

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152500	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 02/08/2012
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS			STREET ADDRESS, CITY, STATE, ZIP CODE 2480 N MERIDIAN ST INDIANAPOLIS, IN 46208		
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V0000	<p>This was an ESRD federal recertification survey.</p> <p>Facility #: 005147</p> <p>Survey Dates: 2-1-12, 2-2-12, 2-3-12, 2-6-12, 2-7-12, & 2-8-12</p> <p>Medicaid Vendor #: 100172360C</p> <p>Surveyor: Vicki Harmon, RN, PHNS</p> <p>177 total patients 20 CAPD 8 CCPD 12 home hemodialysis 137 incenter</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN February 21, 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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V0413	<p>Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available.</p> <p>Based on observation, interview, and facility policy review, the facility failed to ensure all required emergency equipment was on the premises creating the potential to affect all of the facility's 177 current patients.</p> <p>The findings include:</p> <p>1. Observation noted, on 2-7-12 at 10:10 AM, an automated external defibrillator hanging on the wall behind the nurse's station and 2 suction machines located on opposite ends of the nurse's station on the bottom shelf pushed to the back of the shelf. An oxygen canister was observed across the room from the nurse's station. Observation failed to evidence any airways or emergency drugs on the premises.</p> <p>A. The clinic manager, employee C, stated, "We do not have a crash cart. That is all of the emergency equipment we have."</p> <p>B. The medical director, employee A, stated, on 2-7-12 at 10:30 AM, "I do not know where the emergency equipment</p>	V0413	<p>The Area Manager will meet with the facility's staff on or before 3/8/2012 to review the requirements detailed in Fresenius policy, "Emergency Equipment/Supplies" to ensure that emergency supplies are maintained at the dialysis facility. The Clinical Manager, under the guidance of the Medical Director, will obtain the medications and equipment that is to be kept at the facility. The Clinical Manager will create a checklist on or before 3/8/2012 containing all medications and supplies that are kept in the facility. The supplies and equipment will be checked monthly for expiration dates, quantities and the medications and supplies are covered and locked. The Area Manager 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 Clinical Manager is responsible to report a summary of findings monthly to the QAI Committee. The QAI Committee is responsible to analyze the results and determine a root cause</p>	03/08/2012			

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	<p>is." After pointing out the location of the emergency equipment the facility did have on hand, the medical director indicated the staff would be "running around trying to gather the equipment up."</p> <p>2. The facility's 11-19-03 "Emergency Equipment/Supplies Policy" number 138-020-120 states, "Emergency supplies are maintained at this dialysis facility for use in life threatening circumstances such as cardiac / respiratory arrest. It is the responsibility of the medical Director in conjunction with the Governing Body and medical staff to determine the medications and equipment that are to be kept in the emergency cart/box . . . The supplies should be contained in a box or cart that is covered and locked and is equipped with a dedicated oxygen tank."</p>		<p>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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V0454	<p>The patient has the right to-</p> <p>(3) Privacy and confidentiality in all aspects of treatment;</p> <p>Based on administrative record and facility policy review, observation, and interview, the facility failed to ensure patients' right to confidentiality had been preserved affecting all of the facility's 177 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The facility's administrative records included a "Security Services Agreement" dated 8-5-10. The agreement failed to provide for confidentiality of patient information observed and/or overheard at the dialysis facility by the security guards. 2. On 2-1-12, 2-2-12, 2-3-12, 2-6-12, 2-7-12, and 2-8-12, observation noted a security guard in and around the facility at all times the surveyor was on the premises. 3. Employee II, one of the security guards, indicated, on 2-8-12 at 12:30 PM, she had not signed an agreement to keep any and all patient information observed and/or overheard confidential. The security guard stated, "We do have access to all parts of the facility including the treatment floor when needed." 	V0454	<p>On 2/08/2012, the Area Manager met with Vincent Williams, owner of Williams Associates Security Company, the vendor used by the facility to provide security services, reviewed the contents and executed a Business Associate Agreement as an addendum to the existing Security Services Agreement. The Business Associate Agreement outlines the requirements for the vendor to protect the privacy and security of PHI and other medical, health or personal information protected by federal or state law and satisfy certain standards and requirements of HIPAA Regulations, the Privacy Rule and the Security Rule. A fully executed Business Associate Agreement was placed in the Facility Agreements Manual with the existing Security Services Agreement on 2/08/2012. To further protect the patient's right to privacy and confidentiality in all aspects of treatment, the Area Manager will meet with Vincent Williams, owner of Williams and Associates Security Company, and each of the security guards, discuss the HIPPA policy and have each security guard sign an acknowledgement form documenting review and discussion of the policy on or</p>	03/08/2012			

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	<p>4. The clinic manager, employee C, stated, on 2-8-12 at 11:30 AM, "There is no HIPPA provision in place. The likelihood of [the security guards] overhearing confidential patient information is high. The security people have access to all parts of the building."</p> <p>5. The facility's 2-11-09 "Patient Rights and Responsibilities" policy number FMS-138-020-060 states, "The patient has the right to . . . privacy and confidentiality in all aspects of treatment."</p>		<p>before 3/08/2012. The Clinical Manager will ensure that all new security guards complete the review of the HIPPA policy and sign the acknowledgement documenting review and discussion of the policy on or before the first day of duty at the clinic. The Clinical Manager will report a summary of any breaches in confidentiality by the security guards monthly in QAI, and compliance will be monitored by the QAI committee and addressed by the Governing Body.</p>		

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V0504	<p>The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>Blood pressure, and fluid management needs.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure comprehensive interdisciplinary assessments (CIA) included an evaluation of the patients' blood pressure and fluid management needs in 1 (# 12) of 15 records reviewed creating the potential to affect all of the facility's 177 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 12 included a CIA dated 8-10-11 that failed to include an assessment of the patient's blood pressure and fluid management needs. The blood pressure and fluid management portion of the CIA had been left blank. 2. The home program director, employee DD, was unable to provide any additional documentation and/or information regarding this finding when asked on 2-6-12 at 4:50 PM and just prior to the exit conference on 2-8-12 at 1:30 PM. 3. The facility's 2-2-11 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-138-020-091 	V0504	<p>The Clinical Manager, Home Program Manager and/or designee will complete 100% chart audit of all patients' Comprehensive Interdisciplinary Assessments (CIA) by 3/6/2012 to review the blood pressure and fluid volume status section. Any patient whose sections are found to be blank or incomplete will be presented at the Interdisciplinary Team Meeting conducted on or before 3/21/2012, including Patient #12.A mandatory inservice will be held on or before 3/8/2012 for all nursing staff, social worker and registered dietitian. The Area Manager, Clinical Manager and Home Program Manager reviewed the "Comprehensive Interdisciplinary Assessment and Plan of Care Policy" with emphasis on ensuring that the blood pressure and fluid volume status are completed.The Clinical Manager and Home Program Manager will monitor the Comprehensive Interdisciplinary Assessments and Plan of Care monthly, using the Medical Record Audit Tool, for four months, and then ongoing according to the frequency on the QAI Calendar.Any issues of noncompliance will be addressed by the Clinical Manager and</p>	03/23/2012
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	states, "The comprehensive interdisciplinary assessment must include the following: . . . Blood pressure and fluid management needs."		Home Program Manager immediately, the patient situation addressed, and corrective action taken as appropriate. The Clinical Manager is responsible to report a summary of findings monthly to the QAI Committee, and compliance will be monitored by the Governing Body.	
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V0506	<p>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 comprehensive assessments included a review of all medications the patients were known to be taking in 2 (#s 1 and 5) of 15 records reviewed creating the potential to affect all of the facility's 177 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 1 included a comprehensive interdisciplinary assessment (CIA) dated 12-6-11 that failed to evidence a medication review of all medications the patient was known to be taking had been completed. 2. Clinical record number 5 included a CIA dated 12-13-11 that failed to evidence a medication review of all medications the patient was known to be taking had been completed. 3. The clinic manager, employee C, was unable to provide any additional documentation and/or information regarding these findings when asked on 2-7-12 at 9:15 AM and 2-8-12 at 9:20 AM and also just prior to the exit 	V0506	<p>The Area Manager met with the facility's Interdisciplinary Team on 2/28/2012 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care", FMS-CS-IC-I-110-125A, to ensure that every patient will have a timely, complete and current Comprehensive Interdisciplinary 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. The Clinical Manager, Home Program Manager, and/or designee will complete a 100% review of all patients' Comprehensive Interdisciplinary Assessments by 3/8/2012 to ensure that all Assessments include a medication review that is complete and current. Any patients' Assessment found to be out of compliance, including Patients #1 and #5, will be presented to the Interdisciplinary Team for completion on or before 3/23/2012. The Clinical Manager and Home Program Manager will utilize the QAI Tool for Assessment and Care-Plan</p>	03/23/2012			

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	<p>conference on 2-8-12 at 1:30 PM.</p> <p>4. The facility's 2-2-11 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-138-020-091 states, "The comprehensive interdisciplinary assessment must include the following: . . . medication history."</p>		<p>tracking of all patients monthly to ensure timely completion of all patients' medication review as part of their Comprehensive Interdisciplinary Assessment. The Clinical Manager and Home Program 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 Committee. 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 Area Manager 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 recurring. Ongoing compliance will be monitored by the QAI Committee and Governing Body.</p>		

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V0541	<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 patients had participated in the development of the plan of care in 7 (#s 1, 4, 7, 9, 10, 13, and 14) of 15 records; failed to ensure plans of care included measurable outcomes in 3 (#s 1, 7, and 12) of 15 records; and failed to ensure plans of care included estimated timetables to achieve desired goals in 10 (#s 1, 2, 3, 4, 9, 10, 11, 12, 13, and 15) of 15 records reviewed creating the potential to affect all of the facility's 177 current patients.</p> <p>The findings include:</p> <p>Regarding patient participation in the development of plans of care:</p> <p>1. Clinical record number 1 included a plan of care developed by the interdisciplinary team (IDT) on 12-6-11.</p>	V0541	<p>On 2/28/12, the Area Manager met with the facility's Interdisciplinary Team to emphasize the requirements defined in the Conditions for Coverage and Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care", FMS-CS-IC-I-110-125A, 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 measureable outcomes and timetables estimated to obtain each patient's outcomes. Also, each Plan of Care must be reviewed and signed by the patient within seven (7) days of the Plan of Care Meeting or have documentation as to why it was not signed within the appropriate time frame. The Clinical Manager, Home Program Manager, and/or designee will</p>	03/23/2012			

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	<p>The plan of care evidenced the patient had not signed until 1-30-12, 55 days after the plan of care had been developed and implemented.</p> <p>2. Clinical record number 4 included a plan of care developed by the IDT on 12-13-11. The plan of care evidenced the patient had not signed until 1-4-12, 22 days after the plan of care had been developed and implemented.</p> <p>3. Clinical record number 7 included a plan of care developed by the IDT on 10-18-11. The plan of care evidenced the patient had not signed until 10-27-11, 9 days after the plan of care had been developed and implemented.</p> <p>4. Clinical record number 9 included a plan of care developed by the IDT on 9-21-11. The plan of care evidenced the patient had not signed until 10-13-11, 22 days after the plan of care had been developed and implemented.</p> <p>5. Clinical record number 10 included a plan of care developed by the IDT on 9-21-11. The plan of care evidenced the patient had not signed until 9-26-11, 5 days after the plan of care had been developed and implemented.</p> <p>6. Clinical record number 13 included a</p>		<p>complete a 100% review of all patients' Plans of Care by 3/8/2012 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 seven (7) day time frame. Any patient's Plan of Care found ot be count of compliance, including Patients #1, #2, #3, #4, #7, #9, #11, #12, #13 and #14 will be presented to the Interdisciplinary Team for completion by 3/21/2012. The Clinical Manager and Home Program Manager will review all Plans of Care monthly to ensure that desired outcomes/goals, estimated timetables and signatures are present. Any Plans of Care found out of compliance will be scheduled for completion within the next thirty (30) days, and corrective action will be taken as appropriate. The Clinical Manager and Home Program Manager is responsible to report a summary of findings monthly to the QAI Committee. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI Committee. The Area Manager is responsible to ensure the results of the audits will be reviewed during the monthly QAI</p>		

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	<p>plan of care developed by the IDT on 7-18-11. The plan evidenced the patient had not signed until 9-7-11, 51 days after the plan had been developed and implemented.</p> <p>7. Clinical record number 14 included a plan of care developed by the IDT on an unknown date. The signatures of the IDT were not dated. The plan of care failed to evidence any patient participation in the development of the plan.</p> <p>8. The clinic manager, employee C, was unable to provide any additional documentation and/or information regarding these findings when asked on 2-7-12 at 9:15 AM and 2-8-12 at 9:20 AM and also just prior to the exit conference on 2-8-12 at 1:30 PM.</p> <p>9. The home program director, employee DD, was unable to provide any additional documentation and/or information regarding this finding when asked on 2-6-12 at 4:50 PM and just prior to the exit conference on 2-8-12 at 1:30 PM.</p> <p>10. The facility's 2-2-11 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-138-020-091 states, "The Comprehensive Interdisciplinary Assessment and Plan of Care must be developed and implemented</p>		Committee meeting and reported to the Governing Body.				

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	<p>by an interdisciplinary team (IDT) consisting of at a minimum, the patient or patient's designee (if the 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 dietician."</p> <p>Regarding measurable outcomes:</p> <ol style="list-style-type: none"> 1. Clinical record number 1 included a plan of care developed by the IDT on 12-6-11. The plan of care failed to include measurable outcomes for dialysis access and patient education. 2. Clinical record number 7 included a plan of care developed by the IDT on 10-18-11. The plan of care failed to include measurable outcomes for the psychosocial portion of the plan. 3. Clinical record number 12 included a plan of care developed by the IDT on 8-10-11. The plan of care identified the patient has a peritoneal dialysis catheter. The plan failed to include measurable outcomes related to the catheter. <p>The plan identified the physician is "addressing pt [patient] inability to meet Kt/V goal of 2.0." The expected outcome states, "Pt will try harder." The plan</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	
	<p>failed to include a measurable outcome for the Kt/V goal.</p> <p>4. The clinic manager, employee C, was unable to provide any additional documentation and/or information regarding these findings when asked on 2-7-12 at 9:15 AM and 2-8-12 at 9:20 AM and also just prior to the exit conference on 2-8-12 at 1:30 PM.</p> <p>5. The facility's 2-2-11 "Comprehensive Interdisciplinary Assessment and Plan of Care" MS 138-020-091 states, "The Plan of Care must include measurable and expected outcomes and an estimated timetable to achieve these outcomes."</p> <p>Regarding estimated timetables:</p> <p>1. Clinical record number 1 included a plan of care developed by the IDT on 12-6-11. The plan of care failed to include estimated timetables for the achievement of specific outcomes as follows:</p> <p>A. The plan of care included an albumin management goal of 4.0 or higher. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>B. The plan included a body weight management goal of a BMI of 24.9. The</p>				

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	<p>plan failed to evidence an estimated timetable to achieve the goal.</p> <p>C. The plan included a mineral metabolism goal of a PTH of less than 600. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>2. Clinical record number 2 included a plan of care developed by the IDT on 11-1-11. The plan of care failed to include estimated timetables for the achievement of specific outcomes as follows:</p> <p>A. The plan of care included an albumin management goal of 4.0. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>B. The plan of care included mineral metabolism goals of a phosphorous of 3.0 to 5.5 and a corrected calcium of 8.4 to 9.5. The plan failed to evidence an estimated timetable to achieve the goals.</p> <p>C. The plan of care included a psychosocial status goal to have a primary care doctor. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>D. The plan included a patient education goal to verbalize understanding</p>			
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	<p>of education. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>3. Clinical record number 3 included a plan of care developed by the IDT on 11-15-11. The plan failed to include estimated timetables for the achievement of specific outcomes as follows:</p> <p>A. The plan of care included mineral metabolism goals of phosphorous 3.0 to 5.5, corrected calcium 8.4 yo 9.5, and PTH 150 to 300. The plan failed to evidence an estimated timetable to achieve the goals.</p> <p>B. The plan included a transplantation goal to "complete dental and pap." The plan failed to evidence an estimated timetable to achieve the goals.</p> <p>4. Clinical record number 4 included a plan of care developed by the IDT on 12-13-11. The plan failed to include estimated timetables for the achievement of specific outcomes as follows:</p> <p>A. The plan of care included a blood pressure and fluid management goal to "achieve EDW at end of each tx [treatment]." The plan failed to evidence an estimated timetable to achieve the goal.</p>				

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	<p>B. The plan included an anemia management goal of a T-sat of 30 to 50 and ferritin level of 200-500. The plan failed to evidence an estimated timetable to achieve the goals.</p> <p>C. The plan included a goal to achieve a bicarbonate value of 22-28. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>D. The plan included a body weight management goal of a BMI of 25.6. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>5. Clinical record number 9 included a plan of care developed by the IDT on 9-21-11. The plan failed to include estimated timetables for the achievement of specific outcomes as follows:</p> <p>A. The plan included a goal to achieve a bicarbonate goal of 22-28. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>B. The plan included goals to achieve a phosphorous level of 3.0 to 5.5, a corrected calcium goal of 8.4 to 9.5, and a potassium of 3.5 to 5.5. The plan failed to evidence an estimated timetable to achieve the goals.</p>			
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	<p>6. Clinical record number 10 included a plan of care developed by the IDT on 9-21-11. The plan failed to include estimated timetables for the achievement of specific outcomes as follows:</p> <p>A. The plan included an albumin management goal of 4.0. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>B. The plan included a body weight management goal of a BMI of 24.9. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>7. Clinical record number 11 included a plan of care developed by the IDT on 12-19-11. The plan failed to include estimated timetables for the achievement of specific outcomes as follows:</p> <p>A. The plan included a dialysis prescription goal to "complete adequacy." The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>B. The plan included a language barrier goal to "understand each other every time we communicate." The plan failed to evidence an estimated timetable to achieve the goal.</p>						

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	<p>C. The plan included an albumin management goal of 3.7. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>D. The plan included a psychosocial status goal that states, "Patient to have adequate insurance coverage, patient to make smooth transition to facility." The plan failed to evidence an estimated timetable to achieve the goals.</p> <p>8. Clinical record number 12 included a plan of care developed by the IDT on 8-10-11. The plan failed to include estimated timetables for the achievement of specific outcomes as follows:</p> <p>A. The plan includes a dialysis prescription goal that states, "Try to get pt to perform Rx [treatments] to get to goal." The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>B. The plan includes a mineral metabolism goal of a corrected calcium of 8.4 to 9.5. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>9. Clinical record number 13 included a plan of care developed by the IDT on 11-9-11. The plan failed to include estimated timetables for the achievement of specific outcomes as follows:</p>				

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	<p>A. The plan includes an anemia management goal to "keep HGB [hemoglobin] between 10-12." The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>B. The plan includes an albumin management goal of an albumin of 4.0. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>C. The plan includes a body weight management goal of a BMI [basal metabolic index] of 24.9. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>D. The plan includes a mineral metabolism goal of a phosphorous level of 3.0 to 5.5, a corrected calcium level of 8.4 to 9.5 and a PTH [parathyroid hormone] of 150-300. The plan failed to evidence an estimated timetable to achieve the goals.</p> <p>E. The plan includes a psychosocial status goal for the "pt to actively participate in providing information and completed application for assistance." The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>F. The plan includes a goal for the</p>			
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	<p>patient "to receive some support if available." The plan failed to evidence an estimated to achieve the goal.</p> <p>10. Clinical record number 15 included a plan of care developed by the IDT on 11-1-11. The plan failed to include estimated timetables for the achievement of specific outcomes as follows:</p> <p>A. The plan includes a blood pressure and fluid management goal to "achieve EDW at end of each tx." The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>B. The plan includes an anemia management goal of a T-sat equal to 30 to 50. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>C. The plan includes a dialysis access goal for the "pt to have permanent access placed." The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>D. The plan includes an albumin management goal for an albumin level of 4.0. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>E. The plan includes a body weight management goal for a BMI of 24.9. The plan failed to evidence an estimated</p>			

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	<p>timetable to achieve the goal.</p> <p>F. The plan includes a mineral metabolism goal for a phosphorous level of 3.5 to 5.5. The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>G. The plan includes a psychosocial status goal for the "pt to come to tx and stay on fill tx time." The plan failed to evidence an estimated timetable to achieve the goal.</p> <p>11. The clinic manager, employee C, was unable to provide any additional documentation and/or information regarding these findings when asked on 2-7-12 at 9:15 AM and 2-8-12 at 9:20 AM and also just prior to the exit conference on 2-8-12 at 1:30 PM.</p> <p>12. The home program director, employee DD, was unable to provide any additional documentation and/or information regarding this finding when asked on 2-6-12 at 4:50 PM and just prior to the exit conference on 2-8-12 at 1:30 PM.</p> <p>13. The facility's 2-2-11 "Comprehensive Interdisciplinary Assessment and Plan of Care" MS 138-020-091 states, "The Plan of Care must include measurable and</p>				

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	expected outcomes and an estimated timetable to achieve these outcomes."			

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V0543	<p>The plan of care must address, but not be limited to, the following:</p> <p>(1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status;</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure the necessary care and services had been provided to manage the patients' blood pressure and volume status by failing to ensure low blood pressures had been addressed in 6 (#s 1, 5, 6, 7, 9, and 10) of 15 records and by failing to ensure estimated dry weights had been achieved in 3 (#s 2, 3, and 15) of 15 records reviewed creating the potential to affect all of the facility's 177 current patients.</p> <p>The findings include:</p> <p>Regarding lower than normal blood pressures:</p> <p>1. Clinical record number 1 evidenced the patient's blood pressure (BP) was below the desired level of 120/80 throughout the treatments as follows:</p> <p>A. A treatment flow sheet dated 1-2-12 evidenced the patient's BP had ranged from 97/63 to 152/78 throughout the treatment with a post treatment standing BP of 94/40.</p>	V0543	<p>A mandatory in-service is scheduled for all patient care staff on 3/8/2012. The Clinical Manager, Charge Nurse or Educator RN will review the "Evaluating the Patient Pre and Post Dialysis" policy with emphasis on ensuring that the patient's blood pressures run in the range according to physician order. If unable to achieve the desired blood pressure, the Patient Care Technician will notify the Charge Nurse, document notification on the flow-sheet, and document the reason and any interventions taken on the flow-sheet. The nurse will further evaluate the patient and notify the physician if necessary. The Clinical Manager and Home Program Manager or designee will complete 100% chart review of all patient's Plans of Care by 3/8/2012 to review the patient's blood pressure and to see if the necessary care/services were provided to manage the patient's blood pressure. Any patient found unable to reach or maintain their target blood pressure will be presented at the Interdisciplinary Team meeting conducted by 3/21/2012, including Patients # 1, #5, #6, #7, #9 and #10. Patient specific issues identified will be</p>	03/23/2012			

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	<p>B. A treatment flow sheet dated 1-6-12 evidenced the patient's BP had ranged from 99/40 to 111/46 throughout the treatment with a post treatment standing BP of 114/39.</p> <p>C. A treatment flow sheet dated 1-9-12 evidenced the BP had ranged from 79/52 to 135/68 with a post treatment standing BP of 115/64.</p> <p>D. A treatment flow sheet dated 1-11-12 evidenced the BP had ranged from 89/57 to 106/57 with a post treatment standing BP of 102/56.</p> <p>E. A treatment flow sheet dated 1-13-12 evidenced the BP had ranged from 72/43 to 106/58 with a post treatment sitting BP of 95/58.</p> <p>F. A treatment flow sheet dated 1-20-12 evidenced the BP had ranged from 75/46 to 116/60 with a post treatment standing BP of 103/30.</p> <p>G. A treatment flow sheet dated 1-23-12 evidenced the BP had ranged from 84/49 to 110/53 with a post treatment standing BP of 95/59. The record included an "Early Termination of Treatment Against Medical Advice" form signed by the patient to end the treatment</p>		<p>included in the patient's specific Plan of Care. Patients' blood pressures will be monitored daily by the Charge Nurse using the RN Rounding Tool. Any issues of noncompliance will be referred to the Clinical Manager immediately, the patient situation addressed, the Medical Director and/or attending physician notified as appropriate and corrective action taken as appropriate. The Clinical Manager will monitor the rounding tool weekly for 4 weeks using the Rounding Tool Summary and then monthly ongoing. The Clinical Manager is responsible to report a summary of findings monthly in QAI. If resolution is not evident, the QAI Committee will complete a root cause analysis and the Plan of Correction will be revised as necessary. The Area Manager is responsible to ensure the results of the audits are reviewed during the monthly QAI meeting and reported to the Governing Body.</p>				

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	<p>33 minutes early. The form states, "I am nauseated. I don't think I can finish my treatment."</p> <p>H. A treatment flow sheet dated 1-25-12 evidenced the BP had ranged from 84/52 to 122/50 with a post treatment standing BP of 114/57.</p> <p>I. A treatment flow sheet dated 1-27-12 evidenced the BP had ranged from 80/36 to 106/68 throughout the treatment with a post treatment standing BP of 100/68.</p> <p>J. A treatment flow sheet dated 1-30-12 evidenced the patient's BP had ranged from 87/57 to 126/60 throughout the treatment.</p> <p>2. Clinical record number 5 evidenced the patient's BP was below the desired level of 120/80 throughout the treatments as follows:</p> <p>A. A treatment flow sheet dated 1-3-12 evidenced the patient's BP had ranged from 78/54 to 131/54 throughout the treatment with a post treatment standing BP of 130/48.</p> <p>B. A treatment flow sheet dated 1-5-12 evidenced the patient's BP had ranged from 84/45 to 130/71 throughout</p>						

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	<p>the treatment with a post treatment standing BP of 98/44.</p> <p>C. A treatment flow sheet dated 1-7-12 evidenced the BP had ranged from 84/46 to 123/57 with a post treatment standing BP of 101/43.</p> <p>D. A treatment flow sheet dated 1-10-12 evidenced the BP had ranged from 93/37 to 116/66 with a post treatment standing BP of 158/60.</p> <p>E. A treatment flow sheet dated 1-14-12 evidenced the BP had ranged from 97/39 to 112/96 with a post sitting BP of 107/55.</p> <p>F. A treatment flow sheet dated 1-17-12 evidenced the BP had ranged from 70/51 to 125/71 with a post treatment standing BP of 92/50.</p> <p>G. A treatment flow sheet dated 1-19-12 evidenced the BP had ranged from 68/50 to 137/74 with a post sitting BP of 102/49.</p> <p>H. A treatment flow sheet dated 1-21-12 evidenced the BP had ranged from 99/48 to 123/56 with a post standing BP of 99/61.</p> <p>I. A treatment flow sheet dated</p>			
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	<p>1-28-12 evidenced the BP had ranged from 82/36 to 128/69 with a post sitting BP of 108/70.</p> <p>3. Clinical record number 6 evidenced the patient's BP was below the desired level of 120/80 throughout the treatment as follows:</p> <p>A. A treatment flow sheet dated 1-3-12 evidenced the patient's BP had ranged from 87/41 to 115/56 throughout the treatment with a post treatment standing BP of 112/59.</p> <p>B. A treatment flow sheet dated 1-5-12 evidenced the BP had ranged from 86/27 to 106/62 throughout the treatment with a post treatment standing BP of 104/47.</p> <p>C. A treatment flow sheet dated 1-7-12 evidenced the BP had ranged from 90/44 to 106/46 with a post standing BP of 102/43.</p> <p>D. A treatment flow sheet dated 1-10-12 evidenced the BP had ranged from 78/46 to 109/59 with a post treatment standing BP of 109/54.</p> <p>E. A treatment flow sheet dated 1-12-12 evidenced the BP had ranged from 77/37 to 115/50 with a post</p>			
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS			STREET ADDRESS, CITY, STATE, ZIP CODE 2480 N MERIDIAN ST INDIANAPOLIS, IN 46208		
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	<p>treatment standing BP of 102/46.</p> <p>F. A treatment flow sheet dated 1-14-12 evidenced the BP had ranged from 86/49 to 106/57 with a post sitting BP of 96/43.</p> <p>G. A treatment flow sheet dated 1-17-12 evidenced the BP had ranged from 86/39 to 118/60 with a post sitting BP of 99/51.</p> <p>H. A treatment flow sheet dated 1-21-12 evidenced the BP had ranged from 95/53 to 124/51 throughout the treatment.</p> <p>I. A treatment flow sheet dated 1-31-12 evidenced the BP had ranged from 94/34 to 141/73 with a post sitting BP of 109/33.</p> <p>4. Clinical record number 7 evidenced the patient's BP was below the desired level of 120/80 throughout the treatments as follows:</p> <p>A. A treatment flow sheet dated 1-10-12 evidenced the patient's BP had ranged from 87/40 to 118/60 throughout the treatment.</p> <p>B. A treatment flow sheet dated 1-12-12 evidenced the patient's BP had</p>				

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	<p>ranged from 86/51 to 133/64 throughout the treatment.</p> <p>C. A treatment flow sheet dated 1-19-12 evidenced the patient's BP had ranged from 80/45 to 134/74 with a post standing BP of 98/48.</p> <p>D. A treatment flow sheet dated 1-21-12 evidenced the BP had ranged from 80/45 to 134/74 with post standing BP of 97/54.</p> <p>E. A treatment flow sheet dated 1-23-12 evidenced the BP had ranged from 89/22 to 133/70 with a post standing BP of 102/59.</p> <p>F. A treatment flow sheet dated 1-25-12 evidenced the BP had ranged from 88/48 to 135/68 with a post standing BP of 104/56.</p> <p>G. A treatment flow sheet dated 1-27-12 evidenced the BP had ranged from 91/49 to 133/53 with a post standing BP of 94/50.</p> <p>H. A treatment flow sheet dated 1-30-12 evidenced the BP had ranged from 76/44 to 118.69 with a post standing BP of 111/62.</p> <p>I. A treatment flow sheet dated 2-1-12</p>			

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	<p>evidenced the BP had ranged from 83/37 to 111/57 with a post standing Bp of 97/51.</p> <p>5. Clinical record number 9 evidenced the patient's BP was below the desired level of 120/80 through the treatments as follows:</p> <p>A. A treatment flow sheet dated 1-12-12 evidenced the patient's BP had ranged from 71/36 to 104/45 throughout the treatment with a post treatment standing BP of 91/43.</p> <p>B. A treatment flow sheet dated 1-26-12 evidenced the BP had ranged from 74/33 to 180/80 with a post standing BP of 99/40.</p> <p>C. A treatment flow sheet dated 1-28-12 evidenced the BP had ranged from 66/30 to 117/54 with a post standing BP of 110/50.</p> <p>D. A treatment flow sheet dated 2-2-12 evidenced the BP had ranged from 85/44 to 113/46 throughout the treatment with a post standing BP of 98/48.</p> <p>6. Clinical record number 10 evidenced the patient's BP was below the desired level of 120/80 throughout the treatments as follows:</p>			
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	<p>A. A treatment flow sheet dated 1-11-12 evidenced the patient's BP had ranged from 98/53 to 114/61 throughout the treatment.</p> <p>B. A treatment flow sheet dated 1-16-12 evidenced the patient's BP had ranged from 83/40 to 117/67 with a post treatment sitting BP of 94/64.</p> <p>C. A treatment flow sheet dated 1-23-12 evidenced the BP had ranged from 82/40 to 128/58 throughout the treatment.</p> <p>D. A treatment flow sheet dated 1-25-12 evidenced the BP had ranged from 82/31 to 111/54 with a post sitting BP of 111/54.</p> <p>E. A treatment flow sheet dated 2-1-12 evidenced the BP had ranged from 79/44 to 121/70 throughout the treatment.</p> <p>F. A treatment flow sheet dated 2-6-12 evidenced the BP had ranged from 76/40 to 120/51 with a post sitting BP of 102/46.</p> <p>6. The clinic manager, employee C, was unable to provide any additional documentation and/or information regarding these findings when asked on</p>			
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	<p>2-7-12 at 9:15 AM and 2-8-12 at 9:20 AM and also just prior to the exit conference on 2-8-12 at 1:30 PM.</p> <p>Regarding estimated dry weight (EDW):</p> <p>1. Clinical record number 2 failed to evidenced physician ordered estimated dry weight (EDW) of 66.50 kilograms (kg) as follows:</p> <p>A. A treatment sheet dated 1-4-12 evidenced the patient's EDW post treatment was 67.90 kg.</p> <p>B. A treatment sheet dated 1-6-12 evidenced the patient's EDW post treatment was 68 kg.</p> <p>C. A treatment sheet dated 1-9-12 evidenced the patient's EDW post treatment was 69.7 kg.</p> <p>D. Treatment sheets dated 1-11-12 and 1-18-12 evidenced the EDW post treatment was 69 kg.</p> <p>E. A treatment sheet dated 1-13-12 evidenced the EDW post treatment was 68.2 kg.</p> <p>F. A treatment sheet dated 1-16-12 evidenced the EDW post treatment was 69.7 kg.</p>						

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	<p>G. A treatment sheet dated 1-19-12 evidenced the EDW post treatment was 67.3 kg.</p> <p>H. A treatment sheet dated 1-25-12 evidenced the EDW post treatment was 68 kg.</p> <p>2. Clinical record number 3 failed to evidence the physician ordered EDW of 62 kg had been achieved as follows:</p> <p>A. A treatment sheet dated 1-3-12 evidenced the patient's EDW post treatment was 62.8 kg.</p> <p>B. A treatment sheet dated 1-5-12 evidenced the EDW post treatment was 63.6 kg.</p> <p>C. A treatment sheet dated 1-12-12 evidenced the EDW post treatment was 62.5 kg.</p> <p>D. A treatment sheet dated 1-14-12 evidenced the EDW post treatment was 64.2 kg.</p> <p>E. A treatment sheet dated 1-17-12 evidenced the EDW post treatment was 64 kg.</p> <p>F. A treatment sheet dated 1-19-12</p>			
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	<p>evidenced the EDW post treatment was 63.4 kg.</p> <p>G. A treatment sheet dated 1-23-12 evidenced the EDW post treatment was 63.4 kg.</p> <p>H. A treatment sheet dated 1-30-12 evidenced the EDW post treatment was 62.7 kg.</p> <p>3. Clinical record number 15 failed to evidence the physician ordered EDW of 110 kg had been achieved as follows:</p> <p>A. A treatment sheet dated 1-16-12 evidenced the patient's EDW post treatment was 111 kg.</p> <p>B. A treatment sheet dated 1-18-12 evidenced the patient's EDW post treatment was 111.1 kg.</p> <p>C. A treatment sheet dated 1-20-12 evidenced the EDW post treatment was 113.5 kg.</p> <p>D. A treatment sheet dated 1-23-12 evidenced the EDW post treatment was 116.2 kg.</p> <p>E. A treatment sheet dated 1-25-12 evidenced the EDW post treatment was 113.9 kg.</p>						

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	<p>F. A treatment sheet dated 1-27-12 evidenced the EDW post treatment was 112.3 kg.</p> <p>G. A treatment sheet dated 1-30-12 evidenced the EDW post treatment was 113.3 kg.</p> <p>H. A treatment sheet dated 2-2-12 evidenced the EDW post treatment was 112.1 kg.</p> <p>I. A treatment sheet dated 2-6-12 evidenced the EDW post treatment was 110.9 kg.</p> <p>4. The clinic manager, employee C, was unable to provide any additional documentation and/or information regarding these findings when asked on 2-7-12 at 9:15 AM and 2-8-12 at 9:20 AM and also just prior to the exit conference on 2-8-12 at 1:30 PM.</p> <p>5. The facility's 2-2-11 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number 138-020-091 states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Dose of Dialysis . . . Provide necessary care and services to manage the patient's volume status."</p>			
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V0544	<p>Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.</p> <p>Based on clinical record and facility policy review, the facility failed to ensure patients achieved the prescribed dose of dialysis by ensuring heparin had been administered as ordered in 2 (#s 1 and 14) of 15 records reviewed.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Clinical record number 1 included a physician order dated 1-23-12 that identified 6000 units of heparin was to be administered mid-treatment during every treatment. <ul style="list-style-type: none"> A. A treatment flow sheet dated 1-27-12 failed to evidence the 6000 units of heparin had been administered mid-treatment as ordered. B. The facility administrator, employee C, indicated, on 2-1-12 at 3:15 PM, the 600 units of heparin mid-treatment had not been administered on 1-27-12. Employee C stated, "I don't see where it was given either." Clinical record number 14 identified the patient as a home hemodialysis 	V0544	<p>A mandatory in-service is scheduled for all staff on 3/8/2012 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. Frequency of ongoing monitoring will be determined by the QAI Committee upon review of monitoring results and resolution of the issue. Any heparin dosages found out of compliance will be corrected immediately and corrective action will be taken as appropriate. The Home Program Manager will monitor this on a monthly basis by reviewing home patient's treatment records. Any home patient's heparin doses found out of compliance will result in immediate education with the patient.</p> <p>The Clinical 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>	03/23/2012			

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	<p>patient. The record included physician orders dated 11-14-12 that evidenced 6000 units of bolus heparin was to be administered each treatment.</p> <p>A. Home hemodialysis treatment flow sheets, dated 12-2-11, 12-5-11, 12-6-11, 12-7-11, and 12-11-11, evidenced 7000 units of bolus heparin had been administered.</p> <p>B. The home program director, employee DD, was unable to provide any additional documentation and/or information regarding this finding when asked on 2-6-12 at 4:50 PM and just prior to the exit conference on 2-8-12 at 1:30 PM.</p> <p>3. The facility's 3-24-04 "Guidelines for Administration of Medical Services In Dialysis Facilities" policy number 138-020-016 states, "Administration of Medications. Staff will administer any medication on the FMCNA pharmaceutical formulary for which the physician has written a proper order."</p>		<p>The Clinical Manager and Home Program Manager are responsible to report a summary of findings monthly in QAI. If resolution is not evident, the QAI Committee will complete a root cause analysis and the Plan of Correction will be revised as necessary.</p> <p>The Area Manager 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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V0551	<p>The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care provided for the monitoring and maintenance of dialysis accesses in 3 (#s 9, 11, and 12) of 15 records reviewed creating the potential to affect all of the facility's 177 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 9 included a plan of care, developed by the interdisciplinary team (IDT) on 9-21-11, that identified the patient had a left upper arm brachiocephalic graft and a failed right arm arteriovenous fistula (AVF). <p>The plan failed to include interventions to monitor and maintain the patient's graft.</p> <ol style="list-style-type: none"> 2. Clinical record number 11 identified the patient was a home peritoneal dialysis patient and included a plan of care developed by the IDT on 12-19-11. The plan identified the patient had a peritoneal catheter. <p>The plan failed to include interventions to monitor and maintain the</p>	V0551	<p>On 2/28/12, the Area Manager 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 location, monitoring and timely referrals to achieve and sustain the appropriate vascular access type for each patient taking into account the patient's co-morbid conditions. Emphasis was placed upon including interventions to monitor and maintain the patient's access. On or before 3/8/2012, the Clinical Manager and Home Program Manager or designee will complete 100% review of all patient's Comprehensive Interdisciplinary 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. All deficiencies and recommendations were reviewed with the IDT and Clinical or Home Program Manager. Any records found out of compliance, including records # 9, #11, and</p>	03/23/2012			

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	<p>peritoneal catheter.</p> <p>3. Clinical record number 12 identified the patient as a home peritoneal dialysis patient and included a plan of care developed by the IDT on 8-10-11. The plan identified the patient had a "CAPD [continuous ambulatory peritoneal dialysis] Tenckhoff" peritoneal catheter.</p> <p>A. The plan failed to include interventions to monitor and maintain the peritoneal catheter.</p> <p>B. Subsequent clinic visit notes identified the patient did develop problems with the peritoneal catheter exit site.</p> <p>1. A "Home Dialysis Support Record" dated 12-7-11 states, "Pt [patient] exit site was checked by both the Dr and myself. It shows no signs of infection but it did look irritated the Dr recommend the pt use bactaban [sic] cream for only a couple of days."</p> <p>2. A "Home Dialysis Support Record" dated 12-12-11 states, "PT exit site is a bit more angry there was nothing to culture." The note indicated the physician was aware and that the patient had not yet gotten the Bactroban to apply to the exit site.</p>		<p>#12 will be reassessed by the members of the IDT with updates to their Plan of Care by 3/21/2012. The Clinical Manager and Home Program Manager will ensure ongoing compliance by auditing 25% of all medical records monthly for a period of 3 months focusing on patient's accesses. Any patient's 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. The Clinical Manager 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 Area Manager 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</p>		

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	<p>3. A "Home Dialysis Support Record" dated 12-21-11 indicated the patient had gotten the Bactroban and had used it but "the exit site is more painful and is having some blood around it."</p> <p>4. The clinic manager, employee C, was unable to provide any additional documentation and/or information regarding these findings when asked on 2-7-12 at 9:15 AM and 2-8-12 at 9:20 AM and also just prior to the exit conference on 2-8-12 at 1:30 PM.</p> <p>5. The home program director, employee DD, was unable to provide any additional documentation and/or information regarding this finding when asked on 2-6-12 at 4:50 PM and just prior to the exit conference on 2-8-12 at 1:30 PM.</p> <p>6. The facility's 2-2-11 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-138-020-091 states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Vascular Access and PD Catheter Access. Provide vascular access monitoring . . . Provide PD Catheter access monitoring for patency, catheter, tunnel, or exit site infection."</p>			
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V0552	<p>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 plans of care included interventions to address and monitor patients' psychosocial status in 8 (#s 1, 2, 3, 5, 6, 7, 12, and 15) of 15 records reviewed creating the potential to affect all of the facility's 177 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Clinical record number 1 included a plan of care developed by the interdisciplinary team (IDT) on 12-6-11. The plan of care identified the medical social worker (MSW) would "monitor monthly." <p>The plan failed to include patient specific, individualized interventions to monitor the patient's psychosocial status.</p> <ol style="list-style-type: none"> Clinical record number 2 included a plan of care developed by the IDT on 11-1-11. The plan of care identified the MSW would "monitor monthly." 	V0552	<p>On 2/28/2012, the Area Manager reviewed the "Comprehensive Interdisciplinary Assessment and Plan of Care" policy with the Dietitian, Social Worker and Nursing Staff in reference to assessing patients' psychosocial status ongoing and timely measurements using a standardized measurement tool.</p> <p>The Clinical Manager and Home Program Manager will complete 100% chart audit of all patients' Plans of Care by 3/8/2012 to review the patient's necessary monitoring of their psychosocial status and social work interventions. Any patient/Plan of Care missing evidence of social work interactions/interventions, will be presented at the Interdisciplinary Team meeting conducted on or before 3/21/2012, including Patients # 1, #2, #3, #5, #6, #7, #12 and #15. Patient specific issues as identified will be included in the patient's specific Plan of Care. The Clinical Manager and Home Program Manager will ensure compliance by auditing 25% of all medical records</p>	03/23/2012			

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	<p>A. The plan failed to include patient specific, individualized interventions to monitor the patient's psychosocial status.</p> <p>B. The plan of care identified the patient was in need of a primary care physician and the MSW would "make referral for pt [patient] if possible."</p> <p>The record failed to evidence any follow-up regarding the identified need for a primary care physician.</p> <p>C. The record included a comprehensive interdisciplinary assessment (CIA) dated 11-1-11. The assessment identifies the patient has "depressed feeling" and is "anxious" and takes medication as needed for the anxiety.</p> <p>The plan of care failed to include interventions to address the identified depressed feelings and anxiety.</p> <p>3. Clinical record number 3 included a CIA dated 11-15-11 that identified the patient has a "depressed feeling sometimes", the patient's spouse is incarcerated, and the patient states "the treatment process is stressful. Pt does not like being dependent on machine . . . Pt struggles [with] attendance & being</p>		<p>monthly for a period of three (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 Clinical Manager 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 Area Manager 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>dependent on machine."</p> <p>The plan of care, developed by the IDT on 11-15-11, failed to address the depressed feelings and the patient's struggle with the treatment process and being dependent upon the dialysis machine.</p> <p>4. Clinical record number 5 included a plan of care developed by the IDT on 12-13-11. The plan of care identified the MSW will "monitor quarterly" with the expected outcome for the patient to "maintain present level of functioning."</p> <p>The plan of care failed to evidence patient specific, individualized interventions to monitor the patient's psychosocial status.</p> <p>5. Clinical record number 5 included a plan of care developed by the IDT on 11-15-11. The plan of care states, "SW [social worker] to monitor for changes in psychosocial status" with an expected outcome that the patient will "maintain adequate psychosocial standing."</p> <p>The plan failed to evidence patient specific, individualized interventions to monitor the patients psychosocial status.</p> <p>6. Clinical record number 6 included a</p>				

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	<p>CIA dated 10-18-11. The CIA states, "Patient lost [patent] and has relocated to live [with] [sibling] and start O/P [outpatient] dialysis treatment process."</p> <p>A. The record included a plan of care developed by the IDT on 10-18-11. The plan of care identified issues with "changes in living situation" and "insurance or financial resources." The plan identified "pt to consider counselling [sic] services for coping support for lifestyle changes & grief support."</p> <p>B. The plan failed to evidence patient specific, individualized interventions to address the identified needs.</p> <p>7. Clinical record number 7 included a CIA dated 8-10-11 that identified the patient had "CA [cancer] & starting radiation soon." The CIA identified "Pt support is limited to [patient's child] and friends at work . . . patient reports problems with short term memory . . . Patient report works a lot, not many hobbies, clean & run errands in spare time."</p> <p>A. The record included a "Multidisciplinary Support Record", signed and dated by the MSW (employee Y) on 8-10-11 that states, "Patient stated has been having some problems with</p>			
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	<p>short term memory and not sleeping . . . Patient seems depressed. [The patient] states is a little down but does not feel that is depressed."</p> <p>B. The record included a plan of care developed by the IDT on 8-10-11. The plan of care states under psychosocial status "no problems identified." The plan failed to evidence patient specific interventions to monitor the patient's psychosocial status with regards to the issues identified in the CIA.</p> <p>C. The record included a "Multidisciplinary Support Record", signed and dated by the MSW (employee Y) on 12-7-11. The note states, "Patient did ask if there is a program available to help with [the patient's] Zemplar. Worker informed patient she will check what available and assist her with application process if needed.</p> <p>1. The record failed to evidence any follow-up with regards to the assistance with the Zemplar.</p> <p>2. On 2-12-12 at 9:30 AM, observation noted the MSW interviewing the patient. The patient indicated a problem with purchasing Zemplar. The patient indicated further the patient only takes the Zemplar every other day. The</p>				

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	<p>MSW stated, "I will see if there are any programs to help with the Zemplar [financial]."</p> <p>8. Clinical record number 15 included a CIA dated 11-1-11 that states, "Pt signs off frequently due to 'anxiety attacks'/cramping. Pt prescribed Xanax 0.25 milligrams [mg] PRN [if needed] once daily." The physician [author unreadable] note included in the CIA states, "panic attacks [leads to or results in] noncompliance." The MSW (employee Y) identified the patient "has anxiety attacks and is on Xanax" and "takes meds to aid sleeping." The MSW identified the patient was not adherent to treatment.</p> <p>A. A "Multidisciplinary Comments" note, signed and dated by employee JJ on 10-31-11, states, "Pt requests off tx [treatment] early due to c/o [complaint of] anxiety. States, 'My heart is pounding out of my chest.'"</p> <p>B. The plan of care developed by the IDT on 11-1-11 identifies the patient's anxiety problem. The plan states, "Some anxiety associated with tx. Unable to complete tx at times . . . pt has been refer for psych consult."</p> <p>The plan of care failed to include</p>						

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	<p>patient specific, individualized interventions to address the identified problem with anxiety and inability to complete a full treatment.</p> <p>C. "Multidisciplinary Comments" dated 11-2-11, 11-4-11, 11-11-11, 11-22-11, 11-25-11, 12-5-11, 12-12-11, 12-26-11, 12-30-11, 1-4-12, 1-6-12, and 1-20-12, evidenced the patient had asked to sign off early and not complete the treatment.</p> <p>The record failed to evidence the plan of care had been updated to address the identified continued issues with anxiety and signing off early.</p> <p>9. The MSW (employee Y) indicated, on 2-2-12 at 10 AM, the plans of care in records numbered 1, 2, 3, 5, 6, 7, 12, and 15, did not include patient specific interventions to monitor the patient's psychosocial status and address identified needs.</p> <p>10. The facility's 2-2-11 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-138-020-091 states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Psychosocial Status. Provide necessary monitoring and social work interventions,</p>			
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	<p>including counseling services and appropriate referrals."</p> <p>11. The facility's 11-19-08 "FMS Clinical Services" policy number 138-030-010 policy states, "The dialysis facility interdisciplinary team must provide the necessary monitoring and social work interventions . . . The qualified social worker is expected to assist patients in achieving their psychological goals by providing education, counseling, and encouragement."</p>			
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V0559	<p>If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must-</p> <p>(i) Adjust the plan of care to reflect the patient's current condition;</p> <p>(ii) Document in the record the reasons why the patient was unable to achieve the goals; and</p> <p>(iii) Implement plan of care changes to address the issues identified in paragraph (b) (3)(ii) of this section.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care identified reasons for goals not met and included adjustments to the plans of care based on identified reasons in 5 (#s 2, 3, 7, 9, and 12) of 15 records reviewed creating the potential to affect all of the facility's 177 current patients.</p> <p>The findings include:</p> <p>1. Clinical record number 2 included laboratory results that identified a decrease in the patient's calcium level to below the desired level of 8.5 to 10 milligrams per deciliter (mg/dL), according the Centers for Medicare and Medicaid Services (CMS) Measurement Assessment Tool (MAT), as follows: 11-7-11: 7.5, 12-5-11: 7.4, and 1-9-12: 7.3 mg/dL.</p>	V0559	<p>The Area Manager met with the facility's Interdisciplinary Team on 2/28/2012 to review the requirements as stated in the Conditions for Coverage and detailed in Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care" FMS-CS-I-110-125A, to ensure that every patient will have a timely, complete and current Comprehensive Interdisciplinary Assessment and Plan of Care available emphasizing that each Plan of Care will be updated if expected outcomes are not achieved. The Clinical Manager and Home Program Manager or designee will complete a 100% chart review of all patients' Plans of Care on or before 3/8/2012, focusing on the patient's laboratory results and treatment adherence. Any patient found with laboratory results that do not meet their patient specific goals or having issues with treatment adherence, will be presented at the Interdisciplinary</p>	03/23/2012
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	<p>The record failed to evidence the interdisciplinary team (IDT) had identified the reasons for the decreasing levels of calcium or had adjusted the plan of care to address the identified reasons.</p> <p>2. Clinical record number 3 identified the patient consistently missed treatments and left early from treatments.</p> <p>A. The record included a "Multi-Disciplinary Comments" note dated 11-19-11 that identified the patient had requested to discontinue the treatment before the prescribed time had expired. The record included notes dated 11-23-11 and 12-10-11 that identified the same. The 12-10-11 notes, signed and dated by the medical social worker (MSW) (employee CC) states, "Patient has missed one treatment in the past 6 weeks and has had 6 shortened treatment."</p> <p>B. Treatment flow sheets, dated 1-7-12, 1-10-12, 1-12-12, 1-14-12, 1-17-12, 1-25-12, and 1-27-12, evidenced the patient had not received the physician ordered 3 hours and 30 minute treatment due to asking to come off the machine early.</p> <p>C. A treatment flow sheet dated 1-21-12 evidenced the patient did not show up for the treatment.</p>		<p>Team meeting by 3/21/2012 including Patients #2, #3, #7, #9 and #12. Patient specific issues as identified will be included in the patient's specific Plan of Care. All members of the IDT, including the Dietitian and Social Worker, will review specific patient issues on a monthly basis. Any patient who is not meeting one or more of his/her specific goals, including laboratory results and treatment adherence, will be included on a monthly list of patients. The Clinical Manager will include patients on the list on the agenda for review by the Interdisciplinary team at the monthly care plan meeting for the purpose of making an adjustment to the Plan of Care. Recommendations of the IDT and actions taken monthly will be documented in each patient's specific Plan of Care update/progress note section. Monthly monitoring of all Plans of Care completed that month will be done by the Clinical Manager and Home Program Manager, to ensure that patients not meeting a goal have been identified, are addressed and Plans of Care are being updated timely and appropriately. Any patient's Plan of Care found out of compliance will be scheduled for completion within the next 30 days and corrective action will be taken as appropriate. The Clinical Manager and Home Program Manager will ensure ongoing compliance by</p>		

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	<p>D. The record failed to evidence the IDT had identified the reasons why the patient had missed treatment and cut treatments short and failed to adjust the plan of care to address any identified reasons.</p> <p>3. Clinical record number 7 included laboratory results that identified a decrease in the patient's calcium level to below the desired level of 8.5 to 10 milligrams per deciliter (mg/dL), according to the CMS MAT, as follows: 11-8-11: 8.0, 12-6-11: 8.0, and 1-10-12: 8.0 mg/dL.</p> <p>The record failed to evidence the interdisciplinary team (IDT) had identified the reasons for the decreased levels of calcium or had adjusted the plan of care to address the identified reasons.</p> <p>4. Clinical record number 9 included laboratory results that identified the patient's potassium level was above the desired value of 3.5 to 5.5 milliequivalents per liter (mEq/L) according to the CMS MAT as follows: 12-6-11: 6.1, 1-10-12: 6.6, 1-17-12: 6.3, 1-24-12: 5.8, and 1-31-12: 6.0 mEq/L.</p> <p>The record failed to evidence the IDT</p>		<p>auditing 25% of all medical records monthly for a period of three (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. The Clinical Manager is responsible to analyze and trend all data and monitor/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee for oversight and review. The Area Manager 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.</p>				

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	<p>had identified the reasons for the increased potassium levels or had adjusted the plan of care to address the identified reasons.</p> <p>5. Clinical record number 12 included laboratory results that identified the patient's albumin level was below the desired value of 4.0 mg/dL according to the CMS MAT as follows: 9-2-11: 3.5, 10-7-11: 3.5, 11-3-11: 3.3, 12-1-11: 3.6, and 1-5-12: 3.4.</p> <p>The record failed to evidence the IDT had identified the reasons for the continued decreased albumin levels or had adjusted the plan of care to address the identified reasons.</p> <p>6. The clinic manager, employee C, was unable to provide any additional documentation and/or information regarding these findings when asked on 2-7-12 at 9:15 AM and 2-8-12 at 9:20 AM and also just prior to the exit conference on 2-8-12 at 1:30 PM.</p> <p>7. The home program director, employee DD, was unable to provide any additional documentation and/or information regarding this finding when asked on 2-6-12 at 4:50 PM and just prior to the exit conference on 2-8-12 at 1:30 PM.</p>			
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	8. The facility's 2-2-11 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-138-020-091 states, "Failure to Achieve Plan of Care Outcome . . . 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 the Plan of Care changes to address the identified issues."			
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V0562	<p>The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care addressed identified educational needs in 6 (#s 2, 3, 9, 11, 13, and 15) of 15 records reviewed creating the potential to affect all of the facility 177 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 2 included a plan of care developed by the interdisciplinary team (IDT) on 11-1-11 that identified additional education was needed in the following subject areas: dialysis experience, dietary management, fluid management, and medication regime adherence. <p>The plan failed to include patient specific, individualized interventions to address the identified educational needs.</p> <ol style="list-style-type: none"> 2. Clinical record number 3 included a plan of care developed by the IDT on 11-15-11 that identified additional education was needed in the following 	V0562	<p>The Area Manager met with the facility's Interdisciplinary Team on 2/28/2012 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care", FMS-CS-I-110-125A, to ensure that every patient will have a timely, complete and current Comprehensive Interdisciplinary Assessment and Plan of Care completed and available within their medical record that meets all criteria including education specific to dialysis experience, dialysis management, infection prevention, personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation and the benefits and risks of various vascular access types.</p> <p>The Clinical Manager and Home Program Manager will complete 100% review of all patients' Plans of Care on or before 3/8/2012 to ensure that all Plans of Care due are complete, current and that educational needs are identified with appropriate interventions provided. Any patient's Plan of</p>	03/23/2012			

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	<p>subject areas: dialysis experience, fluid management, medication regime adherence, quality of life, self care options, rehabilitation, attendance/shortening of treatments, and eating on treatment.</p> <p>The plan failed to include patient specific, individualized interventions to address the identified educational needs.</p> <p>3. Clinical record number 9 included a plan of care developed by the IDT on 9-21-11 that identified additional education was needed in the following subject areas: dialysis experience, fluid management, medication regime adherence, infection prevention/personal care, and quality of life.</p> <p>The plan failed to include patient specific, individualized interventions to address the identified educational needs.</p> <p>4. Clinical record number 11 included a plan of care developed by the IDT on 12-19-11 that identified additional education was needed in the following subject area: infection prevention/personal care.</p> <p>The plan failed to include patient specific, individualized interventions to address the identified educational needs.</p>		<p>Care found to be out of compliance will be presented to the IDT for completion by 3/21/2012, including Patients #2, #3, #9, #11, #13 and #15.</p> <p>The Clinical Manager and Home Program will initiate the use of the Patient Education Record with each initial, 90 day reassessment and annual Plan of Care with each discipline to track education updates and identify patients whose Plan of Care identified issue requiring additional education needs.</p> <p>Monthly monitoring of all Plans of Care completed that month will be done by the Clinical Manager and Home Program Manager, to ensure that patients' educational needs are being addressed and Plans of Care are updated timely and appropriately. Any patient's Plan of Care found out of compliance with education will be scheduled for completion within the next 30 days and corrective action will be taken as appropriate.</p> <p>The Clinical Manager and Home Program Manager will ensure ongoing compliance by auditing 25% of all medical records monthly for a period of three (3) months focusing on all patients' educational needs. Frequency of ongoing monitoring will be determined by the QAI Committee based on resolution of</p>				

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	<p>5. Clinical record number 13 included a plan of care developed by the IDT on 11-9-11 that failed to address education and training for the patient and/or family members. The "Patient Education" portion of the plan of care had not been completed.</p> <p>6. Clinical record number 15 included a plan of care developed by the IDT on 11-1-11 that identified additional education was needed in the following subject areas: dialysis experience, dietary management, fluid management, medication regime adherence, infection prevention / personal care, quality of life, diabetes self management to include diet, exercise, and foot checks.</p> <p>The plan failed to include patient specific, individualized interventions to address the identified educational needs.</p> <p>7. The clinic manager, employee C, was unable to provide any additional documentation and/or information regarding these findings when asked on 2-7-12 at 9:15 AM and 2-8-12 at 9:20 AM and also just prior to the exit conference on 2-8-12 at 1:30 PM.</p> <p>8. The home program director, employee DD, was unable to provide any additional</p>		<p>the issues.</p> <p>The Clinical Manager is responsible to report a summary of findings monthly utilizing the tracking tool as noted above to identify the number of Plans of Care that do not include specific patient education. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring.</p> <p>The Area Manager 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 and Governing Body.</p>				

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	<p>documentation and/or information regarding this finding when asked on 2-6-12 at 4:50 PM and just prior to the exit conference on 2-8-12 at 1:30 PM.</p> <p>9. The facility's 2-2-11 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-138-020-091 states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Patient Education and Training. Include education and training for patients and family members or caregivers as applicable."</p>			
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V0587	<p>The dialysis facility must -</p> <p>(2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and</p> <p>(3) Maintain this information in the patient ' s medical record.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure home patient records included self-monitoring records in 1 (# 12) of 4 home records reviewed creating the potential to affect all of the facility's 40 home dialysis patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 12 evidenced the patient was a home peritoneal dialysis patient. The record failed to include any self-monitoring records. 2. During an observation, on 2-3-12 at 9:30 AM, of the medical social worker (employee Y) interviewing the patient, the patient stated, "I don't bring my logs in. Most of the time I don't even keep the logs. I am too rushed because I do one exchange at work over lunch." 3. The home program director, employee DD, was unable to provide any additional documentation and/or information regarding this finding when asked on 2-6-12 at 4:50 PM and just prior to the 	V0587	<p>The Area Manager met with the facility's patient care staff on 2/28/2012 to review their requirements as stated in the Conditions for Coverage and detailed in Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care", to ensure that every home patient's home record sheets will be reviewed at least every two months with documentation showing the review was completed.</p> <p>The Home Program Manager will complete 100% chart audit of all patient's monthly visit sheets by 3/8/2012 to ensure that all patients have documentation showing that their home record sheets have been reviewed at a minimum of every two months. Any patient found out of compliance will be reviewed at the next monthly clinic visit.</p> <p>The Home Program Manager is responsible to report a summary of findings monthly utilizing the medical record audit tool to the QAI committee. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new</p>	03/23/2012			

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	exit conference on 2-8-12 at 1:30 PM. 4. The facility's 10-21-09 "Patient Home Record Keeping" policy number FMS-CS-HT-200-010A states, "Copies of the Home Treatment log will be kept in the patient medical record."		Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.		

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V0638	<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.</p> <p>Based administrative record and facility policy review and interview, the facility failed to ensure its quality assurance performance improvement (QAPI) program had implemented a plan for improvement of an identified medical error in 6 (August, September, October, November, and December 2011 and January 2012) of 6 months reviewed creating the potential to affect all of the facility's 177 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The facility's 10-06-08 "Quality Assessment and Performance Improvement (QAPI) Program" policy number FMS-138-010-007 states, "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. Elements to be reviewed in the QAI meeting include . . . Patient Safety." 2. The facility's QAPI committee meeting minutes failed to evidence the facility had implemented a plan, monitored the progress, and made adjustments as 	V0638	<p>On 2/28/2012, the Area Manager had 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, analysis, trending and creating a plan <p>The Clinical Manager 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 Area Manager 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>	03/08/2012	

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	<p>necessary to address the wrong dialyzer being used on patients. The meeting minutes identified the following:</p> <p>A. QAPI meeting minutes dated 8-29-11 evidenced 1 incorrect dialyzer.</p> <p>B. QAPI meeting minutes dated 9-21-11 evidenced 5 incorrect dialyzers.</p> <p>C. QAPI meeting minutes dated 10-18-11 failed to address incorrect dialyzers. The facility's "QAI Adverse Event Report Log/Plan" identified there were 2 instances of incorrect dialyzers during the month of September 2011.</p> <p>D. QAPI meeting minutes dated 11-15-11 evidenced 5 incorrect dialyzers.</p> <p>E. QAPI meeting minutes dated 12-13-11 evidenced 4 incorrect dialyzers.</p> <p>F. QAPI meeting minutes dated 1-25-12 evidenced 2 incorrect dialyzers.</p> <p>3. The facility administrator, employee C, stated, on 2-8-12 at 11:25 AM, "There is no action plan or analysis of incorrect dialyzers documented. The corporate people identified the same thing when they did their review."</p>			
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