

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152571	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 10/11/2012
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH	STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804
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V0000	<p>This was a federal complaint investigation survey. This was an expanded survey.</p> <p>Complaint #: IN00117231 - Substantiated: Federal deficiencies related to the allegations are cited; unrelated deficiencies are also cited.</p> <p>Facility #: 005141</p> <p>Survey Dates: 10-9-12, 10-10-12, and 10-11-12</p> <p>Medicaid Vendor #: 200470050D</p> <p>Surveyor: Vicki Harmon, RN, PHNS</p> <p>FMC Terre Haute North was found to be out of compliance with Conditions for Certification 42 CFR 494.80 Patient Assessment, 42 CFR 494.90 Patient Plan of Care, 42 CFR 494.110 Quality Assessment and Performance Improvement, 42 CFR 494.150 Responsibilities of the Medical Director, and 42 CFR 494.180 Governance.</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN</p> <p style="text-align: center;">October 15, 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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V0124	<p>494.30(a)(1)(i) IC: HBV: TEST ALL,REV RESULTS/STATUS B4 ADMIT Routine Testing for Hepatitis B</p> <p>The HBV serological status (i.e. HBsAg, total anti-HBc and anti-HBs) of all patients should be known before admission to the hemodialysis unit.</p> <p>Routinely test all patients [as required by the referenced schedule for routine testing for Hepatitis B Virus]. Promptly review results, and ensure that patients are managed appropriately based on their testing results. Based on administrative record and facility policy review and interview, the facility failed to ensure monthly antigen testing had been completed for 12 (#s 6, 13, 20, 22, 24, 25, 26, 27, 28, 29, 30, and 31) of 73 patients known to be susceptible creating the potential to affect the facility's 73 current incenter patients who were susceptible.</p> <p>The findings include:</p> <p>1. The facility's 01-04-2012 "Patient Testing and Vaccination for Hepatitis B" policy number FMS-CS-IC-II-155-142A policy states, "The following schedule shall be adhered to when testing patients for Hepatitis B: . . . All patients on admission HBsAg [hepatitis B surface antigen], Anti-HBc [antibody to hepatitis B core antigen], Anti-HBs [antibody to hepatitis B surface antigen], HBV -</p>	V0124	<p>As a result of the citations from the October 9 - 11, 2012 CMS Complaint survey and to ensure that the facility fully complies with the Centers of Disease Control and Prevention guidelines to decrease the transmission of infection within the dialysis facility in regards to the care and services of all the patients dialyzing at the facility, the following corrective actions have been implemented by the Governing Body and facility management team:</p> <p>On 10/30/12 upon receipt of the Statement of Deficiencies, the Director of Operations reinforced with the Operations Manager her obligation to ensure staff compliance with all facility polices, inclusive of Infection Control Procedures and CDC's guidelines to prevent the transmission of infections in the dialysis setting in the care and</p>	11/13/2012			

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	<p>(susceptible), including nonresponders to vaccine HBsAg monthly, Anti-HBs positive (10 mIU/mL), anti-HBc negative: annual Anti-HBs, Anti-HBs positive and positive anti_HBc: no additional HBV testing needed."</p> <p>2. The facility's "Hepatitis Status - Detail" report dated 10-11-2012 evidenced monthly hepatitis B antigen testing had not been completed for patients who were known to be susceptible.</p> <p>A. The hepatitis status report evidenced the antibody status for patient number 6 was less than 10. The report failed to evidence monthly antigen testing had been completed in February and March 2012.</p> <p>B. The hepatitis status report evidenced the antibody status for patient number 13 was less than 10. The report failed to evidence monthly antigen testing had been completed in March 2012.</p> <p>C. The report evidenced the antibody status for patient number 20 was less than 10. The report failed to evidence monthly antigen testing had been completed for April, May, June, July, August, and September 2012.</p>		<p>services rendered to all patients dialyzing in the facility.</p> <p>To further ensure compliance and to prevent reoccurrence, on 11/5/12, the facility's management team developed and presented the following Infection Control reeducation for all the Nursing staff:</p> <ul style="list-style-type: none"> · Reeducation and reinforcement of FMS-CS-IC-11-155-142A Policy Patient Testing and Vaccination for Hepatitis B with emphasis on: Routine testing of all patients, prompt review of results and ensuring that patients are managed appropriately based on their results inclusive of, but not limited to: <ul style="list-style-type: none"> o All new patients o Any existing patients <p>A copy of the education provided is maintained available at the facility for review.</p> <p>On November 13, 2012, all existing patients were tested for Hepatitis B antigens and antibodies. Any patient found to be susceptible will be offered the Hepatitis B vaccine. The acceptance or refusal of the vaccine will be documented on the Consent/Declination form and stored as part of their medical record. It will also be tracked on the Vaccination tracking tool as a part of the QAI program.</p>				

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	<p>D. The report evidenced the antibody status for patient number 22 was less than 10. The report failed to evidence monthly antigen testing had been completed for April, May, June, July, August, and September 2012.</p> <p>E. The report evidenced the antibody status for patient number 24 was less than 10. The report failed to evidence monthly antigen testing had been completed for June and July 2012.</p> <p>F. The report evidenced the antibody status for patient number 25 was less than 10. The report failed to evidence monthly antigen testing had been completed for June 2012.</p> <p>G. The report evidenced the monthly antibody status for patient number 26 was less than 10 on 01-11-2011. The report failed to evidence monthly antigen testing had been completed for February, March, April, May, and June 2011. The report evidenced the patient had an antibody value of 91 on 07-12-2011.</p> <p>H. The report evidenced the antibody status for patient number 27 was less than 10. The report failed to evidence monthly antigen testing had been completed for April, May, June, July, August, and September 2012.</p>		<p>To ensure compliance, the Operations Manager reviews the Hepatitis B detailed report and the Vaccination tool with the Medical Director weekly. Once the condition is lifted the Vaccination tracking tool will be reviewed monthly as part of the facility's routine QAI program during which identified variances are summarized and reported as part of the Infection Control review during the monthly QAI meeting.</p> <p>The Clinical Manager is responsible and the QAI committee monitors for compliance</p>				

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	<p>I. The report evidenced the antibody status for patient number 28 was less than 10 on 07-14-2009 and 05-07-2012. The report failed to evidence monthly antigen testing had been completed for for September 2009 to May 2012.</p> <p>J. The report evidenced the antibody status for patient number 29 was less than 10 on 03-13-2012. The report failed to evidence monthly antigen testing had been completed for September 2012.</p> <p>K. The report evidenced the antibody status for patient number 30 was less than 10 on 03-12-2012 The report failed to evidence monthly antigen testing had been completed for April, May, June, and August 2012.</p> <p>L. The report evidenced the antibody status for patient number 31 was less than 10 on 03-13-2012. The report failed to evidence monthly antigen testing had been completed for August and September 2012.</p> <p>3. The Operations Manager, employee CC, was unable to provide any additional documentation and/or information when asked on 10-11-2012 at 12:30 PM.</p>				

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V0196	<p>494.40(a) CARBON ADSORP-MONITOR, TEST FREQUENCY 6.2.5 Carbon adsorption: monitoring, testing freq Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours.</p> <p>Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet.</p> <p>Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N.N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L]. Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly. Based on observation, facility policy and procedure review, and staff interview, the facility failed to ensure all required personal protective equipment had been worn while performing the water test for chlorine in 1 of 1 water test observed creating the potential to affect all of the</p>	V0196	The Clinic Manager held an in-service for all employees that perform the Chlorine/ Chloramines testing on October 12, 2012 to review the procedure of Chlorine/Chloramines	10/12/2012			

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	<p>facility's 130 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The facility's 07-31-2009 "Chlorine / Chloramine Testing of Water Using a Hach Colorimeter" procedure number FMS-TS-IC- I-145-210C2 states, "The following supplies are needed for this procedure: Personal Protective Equipment: Safety glasses/goggles, gloves, gown . . . Don required PPE to protect hands and ensure integrity of testing." 2. On 10-10-2012 at 4:35 PM, employee O was observed to perform a test for the presence of chlorine in the water at the dialysis facility. The employee failed to don any personal protective equipment while performing the test. 3. On 10-10-2012 at 4:55 PM, the Director of Operations, employee AA, stated, "Yes, they are supposed to wear PPE when performing the water check." 		<p>Testing of Water Using a Hach Colorimeter FMS-TS-IC-I-145-210C2. Emphasis was placed on step #1 which states "Disinfect Hands and don appropriate PPE (including face shield) to protect hands and ensure integrity of testing."</p> <p>The Operations Manager will ensure that infection control audits are completed utilizing the QAI Infection Control audit tool daily until the condition is lifted and then ongoing monitoring will occur per the QAIcalendar.</p> <p>The Operations Manager is responsible for reporting her findings of these audits to the QAI committee during the QAI monthly meetings</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>				

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			The QAI Committee is responsible to provide oversight until ongoing resolution has been determined.	

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V0408	<p>494.60(d) PE-EMERGENCY PREPAREDNESS-PROCEDURES The dialysis facility must implement processes and procedures to manage medical and non medical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. Based on observation and interview, the facility failed to ensure emergency evacuation supplies had been maintained and checked monthly for 1 of 1 facility creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> On 10-11-2011 at 1:25 PM, observation noted 3 bottles of "Epi Clenz" cleanser in the facility's emergency evacuation box. The bottles were marked with a 07/2012 expiration date. Employee A, the charge nurse, confirmed the cleanser was expired. The employee stated, "This box has not been checked every month. I cannot find the papers to tell when it was last checked." The employee indicated the supplies are to be checked monthly. 	V0408	<p>The Director of Operations met with the facility's staff on 10/24/12 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.</p> <p>The Operations Manager will create a checklist by 11/2/12 containing all medications and supplies that are kept in the facility. The supplies and equipment will be checked monthly by the charge nurse for expiration dates, quantities and that the medications and supplies are covered and locked.</p> <p>The Operations Manager is responsible to review the checklist monthly to ensure the audits are occurring.</p> <p>The Operations Manager is</p>	11/02/2012			

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			<p>responsible to report a summary of findings and to 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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V0500	<p>494.80 CFC-PATIENT ASSESSMENT</p> <p>Based on clinical record and facility policy review and interview, it was determined the facility failed to ensure compliance with this condition by failing to ensure all members of the interdisciplinary team (IDT) had participated in the completion of the comprehensive interdisciplinary assessment in 4 of 9 records reviewed creating the potential to affect all of the facility's 130 current patients (See V 501); by failing to ensure the comprehensive interdisciplinary assessment included a review of all medications in 4 of 9 records reviewed creating the potential to affect all of the facility's 130 current patients (See V 506); by failing to ensure comprehensive interdisciplinary assessments included an evaluation of the patient's psychosocial needs in 1 of 9 records reviewed creating the potential to affect all of the facility's 130 current patients (See V 510); and by failing to ensure comprehensive interdisciplinary assessments included an evaluation of the access location and/or site in 3 of 9 records reviewed creating the potential to affect all of the facility's 130 current patients (See V 511).</p> <p>The cumulative effect of these systemic problems resulted in the facility being</p>	V0500	<p>The Governing Body of this facility acknowledges its responsibility to ensure that all patient's Comprehensive Interdisciplinary Assessment were implemented by all members of the IDT at the required timelines to address patient needs, that all components of the assessment are completed and that all members participated . Therefore, as noted in detail the Governing Body reviewed the SOD and the following action steps were agreed upon and implemented: Effective immediately: · The Operations Manager (OM) will analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee for oversight and review. · The Director of Operations will present a report on the Plan of Correction data and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the resolution of all identified issues. · 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</p>	11/02/2012			

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	found out of compliance with this condition, 42 CFR 494.80 Patient Assessment.		Correction to ensure it is effective and is providing resolution of the issues · The processes as noted in this POC will be reviewed by the Governing Body at each meeting. These meetings will ensure ongoing progress towards resolution of noted deficiencies that Patient specific Plans of Care are being provided. · Minutes of the Governing Body and QAI meetings, as well as monitoring forms, educational documentation will provide evidence of these actions, the Governing Body's direction and monitoring of facility activities. These will be available for review at the facility. The response provided for V 501 describes, in detail, the processes and monitoring steps taken to ensure that all members participate in the Comprehensive Interdisciplinary Assessment. The response provided for V 506 describes, in detail, the processes and monitoring steps taken to ensure that all patient's medications are reviewed as a part of the comprehensive assessment. The response provided for V 510 describes, in detail, the processes and monitoring steps taken to ensure that all assessments include an evaluation of the patient's psychosocial needs. The response provided for V 511 describes, in detail, the processes and monitoring steps taken to ensure that all patient assessments include an		

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			evaluation of the access location and/or site.	

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V0501	<p>494.80 PA-IDT MEMBERS/RESPONSIBILITIES The facility's interdisciplinary team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure all members of the interdisciplinary team (IDT) had participated in the completion of the comprehensive interdisciplinary assessment (CIA) in 4 (#s 1, 5, 6, and 9) of 9 records reviewed creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 1 included a CIA dated 8-24-12. The CIA failed to evidence the physician member of the IDT had participated in the completion of the assessment. 2. Clinical record number 5 included a CIA dated 7-27-12. The CIA failed to evidence the physician had participated in the completion of the assessment. 	V0501	<p>The Director of Operations met with the facilities interdisciplinary team on 11/2/12 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 participation by the patient's attending Nephrologist and Social Worker.</p> <p>Additionally, the Director of Operations reviewed the Medical Staff By-laws on 11/9/12 with the Medical Director and all attending physicians emphasizing their requirements as related to the Assessment and Plan of Care process.</p> <p>The Operations Manager and her</p>	11/09/2012	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152571	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 10/11/2012
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	<p>3. Clinical record number 6 included a CIA dated 6-25-12. The CIA failed to evidence the physician had participated in the completion of the assessment.</p> <p>4. Clinical record number 9 included a CIA signed by the RN, employee A, on 8-7-12 and the registered dietician (RD), employee W, on 8-23-12. The CIA failed to evidence the medical social worker (MSW) or the physician had participated in the completion of the assessment.</p> <p>The Director of Operations, employee AA, indicated, on 10-11-12 at 9:30 AM, she was aware the CIA lacked documentation of participation by the MSW and the physician.</p> <p>5. The Director of Operations and the Regional Quality Manager were unable to provide any additional documentation and/or information when asked on 10-11-12 at 1:30 PM. The Director of Operations indicated the physicians are to check the boxes on the physician portion of the comprehensive assessment to indicate participation in the completion of the comprehensive assessment findings and review of the medications.</p> <p>6. The facility's 07-04-2012 "Comprehensive Interdisciplinary</p>		<p>designee completed 100% review of all patients' Comprehensive Assessments by 10/15/12 to ensure that all Assessments evidence the nephrologist and Social worker participation. Any patient's Assessment found to be out of compliance including patient's # 1, 5, 6 and 9 will be presented to the IDT for completion by 11/9/12.</p> <p>All patients will have a physician assessment completed by their attending physician and an assessment completed by the social worker as part of the Comprehensive Interdisciplinary Assessment policy FMS-CS-IC-I-110-125A directing the Comprehensive Patient Assessment.</p> <p>The Operations Manager will utilize the QAI tool for Assessment and Care-Plan tracking of all patients monthly to ensure the participation of all members of the IDT.</p> <p>The Operations 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>		

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	Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The Comprehensive Interdisciplinary Assessment and Plan of Care must be developed and implemented by an interdisciplinary team (IDT) consisting at a minimum, the patient or patient's designee (if patient desires), a registered nurse, the patient's attending physician (and physician extender where allowed by State regulations), qualified Master's social worker and qualified registered dietitian."		The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.		

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V0506	<p>494.80(a)(3) PA-IMMUNIZATION/MEDICATION HISTORY The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>Immunization history, and medication history. Based on clinical record and facility policy review and interview, the facility failed to ensure the comprehensive interdisciplinary assessment (CIA) included a review of all medications in 4 (#s 1, 5, 6, and 9) of 9 records reviewed creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 1 included a CIA dated 8-24-12. The CIA failed to evidence a review of all medications the patient was known to be taking had been completed. 2. Clinical record number 5 included a CIA dated 7-27-12. The CIA failed to evidence a review of all medications the patient was known to be taking had been completed. 3. Clinical record number 6 included a CIA dated 6-25-12. The CIA failed to evidence a review of all medications the patient was known to be taking had been 	V0506	<p>The Director of Operations met with the facility's Interdisciplinary Team on 11/2/12 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care" FMS-CS-I-110-125A, to ensure that every patient will have a timely, complete and current Comprehensive Assessment and Plan of Care completed and available within their medical record that meets all criteria including medication history, possible adverse effects/interactions and continued need for the medication.</p> <p>The Operations Manager and her designee completed 100% review of all patients' Comprehensive Assessments by 10/15/12 to ensure that all Assessments include a medication review that is complete and current. Any patient's Assessment found to be out of compliance including patients # 1, 5, 6 and 9 will be presented to the IDT for completion by 11/9/12.</p>	11/09/2012	

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	<p>completed.</p> <p>4. Clinical record number 9 included a CIA signed by the RN, employee A, on 8-7-12 and the registered dietician (RD), employee W, on 8-23-12. The CIA failed to evidence a review of all medications the patient was known to be taking had been completed.</p> <p>5. The Director of Operations and the Regional Quality Manager were unable to provide any additional documentation and/or information when asked on 10-11-12 at 1:30 PM. The Director of Operations indicated the physicians are to check the boxes on the physician portion of the comprehensive assessment to indicate participation in the completion of the comprehensive assessment findings and review of the medications.</p> <p>6. The facility's 07-04-2012 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The comprehensive interdisciplinary assessment must include the following: . . . medication history."</p>		<p>The Operations Manager and her designee will utilize the QAI tool for Assessment and Care-Plan tracking of all patients monthly to ensure that timely completion of all patients' medication review as part of their Comprehensive Assessment.</p> <p>The Operations 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 and Governing Body.</p>				

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V0510	<p>494.80(a)(7) PA-MSW-PSYCHOSOCIAL NEEDS The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>(7) Evaluation of psychosocial needs by a social worker. Based on clinical record and facility policy review and interview, the facility failed to ensure comprehensive interdisciplinary assessments (CIA) included an evaluation of the patient's psychosocial needs in 1 (# 9) of 9 records reviewed creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 9 included a CIA signed by the RN, employee A, on 8-7-12 and the registered dietician (RD), employee W, on 8-23-12. The CIA failed to evidence the medical social worker (MSW) had completed an assessment of the patient's psychosocial needs. 2. The Director of Operations and the Regional Quality Manager were unable to provide any additional documentation and/or information when asked on 10-11-12 at 1:30 PM. 3. The facility's 07-04-2012 "Comprehensive Interdisciplinary 	V0510	<p>The Director of Operations met with the facility's Interdisciplinary Team on 11/2/12 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care" FMS-CS-I-110-125A, to ensure that every patient will have a timely, complete and current Comprehensive Assessment and Plan of Care completed and available within their medical record that meets all criteria including an evaluation of the patient's psychosocial needs.</p> <p>The Operations Manager and her designee completed 100% review of all patients' Comprehensive Assessments by 10/15/12 to ensure that all Assessments due are complete and current. Any patient's Assessment that does not include an evaluation of the patient's psychosocial needs including patient #9 will be presented to the IDT for completion by 11/9/12.</p> <p>The Operations Manager and her designee will utilize the QAI tool for Assessment and Care-Plan</p>	11/09/2012	

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	Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The comprehensive interdisciplinary assessment must include the following: . . . Evaluation of psychosocial needs by a qualified social worker."		tracking of all patients monthly to ensure that all patients Comprehensive Assessment include an evaluation of the patient's psychosocial needs. The Operations 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. The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to analyze the results and determine a root cause analysis then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.		

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V0511	<p>494.80(a)(8) PA-DIALYSIS ACCESS TYPE & MAINTENANCE The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>(8) Evaluation of dialysis access type and maintenance (for example, arteriovenous fistulas, arteriovenous grafts and peritoneal catheters). Based on clinical record and facility policy review and interview, the facility failed to ensure comprehensive interdisciplinary assessments (CIA) included an evaluation of the access location and/or site in 3 (#s 2, 6, and 7,) of 9 records reviewed creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 2 included a CIA dated 01-30-2012 that identified the primary access was an arteriovenous fistula (AVF) located in the right lower arm. The assessment failed to evidence an assessment of the access site. 2. Clinical record number 6 included a CIA dated 06-25-12 that identified the primary access was an AVF located in the right lower arm. The assessment failed to evidence an assessment of the access site. 	V0511	<p>The Director of Operations met with the facility's Interdisciplinary Team on 11/2/12 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care" FMS-CS-I-110-125A, to ensure that every patient will have a timely, complete and current Comprehensive Assessment and Plan of Care completed and available within their medical record that meets all criteria including assessment/type/location of patient's access.</p> <p>The Operations Manager completed 100% review of all patients' Comprehensive Assessments by 10/15/12 to ensure that all Assessments due are complete and current. Any patient's Assessment that does not include the assessment/type/location of patient's access including patient #2, 6 and 7 will be presented to the IDT for completion by 11/9/12.</p>	11/09/2012	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152571	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 10/11/2012
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	<p>3. Clinical record number 7 included a CIA dated 11-03-11. The assessment failed to identify the type and location of the access and failed to evidence an assessment of the access site.</p> <p>4. The Director of Operations and the Regional Quality Manager were unable to provide any additional documentation and/or information when asked on 10-11-12 at 1:30 PM.</p> <p>5. The facility's 07-04-2012 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The comprehensive interdisciplinary assessment must include the following: . . . Evaluation of dialysis access types and maintenance."</p>		<p>The Clinical Manager will utilize the QAI tool for Assessment and Care-Plan tracking of all patients monthly to ensure that all patients Comprehensive Assessment is completed including the assessment/type/location of patient's access.</p> <p>The Operations 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 then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the Governing Body.</p>		

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V0540	<p>494.90 CFC-PATIENT PLAN OF CARE</p> <p>Based on clinical record and facility policy review and interview, it was determined the facility failed to maintain compliance with this condition by failing to ensure all members of the interdisciplinary team (IDT), including the patient, had participated in the development and implementation of the plan of care in 6 of 9 records reviewed creating the potential to affect all of the facility's 130 current patients (See V 541); by failing to ensure heparin had been administered as ordered to achieve and sustain the prescribed dose of dialysis in 2 of 7 records reviewed of patients that had heparin prescribed as a part of their treatment regimen creating the potential to affect all of the facility's 130 current patients (See V 544); by failing to provide the necessary care and services to maintain the clinically appropriate hemoglobin level in 1 of 9 records reviewed creating the potential for an increased risk of stroke, heart attack, or clotting for all of the facility's 130 current patients (See V 547); by failing to ensure plans of care provided for vascular access monitoring in 8 of 9 records reviewed creating the potential to affect all of the facility's 130 current patients (See V 551); by failing to ensure medical social services was available to provide the</p>	V0540	<p>The Governing Body of this facility acknowledges its responsibility to ensure that all patients' Plans of Care are completed and implemented by all members of the IDT at the required timelines to ensure all patients' current needs are addressed and that all members have participated including the patient. Therefore, as noted in detail above, Governing Body reviewed the SOD and the following action steps were agreed upon and implemented:</p> <p>Effective immediately:</p> <ul style="list-style-type: none"> · The Operations Manager (OM) will analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee for oversight and review. · The Director of Operations will present a report on the Plan of Correction data and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the resolution. · 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 	11/02/2012			

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	<p>necessary monitoring and social work interventions as needed in 9 of 9 records reviewed creating the potential to affect all of the facility's 130 current patients (See V 552); by failing to ensure plans of care provided for transplant referral tracking in 2 of 2 records reviewed of patients eligible for transplant referral creating the potential to affect all of the facility's eligible transplant patients (See V 554); and by failing to ensure plans of care identified reasons for goals not attained and changes to address any identified reasons in 4 of 9 records reviewed creating the potential to affect all of the facility's 130 current patients (See V 559).</p> <p>The cumulative effect of these systemic problems resulted in the facility being found out of compliance with this condition, 42 CFR 494.90 Patient Plan of Care.</p>		<p>review and evaluate the Plan of Correction to ensure it is effective and is providing resolution of the issues</p> <ul style="list-style-type: none"> · The processes as noted in this POC will be reviewed by the Governing Body at each meeting. These meetings will ensure ongoing progress towards resolution of noted deficiencies is being provided. · Minutes of the Governing Body and QAI meetings, as well as monitoring forms, educational documentation will provide evidence of these actions, the Governing Body's direction and monitoring of facility activities. These will be available for review at the facility. <p>The response provided for V 541 describes, in detail, the processes and monitoring steps taken to ensure that all members of the interdisciplinary including the patient, had participated in the development and implementation of the plan of care.</p> <p>The response provided for V 544 describes, in detail, the processes and monitoring steps taken to ensure that all patients are administered heparin as ordered to achieve and sustain the prescribed dose of dialysis.</p> <p>The response provided for V 547 describes, in detail, the processes and monitoring steps taken to ensure that patients are</p>		

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			<p>provided the necessary care and services to maintain the clinically appropriate hemoglobin level.</p> <p>The response provided for V 551 describes, in detail, the processes and monitoring steps taken to ensure that all vascular accesses are monitored including interventions to sustain the access with monthly updates being done on the Plan of Care.</p> <p>The response provided for V 552 describes, in detail, the processes and monitoring steps taken to ensure that a medical social worker was available to provide the necessary monitoring and social work interventions.</p> <p>The response provided for V 554 describes, in detail, the processes and monitoring steps taken to ensure that all patient's plans of care include transplant referral tracking.</p> <p>The response provided for V 559 describes, in detail, the processes and monitoring steps taken to ensure that patient's plan of care identified reasons for goals not attained and changes to address any identified reasons.</p>		

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH	STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804
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V0541	<p>494.90 POC-GOALS=COMMUNITY-BASED STANDARDS</p> <p>The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure all members of the interdisciplinary team (IDT), including the patient, had participated in the development and implementation of the plan of care in 6 (#s 1, 4, 5, 6, 8, and 9) of 9 records reviewed creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 1 included a plan of care (PoC) dated 8-24-12. The PoC failed to evidence any participation by the patient in the development and implementation of the plan. 2. Clinical record number 4 included a 	V0541	<p>On 11/2/12, the Director of Operations met with the members of the IDT to emphasize the requirements as defined within the Conditions of Coverage and Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care" that all patients must have a Plan of Care that is specific to address the patient's needs and is based upon that patient's specific Comprehensive Assessment. The patient's Plan of Care must include specific measurable outcomes and timetables estimated to obtain each patient's outcomes. Also each patient's Plan of Care must be reviewed and signed by the patient within 7 days of the Plan of Care meeting or have documentation as to why it was not signed within the appropriate time-frame. The Operations Manager completed 100% review</p>	11/09/2012

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152571	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 10/11/2012
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH			STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804		
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	<p>PoC dated 12-29-2011. The PoC evidenced the patient had not signed the PoC until 1-5-12, 7 days after the IDT had developed and implemented the plan.</p> <p>3. Clinical record number 5 included a PoC dated 07-27-2012. The PoC evidenced the patient had not signed the PoC until 08-21-2012, 25 days after the IDT had developed and implemented the plan.</p> <p>4. Clinical record number 6 included a PoC dated 06-25-2012. The PoC evidenced the patient had not signed the PoC until 07-01-2012, 6 days after the IDT had developed and implemented the plan.</p> <p>5. Clinical record number 8 included a PoC dated 09-20-2012. The PoC failed to evidence any participation by the patient in the development and implementation of the plan.</p> <p>6. Clinical record number 9 included a partially complete PoC with no date. The PoC failed to evidence any member of the IDT, including the patient, had participated in the development and implementation of the plan.</p> <p>7. The Director of Operations and the Regional Quality Manager were unable to</p>		<p>of all patients' Plans of Care by 10/15/12 to ensure that all Plans of Care have desired outcomes/goals, estimated timetables to achieve those outcomes/goals and that the Plan of Care has been signed within the 7 day timeframe. Any patient's Plan of Care found to be out of compliance including patients # 1, 4, 5, 6, 8 and 9 will be presented to the IDT for completion by 11/9/12. The Operations Manager and/or her designee will review all Plans of Care monthly to ensure that desired outcomes/goals, estimated timetables and signatures have been included. Any POC's found out of compliance will be scheduled for completion within the next 30 days and corrective action will be taken as appropriate. The Operations Manager is responsible to report a summary of findings monthly to the QAI. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee. The Director of Operations is responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body.</p>		

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	<p>provide any additional documentation and/or information when asked on 10-11-12 at 1:30 PM.</p> <p>8. The facility's 07-04-2012 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The Plan of Care must be signed by team members including the patient or patient designee. If the patient is unable 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."</p>			

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V0544	<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. Based on clinical record review and interview, the facility failed to ensure heparin had been administered as ordered to achieve and sustain the prescribed done of dialysis in 2 (#s 1 and 3) of 7 records reviewed of patients that had heparin prescribed as a part of their treatment regimen creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <p>1. Clinical record number 1 included physician orders dated 05-07-2012 and 05-09-2012 that identified the patient was to receive a total of 9000 units of heparin during the treatment.</p> <p>A. A post treatment flow sheet dated 09-27-2012 evidenced only 6000 units of heparin had been administered during the treatment.</p> <p>B. The Operations Manager, employee CC, stated, on 10-09-12 at 4:15 PM, "I don't know why only 6000 [units of heparin] was given on 09-27-2012."</p>	V0544	<p>A mandatory in-service is scheduled for all staff on 11/2/12 with emphasis on ensuring that the patient's heparin is delivered according to the physician's prescription.</p> <p>This will be monitored daily by the Charge Nurse using the Rounding Tool and treatment sheets until the condition is lifted. Frequency of ongoing monitoring will be determined by the QAI Committee upon review of monitoring results and resolution of the issue. Any heparin dosages found out of compliance will be corrected immediately and corrective action will be taken as appropriate.</p> <p>The Operations Manager will monitor the results of the Rounding Tool audits weekly for 4 weeks and ongoing monitoring will be determined by the QAI Committee upon review of monitoring results and resolution of the issue.</p> <p>The Operations Manager is responsible to report a summary of findings monthly in QAI. If resolution is not evident, the QAI</p>	11/02/2012			

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	<p>2. Clinical record number 3 included physician orders dated 09-21-2011 that identified the patient was to receive 5000 units of heparin during the treatment.</p> <p>Post treatment flow sheets, dated 09-13-2012, 09-18-2012, 09-20-2012, 09-22-2012, 09-25-2012, 09-27-2012, 09-29-2012, 10-02-2012, 10-04-2012, and 10-06-2012, failed to evidence any heparin had been administered during the treatment.</p>		<p>Committee will complete a root cause analysis and the Plan of Correction will be revised as necessary.</p> <p>The Director of Operations is responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body</p>		

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V0547	<p>494.90(a)(4) POC-MANAGE ANEMIA/H/H MEASURED Q MO</p> <p>The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level.</p> <p>The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs. Based on clinical record and facility policy review and interview, the facility failed to provide the necessary care and services to maintain the clinically appropriate hemoglobin level in 1 (# 6) of 9 records reviewed creating the potential for an increased risk of stroke, heart attack, or clotting for all of the facility's 130 current patients.</p> <p>The findings include:</p> <p>1. Clinical record number 6 included a physician order dated 08-23-2012 that evidenced the current Epogen (EPO) dose of 6400 units was to be held effective 08-24-2012.</p> <p>A. Post treatment flow sheets, dated 08-24-2012, 08-27-2012, 08-29-12, 08-31-2012, 09-03-2012, 09-07-2012, 09-10-2012, 09-12-2012, 09-14-2012, 09-17-2012, 09-29-2012, 09-21-2012, 09-24-2012, 09-26-2012, and 09-28-2012</p>	V0547	<p>To specifically address inclusion of managing anemia and monitoring hemoglobin/hematocrit monthly as part of the developed patient care plan, the following has occurred:</p> <ul style="list-style-type: none"> · Reeducation of the IDT and attending physicians to facility policy · Review of 100% of the patient records · Scheduled a care plan meeting for 11/9/12 · Implemented a monthly monitoring process <p>The Operations Manager is responsible to report a summary of findings monthly to the QAI. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.</p> <p>The Director of Operations is responsible to ensure the results</p>	11/09/2012			

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	<p>evidenced 6400 units of Epogen had been administered during the treatment.</p> <p>B. According to the Centers for Medicare and Medicaid Services (CMS) Measurement Assessment Tool (MAT), the desired hemoglobin value is 10 to 12 grams per deciliter (g/dL). The record included laboratory results that evidenced the patient's hemoglobin values were above the desired values as follows: On 08-27-2012 the value was 12.2 g/dL, on 09-03-2012 13.0 g/dL, on 09-10-2012 12.8 g/dL, on 09-17-2012 12.9 g/dL, on 09-24-2012 12.6 g/dL, on 10-01-2012 13.5 g/dL, and on 10-08-12 13.2 g/dL.</p> <p>2. The charge nurse, employee A, stated, on 10-11-2012 at 8:50 AM, "I missed writing the EPO orders. [The patient's] hemoglobin got a little high didn't it?"</p> <p>3. The facility's "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Anemia. Provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin level."</p>		<p>of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body.</p> <p>Please refer to V 540</p>				

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V0551	<p>494.90(a)(5) POC-VA MONITOR/PREVENT FAILURE/STENOSIS The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis. Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care provided for vascular access monitoring in 8 (#s 1, 2, 3, 4, 6, 7, 8, and 9) of 9 records reviewed creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 1 included a plan of care (PoC) dated 08-24-2012 that identified the patient's access was an arteriovenous graft (AVG). The plan of care states, "Unable to place AVF [arteriovenous fistula d/t [due to] small veins." The PoC failed to include interventions to monitor and maintain the AVG. 2. Clinical record number 2 included a PoC dated 01-30-2012 that failed to identify the type of access. The plan states, "access fragile." The PoC failed to include interventions to monitor and maintain the patient's "fragile" access. 3. Clinical record number 3 included a 	V0551	<p>On 11/2/12 the Director of Operations met with members of the IDT to emphasize the requirements as defined within the Conditions of Coverage and Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care" that all patients must have a Plan of Care that includes vascular access monitoring. Emphasis was placed upon including interventions to monitor and maintain the patient's access.</p> <p>On 10/15/12 the Operations Manager completed 100% review of all Patient Assessments and Plans of Care to determine if documentation of access type/location was correct, all patient's had specific orders related to the care of their access sites and if their Plans of Care addressed the status of the access through monitoring of the patient's access. Any records found out of compliance, including records # 1, 2, 3, 4, 5, 6, 7, 8, and 9, were reassessed by the members of the IDT with updates to their Plan of Care by 11/9/12. The Operations Manager will ensure ongoing compliance by</p>	11/09/2012	

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	<p>PoC dated 01-30-2012 that identified the patient's access was an AVF. The plan failed to include interventions to monitor and maintain the access.</p> <p>4. Clinical record number 4 included a PoC dated 12-29-2011 that identified the patient's access was a "graft." The PoC states, "Pt [patient] has had failed fistula in past, surgeon deemed graft only option." The plan failed to include interventions to monitor and maintain the access.</p> <p>5. Clinical record number 6 included a PoC dated 06-25-2012 that identified the patient's access was an AVF. The plan failed to include interventions to monitor and maintain the access.</p> <p>6. Clinical record number 7 included a PoC dated 11-03-2011 that identified the patient's access was an AVF. The plan failed to include interventions to monitor and maintain the access.</p> <p>7. Clinical record number 8 included a PoC dated 09-20-2012 that identified the patient's access was an AVF. The plan failed to include interventions to monitor and maintain the access.</p> <p>8. Clinical record number 9 included a PoC with no date that identified the</p>		<p>auditing 25% of all medical records monthly for a period of 3 months focusing on patient's accesses. Any Plan of Care found out of compliance will be addressed immediately and corrective action will occur as appropriate. Frequency of ongoing monitoring will be determined by the QAI Committee based on resolution of the issues.</p> <p>The Operations Manager (OM) 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 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>patient's access was an AVF. The plan failed to include interventions to monitor and maintain the access.</p> <p>9. The Director of Operations and the Regional Quality Manager were unable to provide any additional documentation and/or information when asked on 10-11-12 at 1:30 PM.</p> <p>10. The facility's 07-04-2012 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Vascular Access and PD Catheter Access. Provide vascular access monitoring."</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 and facility policy review and interview, the facility failed to ensure a medical social worker was available to provide the necessary monitoring and social work interventions as needed in 9 (#s 1, 2, 3, 4, 5, ,6 ,7 8, and 9) of 9 records reviewed creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <p>1. Clinical record number 1 included a plan of care (PoC) dated 08-24-2012 that evidenced issues identified in the comprehensive interdisciplinary assessment (CIA) related to "ability to meet activities of daily living [ADL]- (bathing, dressing, eating, shopping, cooking, etc.)."</p> <p>The PoC included the expected outcome "Pt [patient] is adequately</p>	V0552	<p>On 11/2/12, the Director of Operations reviewed the "Comprehensive Interdisciplinary Assessment and Plan of Care" policy with the Social Worker in reference to the requirement to include interventions in each patient's Plan of Care for identified psychosocial needs. The Operations Manager completed 100% chart review of all patients' Plans of Care by 10/15/12, to 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 11/9/12 including patient's # 1, 2, 3, 4, 5, 6, 7, 8 and 9. Patient specific issues as identified will be included in the patient's specific Plan of Care. In addition, a counseling session was held with the social worker to</p>	11/09/2012	

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	<p>meeting needs of ADLs in the home without difficulty." The PoC failed to include interventions to achieve the desired outcome.</p> <p>2. Clinical record number 2 included a PoC dated 01-30-2012 that evidenced issues identified in the CIA related to "relationship /social network problems."</p> <p>A. The PoC included the expected outcome "Pt will pursue involvement in social activities . . . enjoyed prior to starting dialysis." The plan failed to evidence interventions to achieve the desired outcome.</p> <p>B. The PoC included an estimated timetable to achieve the desired outcome "will monitor quarterly and update as indicated." The record failed to evidence any further medical social services had been provided to the patient.</p> <p>3. Clinical record number 3 included a PoC dated 01-30-2012 that evidenced issues identified in the CIA related to "relationship / social network problems."</p> <p>A. The PoC included the expected outcome "Pt will report decrease in family conflict in the home. Pt. will increase involvement in social activities." The plan failed to evidence interventions to</p>		<p>discuss the details of the survey and the findings and to put a schedule in place that ensures all patient shifts have adequate coverage. Monthly monitoring of all Plans of Care completed that month will be done by the Operations 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 until the Condition level status is lifted. Any POCs found out of compliance will be scheduled for completion within the next 30 days and corrective action will be taken as appropriate. Ongoing, the Operations Manager will ensure compliance by auditing 25% of all medical records monthly for a period of 3 months focusing on the patient's psychosocial status and interventions. Frequency of ongoing monitoring will be determined by the QAI Committee based on resolution of the issues. The Operations Manager (OM) is responsible to analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee for oversight and review. The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current,</p>				

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	<p>achieve the desired outcome.</p> <p>B. The PoC included an estimated timetable to achieve the desired outcome "will monitor quarterly and update as indicated."</p> <p>1.) The record included 1 follow-up medical social services note dated 4-16-12 that evidenced the social worker had provided some assistance with financial matters to the patient.</p> <p>2.) The record failed to evidence any medical social services related to the issues identified on the plan of care or any further services after 4-16-12.</p> <p>4. Clinical record number 4 included a PoC dated 12-29-2011 with an expected psychosocial outcome "Pt will maintain current ADL status and psychosocial status."</p> <p>A. The plan failed to evidence any interventions to achieve the desired outcome. The plan included an estimated timetable "will monitor quarterly and update as indicated."</p> <p>B. The record included a medical social services quarterly note dated 04-13-2012 that evidenced the social worker had provided assistance with</p>		<p>analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to analyze the results and determine a root cause analysis then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee</p>				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152571		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 10/11/2012	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH				STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804			
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	<p>financial matters but failed to mention the patient's ADL or psychosocial status.</p> <p>C. The record failed to evidence any further medical social services had been provided after 04-13-2012.</p> <p>D. During an interview with the patient, on 10-09-2012 at 11:50 AM, the patient stated, "The only complaint I have is that I don't get to see the social worker that much. I put it on the survey they sent me. I have some transportation problems. Faith in Action brings me to dialysis."</p> <p>5. Clinical record number 5 included a PoC dated 07-27-2012 that states, "MSW [medical social worker] will monitor pt status and provide support as needed." The plan included an estimated outcome "Pt will maintain current psychosocial status and meet dialysis needs."</p> <p>The plan failed to include any interventions to monitor the patient's psychosocial status and achieve the desired outcome.</p> <p>6. Clinical record number 6 included a plan of care dated 06-25-2012 that evidenced issues identified in the CIA related to "ability to follow treatment prescription . . . insurance or financial resources."</p>						

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH	STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804
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	<p>A. The plan states, "MSW will educate pt on Hemodialysis. MSW will assist with I.W./HIPP [financial assistance resources]" and included the expected outcome "Pt will verbalize understanding of hemodialysis and will receive I.W." The plan identified an estimated timetable of 3 months.</p> <p>B. The record included a medical social services note dated 8-7-12 that states, "MSW left voice message for pt as pt has been trying to reach for the past few treatment. MSW left phone number and requested pt return call to discuss needs/concerns as social worker is out of the office on Wednesday's [sic]. MSW will continue to assist pt as needed."</p> <p>C. The record failed to evidence any further contact with the patient until 09-23-2012. A medical social services note dated 09-23-2012 that identified the pt "is fulling [sic] ADL's [sic] without difficulty, driving self to treatment . . . Pt enjoying 2nd shift and talks with other pt's [sic]. Pt reported receiving notice for 0 balance. IW met. Will continue to support as needed."</p> <p>D. During an interview with the patient, on 10-10-2012 at 8:30 AM, the patient stated, "I don't see her [the</p>			

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH				STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804			
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	<p>medical social worker] often enough. I kept getting bills and she told me not to worry about it. Then I got a statement that it was paid. She never did get back with me. I've always paid my bills and it bothered me."</p> <p>7. Clinical record number 7 included a PoC dated 11-03-2011 that evidenced issues as identified on the CIA related to "Mental health concerns (depression, anxiety, panic, substance abuse, etc.) Coping and adjustment to dialysis."</p> <p>A. The plan included the expected outcome "Patient demonstrates decreased symptoms of depression. Patient will resume activities enjoyed prior to onset of renal disease." The plan failed to evidence any interventions to achieve the desired outcome. The plan included an estimated timetable of 30 days.</p> <p>B. An update to the plan of care signed by the medical social worker, employee V, on 11-30-2011 states, "Pt verbalizes a hard time adjusting to dialysis. Hates every bit of it. Pt. negative thought process prohibits [the patient] from positive coping capabilities." The plan included the expected outcome "Patient will verbalize decreased symptoms of depression related to ESRD. Pt will verbalize positive</p>						

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH	STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804
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	<p>thoughts . . . Estimated timetable: Will monitor quarterly."</p> <p>1.) The update failed to include interventions to achieve the expected outcome.</p> <p>2.) The record failed to evidence any progress notes to indicate the medical social worker had provided any services to the patient as of 11-30-2011.</p> <p>C. An update to the plan of care signed by the medical social worker on 02-13-2012 states, "Patient continues to express negative thoughts related to dialysis and treatment regimen. Pt considering other options (PD). Pt has limited family support with increased isolation creating negative thought processing. Expected outcome: Pt will verbalize decreased symptoms of depression increase in positive coping skills. Estimated timetable: will monitor quarterly."</p> <p>1.) The update failed to include interventions to achieve the expected outcome.</p> <p>2.) The record failed to evidence any progress notes to indicate the medical social worker had provided any services to the patient as of 02-13-2012.</p>			

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH				STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804			
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	<p>D. The record failed to include any further updates to the plan of care by the medical social worker regarding the patient's mental status.</p> <p>E. The record included a medical social services progress note dated 08-10-2012 that evidenced the medical social worker, employee V, had contacted the patient as a result of receiving a telephone call from the patient. The patient had requested a change in the seating arrangement for the treatment.</p> <p>F. The facility's "Patient Complaint / Grievance Log" included an entry dated 10-03-2012 that identified the patient was "upset that the MSW had not talked to [the patient] about hospice. [The patient] had talked to the DO [director of operations] about hospice and [the patient] knew she had talked with the MSW and was upset that she had not talked with him."</p> <p>1.) The record included a medical social services progress note dated 10-05-2012 that identified the medical social worker had spoken with the patient regarding hospice care and services.</p> <p>2.) The record included a progress note dated 10-08-2012 that identified the</p>						

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH			STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804		
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	<p>social worker, employee V, had met with the patient and the patient had requested information about "end of life and stopping dialysis." The note states, "Pt was holding sticks and stated that [the patient] would just meet with me in office post tx [after treatment]. When pt came off tx MSW had another pt in office for a few minutes. Pt got irritated and told secretary that [the patient] was only waiting for 4 minutes. Pt got up and left. MSW will follow-up with pt at next treatment."</p> <p>The record failed to evidence any follow-up with the patient by the medical social worker.</p> <p>8. Clinical record number 8 included a CIA signed by the medical social worker, employee V, on 09-20-2012, that states, "Pt feels is doing well . . . reports increase in treatment adherence but still has some difficulty."</p> <p>The plan of care dated 09-20-2012 failed to evidence any interventions to address the adherence difficulty identified in the CIA.</p> <p>9. Clinical record number 9 included a CIA completed by the RN, employee A, on 08-07-2012, and the registered dietician, employee W, on 08-23-2012.</p>				

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH	STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804
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	<p>The CIA failed to evidence any participation by the medical social worker.</p> <p>A. The record included an undated PoC. The PoC failed to evidence any participation by the medical social worker.</p> <p>B. During an interview with the patient on 10-11-2012 at 8:45 AM, the patient stated, "I don't see [the medical social worker, employee V] very often. There was a time I needed to talk to her about transplant, but she was not available. I finally got a paper last week."</p> <p>10. Patient number 11 stated, on 10-09-2012 at 3:15 PM, "I don't know if I've seen the medical social worker lately."</p> <p>11. Patient number 12 stated, on 10-09-2012 at 3:20 PM, "I don't know how often I see the medical social worker."</p> <p>12. Patient number 13 stated, on 10-09-2012 at 3:25 PM, "It has been a long time since I've seen [employee V, the medical social worker]. My [spouse] wants me to get a kidney transplant and I don't want to. [Spouse] has been talking to her about it."</p>			

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH				STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804			
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	<p>13. Patient number 23 stated, on 10-11-2012 at 8:00 AM, "I have had to wait to see social worker cause she covers that other unit."</p> <p>14. Employee G, a licensed practical nurse, stated, on 10-09-2012 at 3:30 PM, "Patients complain if they are here early morning because the social worker does not get here until 9 AM. She has the Greencastle unit and also goes to class one day a week."</p> <p>15. On 10-11-2012 at 7:50 AM, employee J, a patient care technician, stated, "I don't see [the medical social worker] a lot. I have heard from patients they do not see the MSW enough."</p> <p>16. The medical social worker was interviewed, on 10-9-2012 at 3:45 PM, per telephone. The social worker stated, "I was seeing approximately 30 patients in Greencastle. I work 10 hours per day Monday, Wednesday, Thursday, and Friday. I come in for a couple of hours on Saturday sometimes. I am totally overwhelmed. I find we have 25 to 35 care plans a month. We meet at least once a month. I have people come to my office. All of my notes are in Proton. We have had some filing issues. Things get lost if they are put in filing. We have</p>						

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH			STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804		
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	<p>been fighting this. I've tried to get on some kind of schedule. I started a 'rounding report' last month. I do not document every encounter with a patient. I don't have time."</p> <p>17. The Director of Operations, employee AA, stated, on 10-11-2012 at 9:55 AM, "The medical social worker does not cover the Greencastle unit. She hasn't for 2 or 3 months now."</p> <p>18. Employee DD, a physician covering for the medical director during the survey, stated, on 10-11-2012, "We are aware medical social services is lacking in this facility."</p> <p>19. The facility's 07-04-2012 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Psychosocial Status. Provide necessary monitoring and social work interventions, including counseling services and appropriate referrals."</p> <p>20. The facility's 04-04-2012 "Social Work Services" policy states, "The services of a qualified social worker shall be made available to all patients of each</p>				

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH			STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804		
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	FMS dialysis facility, including in-center and home patients (as applicable), upon admission and on an ongoing basis."				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152571		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 10/11/2012	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH				STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804			
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V0554	<p>494.90(a)(7)(ii) POC-TRANSPLANT STATUS PLAN OR WHY NOT</p> <p>When the patient is a transplant referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the-</p> <p>(A) Plan for transplantation, if the patient accepts the transplantation referral; (B) Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or (C) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with §494.80(a) (10).</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care provided for transplant referral tracking in 2 (#s 3 and 4) of 2 records reviewed of patients eligible for transplant referral creating the potential to affect all of the facility's eligible transplant patients.</p> <p>The findings include:</p> <p>1. Clinical record number 3 included a plan of care (PoC) dated 01-30-2012. The PoC states, "Discussed treatment option. Pt [patient] may consider meeting with treatment team. Expected outcome: Pt will request referral for transplant eval [evaluation]. Estimated timetable: Will monitor quarterly and update as indicated."</p>	V0554	<p>On 11/2/12, the Director of Operations reviewed the "Comprehensive Interdisciplinary Assessment and Plan of Care" policy with the Physician, Dietitian, Social Worker and Nursing Staff in reference to patient's modality selections and the requirement that every patient must be given the option for transplantation and evaluated if requested.</p> <p>To ensure inclusion of the patient transplant status in the developed patient care plan, the following has occurred:</p> <ul style="list-style-type: none"> · Reeducation of the IDT and attending physicians to facility policy · Review of 100% of the patient records · Scheduled a care plan meeting for 11/9/12 · Implemented a monthly 	11/09/2012			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152571		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 10/11/2012	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH				STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804			
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	<p>The record failed to evidence any further update to the plan of care regarding transplant.</p> <p>2. Clinical record number 4 included a PoC dated 12-29-2011. The PoC identifies the patient as a referral candidate and that the patient was "currently undergoing evaluation." The PoC states, "Expected outcome: Pt will meet with transplant team for eligibility. Estimated timetable: Quarterly monitoring with update as indicated."</p> <p>The record failed to evidence any further update to the plan of care regarding transplant.</p> <p>3. The Director of Operations and the Regional Quality Manager were unable to provide any additional documentation and/or information when asked on 10-11-12 at 1:30 PM.</p> <p>4. The facility's 07-04-2012 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Transplantation Status . . . If patient could be a transplant candidate, the</p>		<p>monitoring process</p> <p>The Operations Manager is responsible to report a summary of findings monthly to the QAI. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.</p> <p>The Director of Operations is responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body.</p> <p>Please refer to V 540</p>				

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH			STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804		
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	interdisciplinary team must develop plans and provide referrals for pursuing transplantation. Document in the patient's Plan of Care the plan for transplantation referral, patient's decision to decline transplant referral; and/or the reason for patient non-referral for transplant."				

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH				STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804			
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V0559	<p>494.90(b)(3) POC-OUTCOME NOT ACHIEVED-ADJUST POC</p> <p>If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must-</p> <p>(i) Adjust the plan of care to reflect the patient's current condition; (ii) Document in the record the reasons why the patient was unable to achieve the goals; and (iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care identified reasons for goals not attained and changes to address any identified reasons in 4 (#s 3, 4, 5, and 7) of 9 records reviewed creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <p>1. Clinical record number 3 included laboratory results that evidenced the patient's albumin level was 3.7 on 06-29-2012 and remained at 3.6 on 07-17-2012, 08-16-2012, and 09-13-2012.</p> <p>The record failed to evidence the interdisciplinary team (IDT) had identified reasons for the patient's lower</p>	V0559	<p>The Director of Operations met with the facility's Interdisciplinary Team on 11/2/12 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care" FMS-CS-I-110-125A, to ensure that every patient will have a timely, complete and current Comprehensive Assessment and Plan of Care available emphasizing that each Plan of Care will be updated with reasons why an expected outcomes is not achieved.</p> <p>The Operations Manager completed a 100% chart review of all patients Plans of Care by 10/15/12 focusing on the patient's albumin, phosphorus and pth levels. Any patient found with albumin, phosphorus or pth levels</p>	11/09/2012			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152571		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 10/11/2012	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH				STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804			
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	<p>than desired albumin level (equal to or greater than 4.0 grams per deciliter (g/dL) according to the Centers for Medicare and Medicaid Services (CMS) Measurement Assessment Tool (MAT)) and had adjusted the plan of care to address any identified reasons.</p> <p>2. Clinical record number 4 included laboratory results that evidenced the patient's phosphorous levels were 6.2 on 08-28-2012 and 09-11-2012. (Desired level is 3.5 to 5.5 milligrams per deciliter (mg/dL) according to the CMS MAT).</p> <p>The record failed to evidence the IDT had identified the reasons for the higher than desired phosphorous levels and had adjusted the plan of care to address any identified reasons.</p> <p>3. Clinical record number 5 included laboratory results that evidenced the patient's intact parathyroid hormone (iPTH) level was greater than the desired level of 150-300 pg/ml. The results evidenced the iPTH was 928.1 on 05-15-2012 and 504.6 on 08-14-12.</p> <p>The record failed to evidence the IDT had identified the reasons for the higher than desired iPTH levels and had adjusted the plan of care to address any identified</p>		<p>that do not meet their patient specific goals will be presented at the Interdisciplinary Team meeting by 11/9/12 including patient's #3, 4, 5 and 9. Patient specific issues as identified will be included in the patient's specific Plan of Care.</p> <p>All members of the IDT, including the Dietitian and Social Worker, will review specific patient issues on a monthly basis. Any patients not meeting any of their specific goals, including albumin, phosphorus and pth will be included on a monthly list of patients. The Operations Manager will include patients on the list on the agenda for review by the Interdisciplinary team at the monthly care plan meeting for the purpose of making an adjustment to the Plan of Care. Recommendations of the IDT and actions taken monthly will be documented in each patient's specific Plan of Care update/progress note section.</p> <p>Monthly monitoring of all Plans of Care completed that month will be done by the Operations Manager, to ensure that patients not meeting a goal have been identified, are addressed and Plans of Care are being updated timely and appropriately. Any Plan of Care found out of compliance will be scheduled for completion within the next 30 days and corrective action will be</p>				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152571	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 10/11/2012
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	<p>reasons.</p> <p>4. Clinical record number 7 included laboratory results that evidenced the patient's albumin levels were below the desired level and the phosphorous levels were higher than the desired levels. The results evidenced the patient's albumin was 3.1 on and the phosphorous was 6.0 on 05-14-2012, the albumin was 3.0 and the phosphorous was 6.5 on 06-11-2012, the albumin was 2.9 and the phosphorous was 7.9 on 07-30-2012, the albumin was 3.0 and the phosphorous was 7.9 on 08-13-2012, and the albumin was 3.0 and the phosphorous 6.8 on 09-10-2012.</p> <p>The record failed to evidence the IDT had identified the reasons for the lower than desired albumin levels and the higher than desired phosphorous levels and had adjusted the plan of care to address any identified reasons.</p> <p>5. The Director of Operations and the Regional Quality Manager were unable to provide any additional documentation and/or information when asked on 10-11-12 at 1:30 PM.</p> <p>6. The facility's 07-04-2012 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states,</p>		<p>taken as appropriate.</p> <p>Ongoing, the Operations Manager and will ensure compliance by auditing 25% of all medical records monthly for a period of 3 months focusing on all patients meeting goals and interventions when that does not occur.. Frequency of ongoing monitoring will be determined by the QAI Committee based on resolution of the issues.</p> <p>The Operations Manager (OM) 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 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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	"If the patient is unable to achieve the desired outcomes, the team must adjust the Plan of Care to reflect the patient's current condition and Document in the medical record the reason(s) why the patient is unable to achieve the goal. Implement Plan of Care changes to address the identified issues."			

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V0625	<p>494.110 CFC-QAPI</p> <p>Based on administrative record and facility policy review and interview, it was determined the facility failed to maintain compliance with this condition by failing to ensure a quality assessment and performance improvement (QAPI) program had been implemented to address adverse events, missed treatment, and assessment and care plan problems in 8 of 8 months reviewed creating the potential to affect all of the facility's 130 current patients (See V 626), by failing to ensure ensure a quality assessment and performance improvement (QAPI) program had been implemented to address medical errors in 8 of 8 months reviewed creating the potential to affect all of the facility's 130 current patients (See V 634), and by failing to ensure performance improvement had been monitored for adverse events, missed treatments, and assessment and care plan problems in 8 of 8 months reviewed creating the potential to affect all of the facility's 130 current patients (See V 638).</p> <p>The cumulative effect of these systemic problems resulted in the facility being found out of compliance with this condition, 42 CFR 494.110 Quality Assessment and Performance Improvement.</p>	V0625	<p>The Governing Body acknowledges its responsibility to ensure that Fresenius Medical Care Terre Haute North has an effective, data driven Comprehensive Quality Assessment and Performance Improvement program that addresses adverse events, missed treatments and assessments and plans of care problems. The Governing Body, on 11/2/12 reviewed the SOD and developed the following Plan of Correction ensuring that the deficiencies are addressed, both immediately and with long term resolution. The following action steps were implemented</p> <p>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.</p> <p>Effective immediately: · The Operations Manager (OM) will analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee.</p>	11/02/2012			

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			<ul style="list-style-type: none"> · A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda. · The QAI Committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution. · The Director of Operations (DO) will present a report on the Plan of Correction data and all actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. · The Governing Body, at its meeting of 11/2/12, designated the Regional Quality Manager to serve as Plan of Correction Monitor and provide additional oversight. She will actively participate in each QAI and Governing Body meeting - either personally or via conference call - and submit a status report at each of the referenced Governing Body meetings with a copy to the RVP. This additional oversight is to ensure the ongoing correction of deficiencies - as cited in the Statement of Deficiency - through to resolution as well as ensure the Governance of the facility is presented current and complete data to enhance their governance oversight role · Minutes of the Governing 		

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			<p>Body and QAI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's direction and oversight and the QAI Committee's ongoing monitoring of facility activities. These are available for review at the facility.</p> <p>The responses provided for V 626, V 634, and V 638 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</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 administrative record and facility policy review and interview the facility failed to ensure a quality assessment and performance improvement (QAPI) program had been implemented to address adverse events, missed treatment, and assessment and care plan problems in 8 (January, February, March, April, May, July, August, and September 2012) of 8 months reviewed creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <p>1. The facility's "QAI Adverse Event Report Log/Plan" evidenced 14 medication errors had been reported</p>	V0626	<p>On November 9 th , 2012 the Regional Quality Manager scheduled a meeting with all participants of the QAI committee for the purpose of reeducation on the QAI process. This education included but was not limited to the following:</p> <ul style="list-style-type: none"> ·QAI Processes ·Adverse event reporting ·Missed treatments ·Assessments and Plan of Care problems <p>The Operations Manager will review all adverse events, missed treatments report and CIA/POC tracking tools. Reports will be analyzed and any identified as not meeting an outcome will have an action plan developed and followed monthly.</p>	11/09/2012			

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	<p>between 01-10-2012 and 06-25-12. The facility's monthly QAPI committee meetings, dated 01-25-12, 02-22-2012, 03-29-2012, 04-25-12, 05-25-2012, and 07-27-2012, acknowledged the medication errors had occurred but failed to evidence a plan had been implemented to address and track the identified medication error problem.</p> <p>2. The "QAI Adverse Event Report Log/Plan" evidenced 20 instances of clotted dialyzers, blood lines, and/or access sites had been reported between 02-29-2012 and 08-03-2012. The facility's monthly QAPI committee meetings, dated 01-25-12, 02-22-2012, 03-29-2012, 04-25-12, 05-25-2012, 08-30-2012, and 09-20-2012 failed to evidence the clotting issues had occurred and failed to evidence a plan to address the clotting issue had been implemented.</p> <p>3. The facility's QAPI meeting minutes evidenced the medical social worker (MSW) had reported patients had missed multiple treatments between 01-25-2012 and 09-20-2012.</p> <p>A. Meeting minutes dated 01-25-2012 evidenced the MSW had reported "the unit had 42 missed treatments for the month."</p>		The Operations Manager is responsible to report a summary of findings monthly. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.				

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	<p>B. Meeting minutes dated 02-22-2012 evidenced the MSW had reported 37 missed treatments for January 2012.</p> <p>C. Meeting minutes dated 03-29-2012 included the same information as the 02-22-2012 meeting minutes, 37 missed treatments for January 2012.</p> <p>D. Meeting minutes dated 04-25-2012 stated, "39 missed treatments for this month."</p> <p>E. Meeting minutes dated 05-25-2012 and 07-27-2012 failed to evidence a MSW report.</p> <p>F. Meeting minutes dated 08-30-2012 stated, "45 unexcused treatments for this month."</p> <p>G. Meeting minutes dated 09-20-2012 stated, "23 unexcused treatments for this month."</p> <p>H. The meeting minutes failed to evidence a plan had been implemented to address the identified problem concerning continued, multiple missed treatments.</p> <p>4. The facility's QAPI meeting minutes identified comprehensive interdisciplinary assessments (CIA) and plans of care (PoC) as areas for improvement.</p>						

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH	STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804
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	<p>A. The QAPI meeting minutes dated 02-22-12 states, "Comprehensive Assessment and Plan of Care Review . . . trend analysis . . . no change . . . Improvement Area: Yes." The meeting minutes failed to evidence a plan to address the identified area for improvement.</p> <p>B. The 03-29-2012 meeting minutes identified there had been "no change" in the trend analysis for the CIAs and PoCs. The minutes failed to indicate whether this was still an improvement area. The "yes" or "no" boxes were blank. The meeting minutes failed to evidence a plan to address the assessments and care plans had been implemented.</p> <p>C. The 04-25-2012 and 05-25-2012 meeting minutes identified "no change" in the trend analysis and the "no" box was checked to indicate this was not an improvement area.</p> <p>D. The 07-27-2012 meeting minutes identified the trend analysis as "declining" and that the area now needed improvement. The meeting minutes stated, "5 late last month. Nursing was not present at Junes meeting (27), so CP [care plans] need to be reviewed for June in July."</p>			

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	<p>The meeting minutes failed to evidence a plan had been developed and implemented to address the identified care plan problem.</p> <p>E. The 08-30-2012 meeting minutes identified the trend analysis as "declining" and that this was an area for improvement. The minutes stated, "Late with 3 care plans due to late admissions. All updates on TTS [Tuesday, Thursday, Saturday] schedule are behind in Nursing. RD updates are also behind. New action plan developed and implemented."</p> <p>F. The 09-20-2012 meeting minutes the assessment and care plan trend analysis is "declining." The minutes state, "14 POCs were late. Trying to catch up. Moving CP meeting up by 1 week in the month to avoid any further late POCs."</p> <p>5. The QAPI findings were reviewed with the Director of Operations, employee AA, on 10-11-2012 at 12:15 PM. The director was unable to provide any additional documentation and/or information related to the findings.</p> <p>6. The facility's 04-04-2012 "Quality Assessment and Performance Improvement Program (QAPI)" policy number FMS-CS-IC-I-101-001A states,</p>			

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH	STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804
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	"The Medical Director, Director of Operations, Area Manager, and Clinical Manager are responsible for monitoring and evaluating the effectiveness of the QAI Programs . . . The facility QAI Committee established priorities, develops and implements improvement projects based on established priorities and monitors these projects for effectiveness . . . An improvement plan (or action plan) will be developed as needed for QAI projects implemented by the QAI Committee to facilitate tracking of action items, monitoring, and follow-up . . . All Adverse Events will be reviewed by the QAI committee to ensure appropriate interventions."			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152571		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 10/11/2012	
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V0634	<p>494.110(a)(2)(vi) QAPI-INDICATOR-MEDICAL INJURIES/ERRORS</p> <p>The program must include, but not be limited to, the following: (vi) Medical injuries and medical errors identification.</p> <p>Based on administrative record and facility policy review and interview the facility failed to ensure a quality assessment and performance improvement (QAPI) program had been implemented to address medical errors in 8 (January, February, March, April, May, July, August, and September 2012) of 8 months reviewed creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <p>1. The facility's "QAI Adverse Event Report Log/Plan" evidenced 14 medication errors had been reported between 01-10-2012 and 06-25-12. The facility's monthly QAPI committee meetings, dated 01-25-12, 02-22-2012, 03-29-2012, 04-25-12, 05-25-2012, and 07-27-2012, acknowledged the medication errors had occurred but failed to evidence a plan had been implemented to address and track the identified medication error problem.</p> <p>2. The QAPI findings were reviewed</p>	V0634	<p>On November 9 th , 2012, the Regional Quality Manager scheduled a meeting with all participants of the QAI committee for the purpose of reeducation on the QAI process. This education included but was not limited to the following:</p> <ul style="list-style-type: none"> ·QAI processes including monthly analysis and trending of adverse events ·Adverse Event reporting as defined with the AE policy, analysis and trending ·Reviewing requirements within the QAI Meeting Minute Template <p>On November 9 th , 2012 the Director of Operations met with the Operations Manager to review and reinforce the Operations Manager's responsibility to utilize the QAI Minute Template to report, analyze, trend and develop action plans as necessary for all indicators defined within QAI. Additionally to utilize the Minutes to document all QAI Committee activities with emphasis placed on hospitalizations, mortality incidents and adverse events as defined within the Adverse Event policy.</p>	11/09/2012			

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	<p>with the Director of Operations, employee AA, on 10-11-2012 at 12:15 PM. The director was unable to provide any additional documentation and/or information related to the findings.</p> <p>3. The facility's 04-04-2012 "Quality Assessment and Performance Improvement Program (QAPI)" policy number FMS-CS-IC-I-101-001A states, "The Medical Director, Director of Operations, Area Manager, and Clinical Manager are responsible for monitoring and evaluating the effectiveness of the QAI Programs . . . The facility QAI Committee established priorities, develops and implements improvement projects based on established priorities and monitors these projects for effectiveness . . . An improvement plan (or action plan) will be developed as needed for QAI projects implemented by the QAI Committee to facilitate tracking of action items, monitoring, and follow-up . . . All Adverse Events will be reviewed by the QAI committee to ensure appropriate interventions."</p>		<p>The Operations Manager or designee will review treatment sheets daily for 2 weeks, weekly until the Condition is lifted, monthly times 2, then quarterly to ensure that all details of an adverse event or other incident as required with the QAI Meeting Template are reported and documented. Any areas of non-compliance will be addressed immediately including corrective action as appropriate and added to the QAI documentation for that date.</p> <p>The Governing Body, through its ongoing monitoring of the QAI committee, will ensure the immediate and on going identification of potential and actual problems to patient care and take appropriate steps to identify the root causes of problems and to develop, implement and track corrective actions through to resolution of those problems. Any issues/problems will be addressed via the above-specified process, documented in the QAI Minutes, and formally reported to the Governing Body by the Minutes. Minutes of both QAI Committee and Governing Body meetings will be available for review at the facility.</p>		

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
V0638	<p>494.110(b) QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE</p> <p>The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time. Based on administrative record and facility policy review and interview, the facility failed to ensure performance improvement had been monitored for adverse events, missed treatments, and assessment and care plan problems in 8 (January, February, March, April, May, July, August, and September 2012) of 8 months reviewed creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <p>1. The facility's "QAI Adverse Event Report Log/Plan" evidenced 14 medication errors had been reported between 01-10-2012 and 06-25-12. The facility's monthly QAPI committee meetings, dated 01-25-12, 02-22-2012, 03-29-2012, 04-25-12, 05-25-2012, and 07-27-2012, acknowledged the medication errors had occurred but failed to evidence a plan had been implemented to address and track the identified medication error problem.</p>	V0638	<p>On November 9, 2012, the Regional Quality Manager scheduled a meeting with all participants of the QAI committee for the purpose of education on the QAI process. This education included but was not limited to the following:</p> <ul style="list-style-type: none"> ·QAI Processes ·Adverse events, missed treatments and assessment and care plan analysis and the identification of trends ·Instituting timely action plans with monthly follow up of action plans and interceding if data does not show resolution <p>The Operations Manager is responsible to review all adverse event logs, missed treatment reports and assessment and plan of care tracking tools monthly. Reports will be analyzed and any identified as not meeting an outcome will have an action plan developed and followed monthly.</p> <p>The Operations Manager is responsible to report a summary of findings monthly. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new</p>	11/09/2012	

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	<p>2. The "QAI Adverse Event Report Log/Plan" evidenced 20 instances of clotted dialyzers, blood lines, and/or access sites had been reported between 02-29-2012 and 08-03-2012. The facility's monthly QAPI committee meetings, dated 01-25-12, 02-22-2012, 03-29-2012, 04-25-12, 05-25-2012, 08-30-2012, and 09-20-2012, failed to evidence the clotting issues had occurred and failed to evidence a plan to address the clotting issue had been implemented.</p> <p>3. The facility's QAPI meeting minutes evidenced the medical social worker (MSW) had reported patients had missed multiple treatments between 01-25-2012 and 09-20-2012.</p> <p>A. Meeting minutes dated 01-25-2012 evidenced the MSW had reported "the unit had 42 missed treatments for the month."</p> <p>B. Meeting minutes dated 02-22-2012 evidenced the MSW had reported 37 missed treatments for January 2012.</p> <p>C. Meeting minutes dated 03-29-2012 included the same information as the 02-22-2012 meeting minutes, 37 missed treatments for January 2012.</p> <p>D. Meeting minutes dated 04-25-2012</p>		Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.		

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	<p>stated, "39 missed treatments for this month."</p> <p>E. Meeting minutes dated 05-25-2012 and 07-27-2012 failed to evidence a MSW report.</p> <p>F. Meeting minutes dated 08-30-2012 stated, "45 unexcused treatments for this month."</p> <p>G. Meeting minutes dated 09-20-2012 stated, "23 unexcused treatments for this month."</p> <p>H. The meeting minutes failed to evidence a plan had been implemented to address the identified problem concerning continued, multiple missed treatments.</p> <p>4. The facility's QAPI meeting minutes identified comprehensive interdisciplinary assessments (CIA) and plans of care (PoC) as areas for improvement.</p> <p>A. The QAPI meeting minutes dated 02-22-12 states, "Comprehensive Assessment and Plan of Care Review . . . trend analysis . . . no change . . . Improvement Area: Yes." The meeting minutes failed to evidence a plan to address the identified area for improvement.</p>						

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	<p>B. The 03-29-2012 meeting minutes identified there had been "no change" in the trend analysis for the CIAs and PoCs. The minutes failed to indicate whether this was still an improvement area. The "yes" or "no" boxes were blank. The meeting minutes failed to evidence a plan to address the assessments and care plans had been implemented.</p> <p>C. The 04-25-2012 and 05-25-2012 meeting minutes identified "no change" in the trend analysis and the "no" box was checked to indicate this was not an improvement area.</p> <p>D. The 07-27-2012 meeting minutes identified the trend analysis as "declining" and that the area now needed improvement. The meeting minutes stated, "5 late last month. Nursing was not present at Junes meeting (27), so CP [care plans] need to be reviewed for June in July."</p> <p>The meeting minutes failed to evidence a plan had been developed and implemented to address the identified care plan problem.</p> <p>E. The 08-30-2012 meeting minutes identified the trend analysis as "declining" and that this was an area for improvement. The minutes stated, "Late</p>				

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	<p>with 3 care plans due to late admissions. All updates on TTS [Tuesday, Thursday, Saturday] schedule are behind in Nursing. RD [registered dietician] updates are also behind. New action plan developed and implemented."</p> <p>F. The 09-20-2012 meeting minutes the assessment and care plan trend analysis is "declining." The minutes state, "14 POCs were late. Trying to catch up. Moving CP meeting up by 1 week in the month to avoid any further late POCs."</p> <p>5. The QAPI findings were reviewed with the Director of Operations, employee AA, on 10-11-2012 at 12:15 PM. The director was unable to provide any additional documentation and/or information related to the findings.</p> <p>6. The facility's 04-04-2012 "Quality Assessment and Performance Improvement Program (QAPI)" policy number FMS-CS-IC-I-101-001A states, "The Medical Director, Director of Operations, Area Manager, and Clinical Manager are responsible for monitoring and evaluating the effectiveness of the QAI Programs . . . The facility QAI Committee established priorities, develops and implements improvement projects based on established priorities and monitors these projects for</p>						

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	effectiveness . . . An improvement plan (or action plan) will be developed as needed for QAI projects implemented by the QAI Committee to facilitate tracking of action items, monitoring, and follow-up . . . All Adverse Events will be reviewed by the QAI committee to ensure appropriate interventions."			

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V0710	<p>Based on administrative record and facility policy review and interview, it was determined the facility had not maintained compliance with condition by failing to ensure the medical director had ensure a quality assessment performance improvement program (QAPI) that addressed adverse events and medical errors, missed treatments, and assessment and care plan problems was in place in 8 of 8 months reviewed creating the potential to affect all of the facility's 130 current patients. (See V 712).</p> <p>The cumulative effect of this systemic problem resulted in the facility being found out of compliance with this condition, 42 CFR 494.150 Responsibilities of the Medical Director.</p>	V0710	<p>The Medical Director understands and acknowledges his role and responsibilities to ensure the delivery of quality patient care and clinical outcomes as required by the Conditions for Coverage through assuring all staff and attending physicians adhere to all patient care policies</p> <p>Therefore, the Medical Director, as a member of the Governing Body met on November 2, 2012, after receipt of the Statement of Deficiencies, to review the Statement and make certain that all identified deficiencies were being addressed, both immediately and with long term resolution. The following action steps were agreed upon and implemented.</p> <p>The Medical Director, as a member of the Governing Body, will meet weekly to monitor the progress of this Plan of Correction as related to the Statement of Deficiencies, until the Condition level deficiencies are lifted, then monthly for an additional three months to make certain that all corrections are being maintained, and then return to quarterly or as needed basis.</p> <p>Effective immediately ·The DO will present a report to the Medical Director on the audit/monitoring results and all</p>	11/02/2012	

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			<p>other actions taken toward the resolution of the Plan of Correction for this SOD at each Governing Body meeting through to the resolution of all identified conditions/deficiencies .</p> <ul style="list-style-type: none"> ·The Operations Manager will present monthly reports on these results to the Medical Director as a member of the QAI committee for review and oversight. ·The processes as noted in this POC will be reviewed weekly by the Medical Director as a member of Governing Body and monthly, as a member of QAI with all parties involved in the POC. These meetings will ensure ongoing progress towards resolution of noted deficiencies and that the facility is delivering safe, quality health care services on a daily basis and that Patient Assessments and Plans of Care, as required, are being provided. ·Minutes of the Governing Body and QAI meetings, as well as monitoring forms, In-service sign-in sheets will document these actions and the Governing Body's direction and monitoring of facility activities. These will be available for review at the facility. <p>The response provided for V 712 describes, in detail, the processes, audits and monitoring steps taken to ensure that QAI members follow all policies related to the QAI program.</p>		

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V0712	<p>494.150(a) MD RESP-QAPI PROGRAM Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program.</p> <p>Based on administrative record and facility policy review and interview, the medical director failed to ensure a quality assessment performance improvement program (QAPI) that addressed adverse events and medical errors, missed treatments, and assessment and care plan problems was in place in 8 of 8 months reviewed creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <p>1. The facility's "QAI Adverse Event Report Log/Plan" evidenced 14 medication errors had been reported between 01-10-2012 and 06-25-12. The facility's monthly QAPI committee meetings, dated 01-25-12, 02-22-2012, 03-29-2012, 04-25-12, 05-25-2012, and 07-27-2012, acknowledged the medication errors had occurred but failed to evidence a plan had been implemented to address and track the identified medication error problem.</p> <p>2. The "QAI Adverse Event Report Log/Plan" evidenced 20 instances of clotted dialyzers, blood lines, and/or</p>	V0712	<p>The Medical Director met with the members of the Governing Body on 11/9/12 to review his requirements as defined with the Conditions for Coverage and the new Medical Staff Bylaws. He approved the final Plan of Correction to ensure that all citations and responses as cited in relation to QAI, that the QAI Committee provides adequate and thorough monitoring techniques to ensure compliance and that corrective actions have been instituted that ensure resolution of the issues.</p> <p>The Medical Director is responsible to review the monitoring data provided as related to the Plan of Correction to ensure that the activities and weekly reports are documenting resolution of the deficiencies as defined throughout the Plan of Correction.</p> <p>The Operations Manager (CM) is responsible to present all data and monitoring/audit results as related to this Plan of Correction to the Medical Director for oversight and review.</p> <p>The Director of Operations is</p>	11/09/2012			

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	<p>access sites had been reported between 02-29-2012 and 08-03-2012. The facility's monthly QAPI committee meetings, dated 01-25-12, 02-22-2012, 03-29-2012, 04-25-12, 05-25-2012, 08-30-2012, and 09-20-2012 failed to evidence the clotting issues had occurred and failed to evidence a plan to address the clotting issue had been implemented.</p> <p>3. The facility's QAPI meeting minutes evidenced the medical social worker (MSW) had reported patients had missed multiple treatments between 01-25-2012 and 09-20-2012.</p> <p>A. Meeting minutes dated 01-25-2012 evidenced the MSW had reported "the unit had 42 missed treatments for the month."</p> <p>B. Meeting minutes dated 02-22-2012 evidenced the MSW had reported 37 missed treatments for January 2012.</p> <p>C. Meeting minutes dated 03-29-2012 included the same information as the 02-22-2012 meeting minutes, 37 missed treatments for January 2012.</p> <p>D. Meeting minutes dated 04-25-2012 stated, "39 missed treatments for this month."</p>		<p>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 then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee</p> <p>The Medical Director acknowledges his role to ensure that any issues that do not show resolution, will be reviewed with a new action plan developed until all issues as cited within the Statement of Deficiency have been resolved and resolution sustained.</p>				

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	<p>E. Meeting minutes dated 05-25-2012 and 07-27-2012 failed to evidence a MSW report.</p> <p>F. Meeting minutes dated 08-30-2012 stated, "45 unexcused treatments for this month."</p> <p>G. Meeting minutes dated 09-20-2012 stated, "23 unexcused treatments for this month."</p> <p>H. The meeting minutes failed to evidence a plan had been implemented to address the identified problem concerning continued, multiple missed treatments.</p> <p>4. The facility's QAPI meeting minutes identified comprehensive interdisciplinary assessments (CIA) and plans of care (PoC) as areas for improvement.</p> <p>A. The QAPI meeting minutes dated 02-22-12 states, "Comprehensive Assessment and Plan of Care Review . . . trend analysis . . . no change . . . Improvement Area: Yes." The meeting minutes failed to evidence a plan to address the identified area for improvement.</p> <p>B. The 03-29-2012 meeting minutes identified there had been "no change" in the trend analysis for the CIAs and PoCs.</p>						

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	<p>The minutes failed to indicate whether this was still an improvement area. The "yes" or "no" boxes were blank. The meeting minutes failed to evidence a plan to address the assessments and care plans had been implemented.</p> <p>C. The 04-25-2012 and 05-25-2012 meeting minutes identified "no change" in the trend analysis and the "no" box was checked to indicate this was not an improvement area.</p> <p>D. The 07-27-2012 meeting minutes identified the trend analysis as "declining" and that the area now needed improvement. The meeting minutes stated, "5 late last month. Nursing was not present at Junes meeting (27), so CP [care plans] need to be reviewed for June in July."</p> <p>The meeting minutes failed to evidence a plan had been developed and implemented to address the identified care plan problem.</p> <p>E. The 08-30-2012 meeting minutes identified the trend analysis as "declining" and that this was an area for improvement. The minutes stated, "Late with 3 care plans due to late admissions. All updates on TTS [Tuesday, Thursday, Saturday] schedule are behind in Nursing.</p>						

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	<p>RD [registered dietician] updates are also behind. New action plan developed and implemented."</p> <p>F. The 09-20-2012 meeting minutes the assessment and care plan trend analysis is "declining." The minutes state, "14 POCs were late. Trying to catch up. Moving CP meeting up by 1 week in the month to avoid any further late POCs."</p> <p>5. The QAPI findings were reviewed with the Director of Operations, employee AA, on 10-11-2012 at 12:15 PM. The director was unable to provide any additional documentation and/or information related to the findings.</p> <p>6. The facility's Medical Director was not available for interview at the time of the survey due to being out of town. The physician filling in the for medical director, employee DD, was interviewed on 10-11-2012 at 10:45 AM. The physician indicated he was aware there were multiple problems with the facility.</p> <p>7. The facility's 04-04-2012 "Quality Assessment and Performance Improvement Program (QAPI)" policy number FMS-CS-IC-I-101-001A states, "The Medical Director, Director of Operations, Area Manager, and Clinical Manager are responsible for monitoring</p>						

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	and evaluating the effectiveness of the QAI Programs . . . All Adverse Events will be reviewed by the QAI committee to ensure appropriate interventions . . . The Medical Director will communicate with the Governing Body regarding QAI activities."			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152571		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 10/11/2012	
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V0750	<p>Based on administrative, clinical record, and facility policy review and interview, it was determined the facility failed to maintain compliance with this condition by failing to ensure the governing body had appointed an individual that would be available to provide oversight and management of the dialysis services provided by the facility creating the potential to affect all of the facility's 130 current patients (See V 752), by failing to ensure ensure a clinic manager and a medical social worker were present a sufficient amount of time to meet the needs of the patients creating the potential to affect all of the facility's 130 current patients (See V 757), and by failing to ensure ensure a medical social worker was present for sufficient periods of time to meet the patients' needs in 6 of 9 records reviewed creating the potential to affect all of the facility's 130 current patients (See V 758).</p> <p>The cumulative effect of these systemic problems resulted in the facility being found out of compliance with this condition, 42 CFR 494.180 Governance.</p>	V0750	<p>The Governing Body understands and acknowledges their role and responsibilities to ensure that the facility staff has appropriate training and that the facility's complaint/grievance process has been implemented as required by the Conditions for Coverage.</p> <p>Therefore the Governing Body met on 11/2/12, after receipt of the Statement of Deficiencies and detailed above in V500, V540 and V625 to review the Statement and make certain that all identified deficiencies were being addressed, both immediately and with long term resolution. The following action steps were agreed upon and implemented.</p> <p>The Governing Body, agreed to meet weekly to monitor the progress of this Plan of Correction as related to the Statement of Deficiencies, until the Condition level deficiencies are lifted, then monthly for an additional three months to make certain that all corrections are being maintained, and then return to quarterly or as needed basis.</p> <p>Effective immediately ·The DO will present a report to the Medical Director and Governing Body on the audit/monitoring results and all other actions taken toward the</p>	11/02/2012			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152571	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 10/11/2012
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH			STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804		
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			<p>resolution of the Plan of Correction for this SOD at each Governing Body meeting through to the resolution of all identified conditions/deficiencies .</p> <ul style="list-style-type: none"> ·The Operations Manager will present monthly reports on these results to the Governing Body for review and oversight. ·The processes as noted in this POC will be reviewed weekly by the Governing Body. These meetings will ensure ongoing progress towards resolution of noted deficiencies and that the facility is delivering safe, quality health care services on a daily basis. ·Minutes of the Governing Body and QAI meetings, as well as monitoring forms, In-service sign-in sheets will document these actions and the Governing Body's direction and monitoring of facility activities. These will be available for review at the facility. <p>The response provided for V 752 describes, in detail, the processes and monitoring steps taken to ensure that the facility appoints an individual to be available to provide oversight and management</p> <p>The response provided for V 757 describes, in detail, the processes and monitoring steps taken to ensure that the facility has a clinical manager and social worker present to meet the needs of the patients.</p>		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152571	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 10/11/2012
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH	STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804
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			The response provided for V 758 describes, in detail, the processes and monitoring steps to ensure that a social worker is present to meet the needs of patients.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152571		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 10/11/2012	
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V0752	<p>494.180(a) GOV-APPOINT CEO/ADMINISTRATOR The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, Based on administrative record review and interview, the governing body failed to appoint an individual that would be available to provide oversight and management of the dialysis services provided by the facility creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Indiana State Department of Health administrative records evidenced employee CC was the facility's administrator. 2. Employee CC indicated, on 10-10-2012 at 11:20 AM, employee AA was the individual responsible for operations of the facility on-site. <p>Employee CC indicated she lived approximately 3 hours away from the facility and was only available to be on-site 2 or 3 days a week.</p> <ol style="list-style-type: none"> 3. Upon entering the facility on 	V0752	<p>The Governing Body met on November 2, 2012 to review the requirement that the facility appoints an individual that would be available to provide oversight and management.</p> <p>Effective immediately, the Operations Manager has been named as the interim manager with coverage provided 5 days per week.</p> <p>The Operations Manager will report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.</p>	11/02/2012			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152571	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 10/11/2012
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH	STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804
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	10-09-2012 at 10:55 AM, employee A indicated she was the charge nurse and that employee CC was the facility's administrator and was functioning as the clinic manager as well.			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152571		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 10/11/2012	
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V0757	<p>494.180(b)(1) GOV-STAFF # & RATIO MEET PT NEEDS The governing body or designated person responsible must ensure that-</p> <p>(1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients; Based on clinical record and facility policy review and interview, the governing body failed to ensure a clinic manager and a medical social worker were present a sufficient amount of time to meet the needs of the patients creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <p>1. Upon entering the facility, on 10-09-2012 at 10:55 AM, employee A indicated the facility did not have a clinic manager. The employee indicated she was the charge nurse and that employee CC was functioning as the clinic manager.</p> <p>A. Employee CC indicated, on 10-10-2012 at 11:20 AM, employee AA was the individual responsible for operations of the facility on-site.</p> <p>B. Employee CC indicated she lived approximately 3 hours away from the facility and was only available to be on-site 2 or 3 days a week.</p>	V0757	<p>The Governing Body met on November 2, 2012 to review the requirement that the facility appoints an individual that would be available to provide oversight and management and that a social worker is present to meet the needs of the patients on all shifts.</p> <p>Effective immediately, the Operations Manager has been named as the interim manager with coverage provided 5 days per week. In addition, a counseling session was held with the social worker to discuss the details of the survey and the findings and to put a schedule in place that ensures all patient shifts have adequate coverage.</p> <p>The Operations Manager will report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.</p>	11/02/2012			

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH			STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804		
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	<p>C. Employee DD, the physician functioning as an alternate medical director, stated, on 10-11-2012 at 10:45 AM, "We are aware the facility does not have a clinic manager. We have talked and talked to administration about this."</p> <p>D. Employee EE, another physician with patients at this facility, stated, on 10-11-2012 at 1:45 PM, "We are very frustrated because this facility does not have a clinic manager."</p> <p>E. Employee AA, the Director of Operations, indicated, on 10-11-2012 at 2:05 PM, the facility had not had a clinic manager since August 2012. She indicated the previous clinic manager had only been in the position for approximately 6 months when he was terminated and the manager prior to this one had only been in the position for approximately 6 months.</p> <p>2. The facility's medical social worker (MSW) was not present in the facility for sufficient periods of time to provide for the needs of the patients.</p> <p>A. Clinical record number 2 included a PoC dated 01-30-2012 that evidenced issues identified in the CIA (comprehensive interdisciplinary</p>				

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	<p>assessment) related to "relationship / social network problems."</p> <p>The plan of care (PoC) included an estimated timetable to achieve the desired outcome "will monitor quarterly and update as indicated." The record failed to evidence any further medical social services had been provided to the patient.</p> <p>B. Clinical record number 3 included a PoC dated 01-30-2012 that evidenced issues identified in the CIA related to "relationship/social network problems."</p> <p>The PoC included an estimated timetable to achieve the desired outcome "will monitor quarterly and update as indicated." The record included 1 follow-up medical social services note dated 4-16-12 that evidenced the social worker had provided some assistance with financial matters to the patient. The record failed to evidence any medical social services related to the issues identified on the plan of care or any further services after 4-16-12.</p> <p>C. Clinical record number 4 included a PoC dated 12-29-2011 with an expected psychosocial outcome "Pt will maintain current ADL [activities of daily living] status and psychosocial status."</p>						

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH				STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804			
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	<p>1). The record included a medical social services quarterly note dated 04-13-2012 that evidenced the social worker had provided assistance with financial matters but failed to mention the patient's ADL or psychosocial status. The record failed to evidence any further medical social services had been provided after 04-13-2012.</p> <p>2.). During an interview with the patient, on 10-09-2012 at 11:50 AM, the patient stated, "The only complaint I have is that I don't get to see the social worker that much. I put it on the survey they sent me. I have some transportation problems. Faith in Action brings me to dialysis."</p> <p>D. Clinical record number 6 included a plan of care dated 06-25-2012 that evidenced issues identified in the CIA related to "ability to follow treatment prescription . . . insurance or financial resources."</p> <p>1). The record included a medical social services note dated 8-7-12 that states, "MSW left voice message for pt as pt has been trying to reach for the past few treatment. MSW left phone number and requested pt return call to discuss needs/concerns as social worker is out of the office on Wednesday's [sic]. MSW will continue to assist pt as needed."</p>						

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH				STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804			
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	<p>2). The record failed to evidence any further contact with the patient until 09-23-2012. A medical social services note dated 09-23-2012 that identified the pt "is fulling [sic] ADL's [sic] without difficulty, driving self to treatment . . . Pt enjoying 2nd shift and talks with other pt's [sic]. Pt reported receiving notice for 0 balance. IW met. Will continue to support as needed."</p> <p>3). During an interview with the patient, on 10-10-2012 at 8:30 AM, the patient stated, "I don't see her [the medical social worker] often enough. I kept getting bills and she told me not to worry about it. Then I got a statement that it was paid. She never did get back with me. I've always paid my bills and it bothered me."</p> <p>E. Clinical record number 7 included a PoC dated 11-03-2011 that evidenced issues as identified on the CIA related to "Mental health concerns (depression, anxiety, panic, substance abuse, etc.) Coping and adjustment to dialysis."</p> <p>1). The plan included the expected outcome "Patient demonstrates decreased symptoms of depression. Patient will resume activities enjoyed prior to onset of renal disease." The plan failed to</p>						

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH	STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804
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	<p>evidence any interventions to achieve the desired outcome. The plan included an estimated timetable of 30 days.</p> <p>2). The record failed to evidence any progress notes to indicate the medical social worker had provided any services to the patient as of 11-30-2011.</p> <p>3). The record included a medical social services progress note dated 08-10-2012 that evidenced the medical social worker, employee V, had contacted the patient as a result of receiving a telephone call from the patient. The patient had requested a change in the seating arrangement for the treatment.</p> <p>4). The record included a progress note dated 10-08-2012 that identified the social worker, employee V, had met with the patient and that the patient had requested information about "end of life and stopping dialysis." The note states, "Pt was holding sticks and stated that [the patient] would just meet with me in office post tx. When pt came off tx MSW had another pt in office for a few minutes. Pt got irritated and told secretary that [the patient] was only waiting for 4 minutes. Pt got up and left. MSW will follow-up with pt at next treatment."</p> <p>The record failed to evidence</p>			

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH			STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804		
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	<p>any follow-up with the patient by the medical social worker.</p> <p>F. Clinical record number 9 included a CIA completed by the RN, employee A, on 08-07-2012, and the RD (registered dietician), employee W, on 08-23-2012. The CIA failed to evidence any participation by the medical social worker.</p> <p>1). The record included an undated PoC. The PoC failed to evidence any participation by the medical social worker.</p> <p>2). During an interview with the patient on 10-11-2012 at 8:45 AM, the patient stated, "I don't see [the medical social worker, employee V] very often. There was a time I needed to talk to her about transplant. But she was not available. I finally got a paper last week."</p> <p>G. Patient number 11 stated, on 10-09-2012 at 3:15 PM, "I don't know if I've seen the medical social worker lately."</p> <p>H. Patient number 12 stated, on 10-09-2012 at 3:20 PM, "I don't know how often I see the medical social worker."</p>				

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH				STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804			
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	<p>I. Patient number 13 stated, on 10-09-2012 at 3:25 PM, "It has been a long time since I've seen [employee V, the medical social worker]. My [spouse] wants me to get a kidney transplant and I don't want to. [Spouse] has been talking to her about it."</p> <p>J. Patient number 23 stated, on 10-11-2012 at 8:00 AM, "I have had to wait to see social worker cause she covers that other unit."</p> <p>K. Employee G, a licensed practical nurse, stated, on 10-09-2012 at 3:30 PM, "patients complain if they are here early morning because the social worker does not get here until 9 AM. She has the Greencastle unit and also goes to class one day a week."</p> <p>L. On 10/11/2012 at 7:50 AM, employee J, a patient care technician, stated, "I don't see [the medical social worker] a lot. I have heard from patients they do not see the MSW enough."</p> <p>3. The medical social worker was interviewed on 10-9-2012 at 3:45 PM per telephone. The social worker stated, "I was seeing approximately 30 patients in Greencastle. I work 10 hours per day Monday, Wednesday, Thursday, and Friday. I come in for a couple of hours on</p>						

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	<p>Saturday sometimes. I am totally overwhelmed. I find we have 25 to 35 care plans a month. We meet at least once a month. I have people come to my office. All of my notes are in Proton. We have had some filing issues. Things get lost if they are put in filing. We have been fighting this. I've tried to get on some kind of schedule. I started a 'rounding report' last month. I do not document every encounter with a patient. I don't have time."</p> <p>4. The Director of Operations, employee AA, stated, on 10-11-2012 at 9:55 AM, "The medical social worker does not cover the Greencastle unit. She hasn't for 2 or 3 months now."</p> <p>5. Employee DD, a physician covering for the medical director during the survey, stated, on 10-11-2012, "We are aware medical social services is lacking in this facility."</p> <p>6. The facility's 04-04-2012 "Social Work Services" policy states, "The services of a qualified social worker shall be made available to all patients of each FMS dialysis facility, including in-center and home patients (as applicable), upon admission and on an ongoing basis."</p>						

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TERRE HAUTE NORTH	STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804
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V0758	<p>494.180(b)(1) GOV-RN, MSW, & RD AVAIL TO MEET PT NEEDS</p> <p>The governing body or designated person responsible must ensure that- The registered nurse, social worker and dietitian members of the interdisciplinary team are available to meet patient clinical needs; Based on clinical record and facility policy review and interview, the governing body failed to ensure a medical social worker (MSW) was present for sufficient periods of time to meet the patients' needs in 6 (#s 2, 3, 4, 6, 7, 9) of 9 records reviewed creating the potential to affect all of the facility's 130 current patients.</p> <p>The findings include:</p> <p>1. Clinical record number 2 included a plan of care (PoC) dated 01-30-2012 that evidenced issues identified in the comprehensive interdisciplinary assessment (CIA) related to "relationship / social network problems."</p> <p>The PoC included an estimated timetable to achieve the desired outcome "will monitor quarterly and update as indicated." The record failed to evidence any further medical social services had been provided to the patient.</p> <p>2. Clinical record number 3 included a</p>	V0758	<p>On November 2, 2012, the Governing Body met to discuss the failure of the MSW to meet the needs of the identified patients. As a result of this meeting, on November 2, 2012, the Operations Manager and Director of Operations met with the assigned MSW to review the citations from the October 11th survey and the responsibilities of the social worker in accordance with the job description and to give her a schedule to meet the needs of all patients. As a result, the Social Worker was directed to review each patient's medical record, participate in the full completion of each patient's plan of care and identify those patients whose status requires more frequent psychosocial adjustment to the plan of care which is inclusive of the following:</p> <ul style="list-style-type: none"> ·Patient depression ·Obtaining prescribed medication ·Patient non compliance to prescribed treatment therapy ·Patient adjustment after hospitalization ·Patients with frequently missed treatments 	11/02/2012			

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	<p>PoC dated 01-30-2012 that evidenced issues identified in the CIA related to "relationship / social network problems."</p> <p>The PoC included an estimated timetable to achieve the desired outcome "will monitor quarterly and update as indicated." The record included 1 follow-up medical social services note dated 4-16-12 that evidenced the social worker had provided some assistance with financial matters to the patient. The record failed to evidence any medical social services related to the issues identified on the plan of care or any further services after 4-16-12.</p> <p>3. Clinical record number 4 included a PoC dated 12-29-2011 with an expected psychosocial outcome "Pt [patient] will maintain current ADL [activities of daily living] status and psychosocial status."</p> <p>A The record included a medical social services quarterly note dated 04-13-2012 that evidenced the social worker had provided assistance with financial matters but failed to mention the patient's ADL or psychosocial status. The record failed to evidence any further medical social services had been provided after 04-13-2012.</p> <p>B. During an interview with the</p>		<p>The MSW will present a patient interaction and QAI report at each month's QAI meeting. The Committee reviews the report and trends report information to determine if there is an opportunity for improvement. If there is such an opportunity, the Committee will investigate to determine the root cause of any variance in compliance and will develop, implement and track an action plan through to resolution and improvement of the issue. These actions will be documented in each month's QAI minutes which will be available for review at the facility.</p> <p>Further, the Operations Manager will review 100% of the MSW progress notes monthly for the next 90 days and discuss areas of improvement/concern at the monthly Governing Body meeting. The Governing Body will revise the corrective action following through to the resolution of all identified conditions/deficiencies</p> <p>Minutes of the Governing Body and QAI meetings, as well as monitoring forms, In-service sign-in sheets will document these actions and the Governing Body's direction and monitoring of facility activities. These will be available for review at the facility.</p>				

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	<p>patient, on 10-09-2012 at 11:50 AM, the patient stated, "The only complaint I have is that I don't get to see the social worker that much. I put it on the survey they sent me. I have some transportation problems. Faith in Action brings me to dialysis."</p> <p>4. Clinical record number 6 included a plan of care dated 06-25-2012 that evidenced issues identified in the CIA related to "ability to follow treatment prescription . . . insurance or financial resources."</p> <p>A. The record included a medical social services note dated 8-7-12 that states, "MSW left voice message for pt as pt has been trying to reach for the past few treatment. MSW left phone number and requested pt return call to discuss needs/concerns as social worker is out of the office on Wednesday's [sic]. MSW will continue to assist pt as needed."</p> <p>B. The record failed to evidence any further contact with the patient until 09-23-2012. A medical social services note dated 09-23-2012 that identified the pt "is fulling [sic] ADL's [sic] without difficulty, driving self to treatment . . . Pt enjoying 2nd shift and talks with other pt's [sic]. Pt reported receiving notice for 0 balance. IW met. Will continue to support as needed."</p>			

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	<p>C. During an interview with the patient, on 10-10-2012 at 8:30 AM, the patient stated, "I don't see her [the medical social worker] often enough. I kept getting bills and she told me not to worry about it. Then I got a statement that it was paid. She never did get back with me. I've always paid my bills and it bothered me."</p> <p>5. Clinical record number 7 included a PoC dated 11-03-2011 that evidenced issues as identified on the CIA related to "Mental health concerns (depression, anxiety, panic, substance abuse, etc.) Coping and adjustment to dialysis."</p> <p>A The plan included the expected outcome "Patient demonstrates decreased symptoms of depression. Patient will resume activities enjoyed prior to onset of renal disease." The plan failed to evidence any interventions to achieve the desired outcome. The plan included an estimated timetable of 30 days.</p> <p>B. The record failed to evidence any progress notes to indicate the medical social worker had provided any services to the patient as of 11-30-2012.</p> <p>C. The record included a medical social services progress note dated</p>				

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	<p>08-10-2012 that evidenced the medical social worker, employee V, had contacted the patient as a result of receiving a telephone call from the patient. The patient had requested a change in the seating arrangement for the treatment.</p> <p>D. The record included a progress note dated 10-08-2012 that identified the social worker, employee V, had met with the patient and that the patient had requested information about "end of life and stopping dialysis." The note states, "Pt was holding sticks and stated that [the patient] would just meet with me in office post tx [after treatment]. When pt came off tx MSW had another pt in office for a few minutes. Pt got irritated and told secretary that [the patient] was only waiting for 4 minutes. Pt got up and left. MSW will follow-up with pt at next treatment."</p> <p>The record failed to evidence any follow-up with the patient by the medical social worker.</p> <p>6. Clinical record number 9 included a CIA completed by the RN, employee A, on 08-07-2012, and the registered dietician, employee W, on 08-23-2012. The CIA failed to evidence a participation by the medical social worker.</p>						

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	<p>A. The record included an undated PoC. The PoC failed to evidence any participation by the medical social worker.</p> <p>B. During an interview with the patient on 10-11-2012 at 8:45 AM, the patient stated, "I don't see [the medical social worker, employee V] very often. There was a time I needed to talk to her about transplant. But she was not available. I finally got a paper last week."</p> <p>7. Patient number 11 stated, on 10-09-2012 at 3:15 PM, "I don't know if I've seen the medical social worker lately."</p> <p>8. Patient number 12 stated, on 10-09-2012 at 3:20 PM, "I don't know how often I see the medical social worker."</p> <p>9. Patient number 13 stated, on 10-09-2012 at 3:25 PM, "It has been a long time since I've seen [employee V, the medical social worker]. My [spouse] wants me to get a kidney transplant and I don't want to. [Spouse] has been talking to her about it."</p> <p>10. Patient number 23 stated, on 10-11-2012 at 8:00 AM, "I have had to wait to see social worker cause she covers</p>			

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	<p>that other unit."</p> <p>11. Employee G, a licensed practical nurse, stated, on 10-09-2012 at 3:30 PM, "Patients complain if they are here early morning because the social worker does not get here until 9 AM. She has the Greencastle unit and also goes to class one day a week."</p> <p>12. On 10/11/2012 at 7:50 AM employee J, a patient care technician stated, "I don't see [the medical social worker] a lot. I have heard from patients they do not see the MSW enough."</p> <p>13. The medical social worker was interviewed on 10-9-2012 at 3:45 PM per telephone. The social worker stated, "I was seeing approximately 30 patients in Greencastle. I work 10 hours per day Monday, Wednesday, Thursday, and Friday. I come in for a couple of hours on Saturday sometimes. I am totally overwhelmed. I find we have 25 to 35 care plans a month. We meet at least once a month. I have people come to my office. All of my notes are in Proton. We have had some filing issues. Things get lost if they are put in filing. We have been fighting this. I've tried to get on some kind of schedule. I started a 'rounding report' last month. I do not document every encounter with a patient.</p>				

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	<p>I don't have time."</p> <p>14. The Director of Operations, employee AA, stated, on 10-11-2012 at 9:55 AM, "The medical social worker does not cover the Greencastle unit. She hasn't for 2 or 3 months now."</p> <p>15. Employee DD, a physician covering for the medical director during the survey, stated, on 10-11-2012, "We are aware medical social services is lacking in this facility."</p> <p>16. The facility's 04-04-2012 "Social Work Services" policy states, "The services of a qualified social worker shall be made available to all patients of each FMS dialysis facility, including in-center and home patients (as applicable), upon admission and on an ongoing basis."</p>						