewed to verify the completion of an initial Plan of Care by all members of the IDT and the patient. Any Plan of Care not found, incomplete or outside of the designated time frame will be reviewed with the patient's attending physician and revised up to 30 each month until all are in compliance to be completed no later than 8/7/13 to reflect the patient's status and condition. The Clinical Manager is</p>	08/07/2013			

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	<p>The record failed to evidence an initial plan of care had been developed by the IDT.</p> <p>5. Clinical record #12 evidenced the patient's first date of dialysis was 10/20/12. The record failed to evidence an initial plan of care had been developed by the IDT.</p> <p>6. On 4/25/13 at 9: 10 AM, Employee C, the operation manager, indicated the initial plans of care were thinned from the patient charts and sent to storage off the premises.</p> <p>7. The agency policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care" with an effective date of July 4, 2012 stated, "An initial comprehensive interdisciplinary assessment must be conducted on all new patients and a plan of care developed within the later of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first dialysis session."</p>		<p>responsible.</p> <p>The Renal Dietitian has developed a tracking tool which will be used on a monthly basis to determine those Assessments and Plans of Care that are due. The Renal Dietitian is responsible to add all new patients, and patients returning from hospitalizations to the tracking tool. This tracking tool will be shared with the entire IDT a month in advance of scheduled Assessment/Plan of Care due dates.</p> <p>The Clinical Manager or designee will perform monthly audits for three months of the Plan of Care to ensure the initial Plan of Care for is completed by all members of the IDT including the patient within the designated time-frame. Frequency of ongoing audits will be determined by the QAI Committee upon review of audit data and resolution of the issue.</p> <p>The Clinical Manager has formalized a Patient Comprehensive Assessment/Plan of Care Report for the monthly QAI meeting detailing compliance gaps between scheduled and completed Assessments and/or Plans of Care and corrective actions implemented to correct any identified deficiencies. The Committee reviews areas of noncompliance, interventions taken and evaluates to determine</p>		

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	8. Clinical record #1 evidenced the patient's first dialysis date was 11/1/2009. The record failed to evidence an initial plan of care had been developed by the		<p>if further action is required. The QAI meeting minutes document this activity and are available for review at the facility.</p> <p>The Director of Operations as the CEO and member of the QAI team is responsible to ensure that all data, including the medical record audits are presented to QAI, are completed, reviewed and trended during the QAI meetings.</p> <p>The QAI Committee is responsible to provide oversight to ensure the Assessments/Plan of Care as written to address the issues identified with the SOD, is effective and is providing resolution of the issues.</p> <p>Governing Body will review the analysis as provided by the QAI including the trending of the issues. If any deficiencies are noted they will work with the QAI Committee to determine the root cause and amend the Plan of Correction to ensure resolution of the deficiency.</p> <p>The Minutes of the QAI Committee and Governing Body are available within the facility for review.</p>		

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	<p>IDT.</p> <p>9. Clinical record #2 evidenced the first dialysis date of 2/4/12. The record failed to evidence an initial plan of care had been developed by the IDT.</p> <p>10. Clinical record #4 evidenced the first dialysis date of 3/6/13. The record failed to evidence an initial plan of care had been developed by the IDT.</p> <p>11. Clinical record #5 evidenced the first dialysis date of 7/27/09. The record failed to evidence an initial plan of care had been developed by the IDT.</p> <p>12. Clinical record # 6 evidenced the first dialysis date of 9/24/2002. The record failed to evidence an initial plan of care had been developed by the IDT.</p>				

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V000544	<p>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.</p> <p>Based on clinical record review, policy review, and interview, the facility failed to ensure the blood flow rate prescription was followed for 4 of 15 records (1, 2, 4, and 8) reviewed with the potential to affect all patients of the facility.</p> <p>Findings</p> <p>1. Clinical record #8 included hemodialysis orders that identified the blood flow rate (BFR) was to be 500 mL/min (milliliters per minute). The flow sheet dated 4/15/2013 evidenced a BFR of 450 with no explanation as to why the BFR prescription was not followed.</p> <p>On 4/25/13 at 2:15 PM, the clinical manager indicated the blood flow rates were to match the orders unless an explanation was given on the treatment flow sheet.</p>	V000544	<p>The Education Coordinator will in-service the staff on the "Patient Monitoring During Patient Treatment" document FMS-CS-IC-I-110-133 on May 14 th with emphasis on ensuring that the patient's treatment is delivered according to the physician's prescription. If unable to achieve prescribed Blood Flow Rate, the Patient Care technician will document the reason and interventions taken on the patient's flowsheet. The Patient Care technician will notify the nurse of the inability to achieve the Prescribed Blood Flow Rate and document notification on the flowsheet. The nurse will assess the patient's access and notify the physician. Specific assessment/observation, interventions and follow-up including outcome will be documented by the staff on the patient's flowsheet.</p> <p>The Education Coordinator will in-service the RN staff on the use of the RN rounding tool on May 14 th . Designated RN will complete on each patient each shift and Clinic Manager will review rounding tools each week</p>	05/14/2013	

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	<p>2. Clinical record #1 included hemodialysis orders that identified the blood flow rate (BFR) was to be 500 mL/min. The flow sheet dated 4/1/2013 evidenced a BFR of 300, 455, 475, and 400 with no explanation as to why the BFR prescription was not followed.</p> <p>3. Clinical record #2 included hemodialysis orders that identified the BFR was to be 500 mL/min. The flow sheet dated 4/4/13 evidenced a BFR of 450 and 425 with no explanation as to why the BFR prescription was not followed.</p> <p>4. Clinical record #4 included hemodialysis orders that identified the BFR was to be 500 mL/min. The flow</p>		<p>and report in QAI.</p> <p>The Clinical Manager or designee will review treatment sheets daily for 2 weeks, weekly until the condition is lifted to ensure that patient's blood flow rate is delivered as prescribed, or if unable to achieve, the action taken is documented; on-going monthly audits will follow as part of the QAI program.</p> <p>The Clinical Manager will report a summary of findings monthly in QAI and compliance will be monitored by the QAI committee.</p>		

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	<p>sheet dated 4/12/13 evidenced a BFR of 450 with no explanation as to why the BFR prescription was not followed.</p> <p>5. The facility policy titled "Patient Monitoring During Patient Treatment" document number FMS-CS-IC-I-110-133 revision date 7/4/12 states, "Documentation of monitoring will be completed on the treatment record. Appropriate interventions in response to changes in vital signs, treatment parameters, or machine adjustments shall be documented in the treatment record."</p>				

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V000556	<p>494.90(b)(1) POC-COMPLETED/SIGNED BY IDT & PT The patient's plan of care must-</p> <p>(i) Be completed by the interdisciplinary team, including the patient if the patient desires; and</p> <p>(ii) Be signed by the team members, including the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided.</p> <p>Based on clinical record review, interview, and policy review, the facility failed to ensure an initial plan of care was developed by the interdisciplinary team for 11 of 15 records (1, 2, 4, 5, 6, 8, 9, 10, 11, 12, and 15) reviewed with the potential to affect any new patients.</p> <p>Findings</p> <p>1. Clinical record #8 evidenced the patient's first date of dialysis was 9/14/12. The record failed to evidence an initial plan of care developed by the IDT.</p> <p>2. Clinical record #9 evidenced the patient's first date of dialysis was 10/20/12. The record failed to evidence an initial plan of care developed by the IDT.</p> <p>3. Clinical record #10 evidenced the patient's first date of dialysis was 3/7/12. The record failed to evidence an initial</p>	V000556	<p>The Director of Operations met with the facility's Interdisciplinary Team on 5/6/13 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy i.e. "Comprehensive Interdisciplinary Assessment and Plan of Care" #FMS-CS-IC-I-110-125A." for the purpose of ensuring that every patient will have a complete, timely and current Plan of Care including IDT and patient signatures available within their medical record that meets all criteria. The Clinic Manager and Education Coordinator will meet with the RNs to review the above policy on 5/8/13.</p> <p>The Clinical Manager or designee will complete an audit of 100% of the current Plan of Care, including patients # 1, 2, 4, 5, 6, 8, 9, 10, 11, 12 and 15 by 5/20/13. All patients' Plan of Care will be reviewed to verify completeness (including all signatures) and timeliness of the initial Plan of Care by the IDT and</p>	08/07/2013	

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	<p>plan of care developed by the IDT.</p> <p>4. Clinical record #11 evidenced the patient's first date of dialysis was 9/14/12. The record failed to evidence an initial plan of care developed by the IDT.</p> <p>5. Clinical record #12 evidenced the patient's first date of dialysis was 10/20/12. The record failed to evidence an initial plan of care developed by the IDT.</p> <p>6. On 4/25/13 at 9: 10 AM, Employee C, the operation manager, indicated the initial plans of care were thinned from the patient charts and sent to storage off the premises.</p> <p>7. The agency policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care" with an effective date of July 4, 2012 stated, "An initial comprehensive interdisciplinary assessment must be conducted on all new patients and a plan of care developed within the later of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first dialysis session."</p>		<p>patient. Any Plan of Care found incomplete (including those without signatures of each IDT member and patient) or late will be revised with the patient's attending physician and revised up to 30 patients each month until all are in compliance to be completed no later than 8/7/13 to reflect the patient's status and condition. The Clinical Manager is responsible.</p> <p>The Renal Dietitian has developed a tracking tool which will be used on a monthly basis to determine those Assessments and Plans of Care that are due. The Renal Dietitian is responsible to add all new patients, and patients returning from hospitalizations to the tracking tool. This tracking tool will be shared with the entire IDT a month in advance of scheduled Assessment/Plan of Care due dates.</p> <p>The Clinical Manager or designee will perform monthly audits for three months to ensure the initial Assessments and Plan of Care are completed by the IDT, including review with the patient within the timeframe designated in the policy. Frequency of ongoing audits will be determined by the QAI Committee upon review of audit data and resolution of the issue.</p> <p>The Clinical Manager has</p>				

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			<p>formalized a Patient Comprehensive Assessment/Plan of Care Report for the monthly QAI meeting detailing compliance gaps between scheduled and completed Assessments and/or Plans of Care and corrective actions implemented to correct any identified deficiencies. The Committee reviews areas of noncompliance, interventions taken and evaluates to determine if further action is required. The QAI meeting minutes document this activity and are available for review at the facility.</p> <p>The Director of Operations as the CEO and member of the QAI team is responsible to ensure that all data, including the medical record audits are presented to QAI, are completed, reviewed and trended during the QAI meetings.</p> <p>The QAI Committee is responsible to provide oversight to ensure the Assessments/Plan of Care, as written to address the deficiencies identified with the SOD, is effective and is providing resolution of the issues.</p> <p>Governing Body will review the analysis as provided by the QAI including the trending of the issues. If any deficiencies are noted they will work with the QAI Committee to determine the root cause and amend the Plan of Correction to ensure resolution of</p>		

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	<p>8. Clinical record #1 evidenced the patient's first dialysis date was 11/1/2009. The record failed to evidence an initial plan of care developed by the IDT.</p> <p>9. Clinical record #2 evidenced the first dialysis date of 2/4/12. The record failed to evidence an initial plan of care developed by the IDT.</p> <p>10. Clinical record #4 evidenced the first dialysis date of 3/6/13. The record failed to evidence an initial plan of care developed by the IDT.</p> <p>11. Clinical record #5 evidenced the first dialysis date of 7/27/09. The record failed to evidence an initial plan of care developed by the IDT.</p> <p>12. Clinical record # 6 evidenced the first dialysis date of 9/24/2002. The record failed to evidence an initial plan of care developed by the IDT.</p> <p>13. Clinical Record #15, start of care 1-9-10, failed to evidence an initial Plan of Care was by the interdisciplinary team.</p>		<p>the deficiency.</p> <p>The Minutes of the QAI Committee and Governing Body are available within the facility for review.</p>	

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	<p>14. On 4-25-13 at 4:30 PM, Person T indicated the initial Plan of Care was not completed within the required time frame or had been "thinned" from the chart against policy and there was no initial Plan of Care or revised annual Plan of Care documentation available other than the revised Care Plan dated 2-14-12.</p> <p>15. On 4-25-13 at 4:00 PM, Employee A, the director of operations, indicated the care plan may have been thinned from the chart against policy and stored at an alternate facility, but the documentation was not available.</p>			

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V000557	<p>494.90(b)(2) POC-INITIAL IMPLEMENTED-30 DAYS/13 TX Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.</p> <p>Based on clinical record review, policy review, and interview, the facility failed to ensure the initial plan of care was completed within the 30 days after admission in 7 of 15 records (4, 8, 9, 10, 11, 12, and 15) reviewed with the potential to affect all new patients.</p> <p>Findings</p> <ol style="list-style-type: none"> 1. Clinical record #8 evidenced the patient's first date of dialysis was 9/14/12. The record failed to evidence the initial plan of care was completed within 30 days after admission. 2. Clinical record #9 evidenced the patient's first date of dialysis was 10/20/12. The record failed to evidence the initial plan of care was completed within 30 days after admission. 3. Clinical record #10 evidenced the patient's first date of dialysis was 3/7/12. The record failed to evidence the initial plan of care was completed within 30 days after admission. 	V000557	<p>The Director of Operations met with the facility's Interdisciplinary Team on 5/6/13 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy i.e. "Comprehensive Interdisciplinary Assessment and Plan of Care" #FMS-CS-IC-I-110-125A." for the purpose of ensuring that every patient will have a complete, timely and current initial Plan of Care available within their medical record that meets all criteria. The Clinic Manager and Education Coordinator will meet with the RNs to review the above policy on 5/8/13.</p> <p>The Clinical Manager or designee will complete an audit of 100% of the current Plan of Care, including patients # 4, 8, 9, 10, 11, 12 and 15 by 5/20/13. Each patient's initial Plan of Care will be reviewed to verify completeness, timeliness and implementation of the Plan of Care as outlined in the policy. Plans of Care identified as incomplete or late will be revised by the patient's attending physician, members of the IDT</p>	08/07/2013	

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	<p>4. Clinical record #11 evidenced the patient's first date of dialysis was 9/14/12. The record failed to evidence the initial plan of care was completed within 30 days after admission.</p> <p>5. Clinical record #12 evidenced the patient's first date of dialysis was 10/20/12. The record failed to evidence the initial plan of care was completed within 30 days after admission.</p> <p>6. The agency policy titled "Comprehensive Interdisciplinary Assessment and Plan of care" with an effective date of July 4, 2012 stated, "An initial comprehensive interdisciplinary assessment must be completed on all new patients and a plan of care developed and implemented within 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session."</p> <p>7. On 4/25/13 at 2:15 PM, the clinical manager indicated the initial plans of care were not in the records.</p>		<p>and the patient up to 30 patients each month until all are in compliance to be completed no later than 8/7/13 to reflect the patient's status and condition. The Clinical Manager is responsible.</p> <p>The Renal Dietitian has developed a tracking tool which will be used on a monthly basis to determine those Assessments and Plans of Care that are due. The Renal Dietitian is responsible to add all new patients, and patients returning from hospitalizations to the tracking tool. This tracking tool will be shared with the entire IDT a month in advance of scheduled Assessment/Plan of Care due dates.</p> <p>The Clinical Manager or designee will perform monthly audits for three months to ensure that each patient's initial Plan of Care is complete, timely and current as designated in the policy. Frequency of ongoing audits will be determined by the QAI Committee upon review of audit data and resolution of the issue.</p> <p>The Clinical Manager has formalized a Patient Comprehensive Assessment/Plan of Care Report for the monthly QAI meeting detailing compliance gaps between scheduled and completed Assessments and/or Plans of Care and corrective</p>		

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			<p>actions implemented to correct any identified deficiencies. The Committee reviews areas of noncompliance, interventions taken and evaluates to determine if further action is required. The QAI meeting minutes document this activity and are available for review at the facility.</p> <p>The Director of Operations as the CEO and member of the QAI team is responsible to ensure that all data, including the medical record audits are presented to QAI, are completed, reviewed and trended during the QAI meetings.</p> <p>The QAI Committee is responsible to provide oversight to ensure the Assessments/Plan of Care, as written to address the deficiencies identified with the SOD, is effective and is providing resolution of the issues.</p> <p>Governing Body will review the analysis as provided by the QAI including the trending of the issues. If any deficiencies are noted they will work with the QAI Committee to determine the root cause and amend the Plan of Correction to ensure resolution of the deficiency.</p> <p>The Minutes of the QAI Committee and Governing Body are available within the facility for review.</p>		

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	<p>8. Clinical Record #15, start of care 1/9/10, failed to evidence the initial plan of care was completed within 30 days after admission.</p> <p>9. On 4-25-13 at 4:30 PM, person T indicated the Plan of Care was not completed within the required timeframe or may have been thinned from the record against policy and stored at another facility.</p> <p>10. Clinical record #4, start of care 3/6/13, failed to evidence an initial comprehensive assessment. The Plan of Care Report signed by the Interdisciplinary Team on 4/15/13, greater than 30 days after the start of care.</p>			

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V000715	<p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; Based on review of facility policy and procedure, review of clinical records, observation, and interview, the medical director failed to ensure all policies and procedures related to infection control and patient care were followed for 1 of 1 facility with the potential to affect all the facility's patients.</p> <p>Findings</p> <p>1. The medical director failed to ensure the facility followed its policy titled "FMS Clinical Services Personal Protective Equipment" with an effective date of March 20, 2013 that stated, "Disposable gloves must be used ... when touching any part of the dialysis machine or equipment ... Gloves must be worn appropriately. Change gloves and practice hand hygiene between each patient and / or station to prevent cross - contamination. Remove gloves and practice hand hygiene between each patient contact ... hand hygiene must be performed after glove removal. Avoid</p>	V000715	<p>The Medical Director met with the members of the Governing Body on 5/6/13 to review and approve the final plan of correction to ensure that citations and responses cited and detailed in V110, V111, V113, V122, V128, V146, V516, V517, V518, V519, V542, V553, V544, V556, and V55 appropriately address the root cause of each citation; additionally, the Medical Director reviewed identified action plans, auditing tools, and techniques which will monitor and measure adherence to policies and procedures and confirm that corrective actions are instituted to ensure resolution of the areas of deficiency.</p> <p>The Medical Director is responsible to review the results of the Plan of Correction and ensuing activities and reports weekly as a member of the Governing Body and to provide oversight monthly ongoing through the QAI Committee.</p> <p>The Medical Director acknowledges his role to ensure</p>	05/06/2013	

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	<p>touching surfaces with gloved hands that will be touched with ungloved hands (for ex. [example] patient charts and computers." (See V 111, V 113, V 146)</p> <p>2. The medical director failed to ensure the facility followed its policy titled "Hand Hygiene" with an effective date of January 4, 2012 that stated, "Hands will be decontaminated using alcohol based hand rub or by washing hands with antimicrobial soap and water ... immediately after removing gloves." (See V 111, V 146)</p> <p>3. The medical director failed to ensure the facility followed its procedure titled "FMS Changing the Catheter dressing procedure" with an effective date of April 4, 2012 that stated, "Follow the steps below to remove a catheter dressing and inspect the exit site: ... Discard dressing and remove gloves. Perform hand hygiene." (See V 111, V 113, 146)</p> <p>4. The medical director failed to ensure the facility followed its policy titled "Dialyzing Patients with Positive Hepatitis B Antigen(HBsAG+)" document number FMS-CS-IC-II-155-140A, revision date 3/20/13, that states, "The area used for HBsAG positive patients must be separated from other stations by a space at</p>		<p>that any issues not resolving will be reviewed with a new root cause analysis and Plan of Action until all issues as cited within the Statement of Deficiency have been resolved and resolution sustained.</p>	

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	<p>least equivalent to the width of one hemodialysis station." (See V 128)</p> <p>5. The medical director failed to ensure the facility followed its policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care" document # FMS-CS-IC-I-110-125A revision date 7/4/12 that states, "An initial comprehensive interdisciplinary assessment must be conducted on all new[SIC]patients and a Plan of Care developed and implemented within the later of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. ...A follow up comprehensive interdisciplinary assessment must occur on all new patients within 3 months after the completion of the initial assessment to adjust the patient's Plan of Care as appropriate or if necessary ... reassessed annually thereafter on all stable patients ... The adequacy of the patient's dialysis prescription must be assessed on an ongoing basis as follows: HD patients at least monthly ...The plan of care must be signed by team members including the patient or patient designee. If the patient is unstable or chooses not to sign the plan of care, this must be documented on the plan of care along with the reason the signature was not provided." (See V 516, V 517, V 518, V 519, V 542, V 556, V</p>			

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	557) 6. The medical director failed to ensure the facility followed its policy titled "Patient Monitoring During Patient Treatment" document number FMS-CS-IC-I-110-133 revision date 7/4/12 that states, "Documentation of monitoring will be completed on the treatment record. Appropriate interventions in response to changes in vital signs, treatment parameters, or machine adjustments shall be documented in the treatment record." (see V 544).				