

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152549	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 04/25/2016
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NAME OF PROVIDER OR SUPPLIER COMPREHENSIVE RENAL CARE MUNSTER	STREET ADDRESS, CITY, STATE, ZIP CODE 9100 CALUMET AVE MUNSTER, IN 46321
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V 0000 Bldg. 00	<p>This was a Federal ESRD complaint investigation survey.</p> <p>Complaint #: IN00186071; Substantiated, Federal deficiencies related to the allegations are cited.</p> <p>Survey dates: 4/18/16, 4/19/16, 4/22/16, and 4/25/16</p> <p>Facility # : 010128</p> <p>Medicare Provider # : 152549</p> <p>Medicaid #: 200315330E</p> <p>Comprehensive Renal Care Munster was found to be out of compliance with the Conditions for Coverage: 42 CFR 494.90 Patient Plan of Care and 494.150: Responsibilities of the Medical Director.</p>	V 0000		
V 0143 Bldg. 00	<p>494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS [The facility must-] (2) Ensure that clinical staff demonstrate</p>			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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

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	<p>compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and</p> <p>Based on observation, interview, and record review, the facility failed to ensure medications were labeled with the date and time of opening and the initials of who had opened the medications for 1 of 1 facility.</p> <p>Findings</p> <p>Regarding a Medication not labeled with date and time of opening</p> <p>1. On 4/18/16 at 10:20 AM, four multi-dose opened vials of heparin, one multi-dose vial of Hectoral, and 1 multi-dose vial of Epogen were observed at the medication preparation station in the incenter hemodialysis room opened and not labeled with the time and date the medication had been opened or with the initials of who had opened the vials.</p> <p>2. On 4/18/16 at 10:25 AM, Employee A, Registered Nurse, indicated the vials were not labeled with the date and time and initials of who had opened and used the vials.</p> <p>3. The policy titled "Medication Policy" with a date of March 2016 stated, "Each vial is labeled with the initials of the</p>	V 0143	<p>V143</p> <p>Identified unlabeled medications were immediately discarded.</p> <p>Facility Administrator (FA) initiated mandatory in-service for allclinical Teammates (TMs) on 04/19/2016 and in-servicing completed 5/13/2016. In-service included but was limited to: review of Policy & Procedure # 1-06-01: Medication Policy emphasizing TMs must label each vial opened with the initials of the person opening the vial and the expiration date. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA or designee will conduct observational audits daily x 2 weeks, weekly x 2 weeks, and then monthly. FA will review results of all audits with TMs during home room meetings and with Medical Director during monthly Facility Health Meeting (FHM), minutes will reflect. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p> <p>Completion date:</p>	05/25/2016

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V 0401 Bldg. 00	<p>person opening the vial and the expiration date."</p> <p>4. During an interview on 4/22/16 at 10:30 AM, Employee C, RN, indicated Venofer should be administered slow push.</p> <p>494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.</p> <p>Based on observation, interview, and record review, the dialysis facility failed to ensure the registered nurse administered the medication according to facility policy for 1 of 2 observations of parenteral medication administration (Employee A, Registered Nurse with patient #5) on the incenter hemodialysis treatment floor.</p> <p>The findings include:</p>	V 0401	<p>05/25/2016</p> <p>V401</p> <p>FA initiated mandatory in-service for all clinical TMs on 04/19/2016 and in-servicing completed 5/24/2016. In-service included but was not limited to: review of Policy & Procedure # 1-06-01A: Preparation and Administration of Parenteral Medications (Non-Epo) with all Dialyzer Types emphasizing 1) TMs must administer IV Parenteral Medication per manufacturer specifications on package insert; 2) Per manufacturer specifications TMs must administer IV Iron (Venofer)</p>	05/25/2016

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	<p>1. The agency policy titled "Medication and Administration of Parenteral Medications [Non - Epo] with all dialyzer types" and date of February 2016 stated, "Inject medication over the time specified in the medication package insert."</p> <p>2. On 4/18/16 at 11:35 AM, Employee A, Registered Nurse, was observed to care for patient # 5 who was receiving hemodialysis at station #14 at machine #22 by administering 50 milligrams of undiluted venofer or iron sucrose into the venous line of the hemodialysis machine by intravenous push over a time span of less than 2 seconds.</p> <p>3. A document titled "Venofer [Iron Sucrose Injection] with a date of 2000 stated, "Dosage and administration Venofer must be administered intravenously either by slow injection or by infusion ... Adult patients with hemodialysis dependent - chronic kidney disease Administer Venofer 100 mg undiluted as a slow intravenous injection over 2 - 5 minutes or as an infusion of 100 mg diluted in a maximum of 100 mL [milliliter] 0.9 NaCl [sodium chloride] over a period of 15 minutes." [this document was an insert that was in the box with the Venofer medication.]</p>		<p>over time frame of 2-5minutes. Verification of attendance at in-service will be evidenced by TMsignature on in-service sheet.</p> <p>FA or designee will conduct observational audits daily x 2 weeks, weeklyx 2 weeks, and then monthly. FA will review results of all audits with TMs during home room meetings and with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p> <p>Completion date: 05/25/2016</p>	

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V 0501 Bldg. 00	<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 record review and interview, the facility failed to ensure each patient had an individualized and comprehensive assessment to meet their needs in 1 of 7 records reviewed(#3).</p> <p>The findings include:</p> <p>1. Clinical record #3 failed to evidence individualized and comprehensive assessments that addressed the patient's needs. This is evidenced by the following:</p> <p>A. An assessment and IDT (interdisciplinary) Patient Plan of Care</p>	V 0501	<p>V501</p> <p>FA held mandatory in-service for all clinical Teammates (TMs) beginning on 5/10/2016. In-service included but was not limited to: review of Policy & Procedure # 1-03-09: Intradialytic Treatment Monitoring and Policy # 1-01-02 Patient Pain Assessment. TMs instructed: 1) Significant changes in patient condition must be reported to the licensed nurse and documented; 2) Appropriate action must be taken and documented including licensed nurse assessing/evaluating patients current health status, contact physician if warranted, and follow physician orders; 3) All findings, interventions and patient response</p>	05/25/2016

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	<p>Meeting Report dated 5/20/14 and signed by the physician, social worker, nurse, and dietician evidenced the patient had a goal to meet or trend toward goal of interdialytic weight gain that was less than 5% of Estimated Dry Weight. This plan of care / comprehensive assessment document did not address any issues the patient had with pain, angina, or shortening treatments, missed treatments, and hospitalization / procedures including a low pulse and implanted pacemaker.</p> <p>B. A post - treatment flow sheet dated 10/1/14 terminated treatment early due to shoulder pain. The patient dialyzed 116 minutes instead of the prescribed 195 minutes. On the flow sheet at 7:06 PM, Employee U wrote, "No complaints ... No pain." On the flow sheet at discontinuation of treatment, Employee E, patient care technician, wrote, "PT [patient] early termination due to shoulder pain."</p> <p>1. A review of the physician and nursing progress notes failed to evidence any clinical notes regarding this shoulder pain.</p> <p>2. During an interview on 4/22/16 at 11:45 AM, Employee A, Registered Nurse, indicated the Employee U,</p>		<p>must be documented in the patient's medical record; 4) Allpatients must be assessed for pain each time they dialyze. Monthly, allpatients must receive a formalized pain screening as part of the dialysispatient assessment and documented in patient medical record. Verification ofattendance at in-service will be evidenced by TMs signature on in-servicesheet.</p> <p>FA held mandatory in-service for Interdisciplinary Team (IDT) by 05/24/2016. In-service included but was not limited to:review of Policy & Procedure #1-14-02 Patient Assessment and Plan of Carewhen Utilizing Falcon Dialysis emphasizing 1) IDT is responsible for providingeach patient with an individualized and comprehensive assessment documentinghis/her needs; 2) the comprehensive assessment must be used to develop thepatient's treatment plan and expectations for care; 3) The plan of care must specifythe services necessary to address patients' needs as identified in thecomprehensive assessment and changes in the patient's condition including painmanagement, fluid volume status, blood pressure management, psychosocial statusas measured by KDQOL, compliance with treatment regimen, frequent/extended hospitalization,and implement plan of care to address issues to achieve specified goals andmeet patient needs; 4) the plan of care must</p>		

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	<p>Registered Nurse, was no longer employed here. This nurse failed to assess the patient's pain or contact the physician about the patient's pain.</p> <p>B. A post - treatment flow sheet dated 10/3/14 evidenced the patient missed a treatment.</p> <p>C. A post treatment flow sheet dated 10/4/14 evidenced the patient missed a treatment.</p> <p>D. A post treatment flow sheet dated 10/6/14 evidenced the Estimated Dry Weight ordered was 73 kilograms. The patient's pretreatment weight was 83.3 kilograms and the post treatment weight was 79.1 kilograms.</p> <p>E. A post treatment flow sheet dated 10/8/14 evidenced Estimated Dry Weight ordered was 73 kilogram. The pretreatment weight was 83.5 kilograms and the post treatment weight was 79 kilograms</p> <p>During an interview on 4/22/16 at 12:10 PM, Employee A, Registered Nurse, indicated the patient's dry weight needed adjusting since the weights were consistently higher than the estimated dry weight.</p>		<p>include measureable and expected outcomes and estimated timetables to achieve those outcomes identified; 5) review of unstable criteria; 6) patients deemed unstable must have comprehensive assessment followed by a plan of care completed monthly until deemed stable, IDT must follow-up and readjust plan of care to address changes in patient condition, and needs; 7) stable comprehensive assessment and plan of care must reflect resolution of unstable issues. Verification of attendance in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA or designee will audit 100% patient census current IDT Assessment and Plan of Care to ensure unstable patients have current individualized comprehensive assessment and plan of care that include changes in condition, measureable outcomes, estimated timetables and resolution of any identified unstable issues.</p> <p>FA or designee to conduct daily audits on 50% of patient post treatment flow sheets x 1 month, then 10% of patient post treatment sheets monthly to ensure TMs are obtaining and documenting pre/post patient data collection, intradialytic treatment monitoring, documentation is present to support any significant changes are reported to licensed nurse, and appropriate action is taken. FA or designee will conduct a</p>				

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	<p>F. A post treatment flow sheet dated 10/14/14 evidenced the patient received Nitroglycerin 0.4 milligrams under the tongue for complaints of chest pain by Employee I, Registered Nurse. This medication for relief of chest pain was given at 7:27 AM and 7:45 AM. The doctor was not notified. At the end of treatment at 8:24 AM, Employee I assessed the patient and documented, "No complaints of ." There was no note that the family was notified of the patient's chest pain or use of nitroglycerin.</p> <p>During an interview on 4/22/16 at 12:11 PM, Employee A, Registered Nurse, indicated the physician was not contacted about the patient's chest pain.</p> <p>G. Post treatment flow sheets dated 10/15/15, 10/17/14, 10/22/14, 10/31/14, 11/3/14, 11/10/14, 11/14/14, 11/17/14, 11/23/14, 11/25/14, 11/28/14, 12/5/14, 12/21/14, 1/7/15, 1/12/15, and 1/19/15 evidenced the patient missed treatments.</p> <p>H. A hemodialysis flowsheet dated 10/20/14 evidenced the patient had requested to discontinue treatment early. The treatment was stopped after 148 minutes of the ordered 195 minutes of treatment. The pain documented on the following document was not on this flow</p>		<p>Medical Record Audit for 100% of newadmissions, 100% patients deemed unstable and 10% of current patients monthly to ensure current individualized Comprehensive Assessments and Plan of Care are in place, up-to-date, and documentation appropriate. FA will review results of all audits with TMs during home room meetings and with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p> <p>Completion date: 05/25/2016</p>				

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	<p>sheet:</p> <p>1. A clinical record document titled "Early Termination of Treatment" with a date of 10/20/14 and signature of Employee U, Registered Nurse, evidenced the following statement written by this nurse: "Prescribed treatment time: 195 minutes, Shortened Treatment time: 52 minutes, Reason ... Pain in Shoulder Blades - angina."</p> <p>2. During an interview on 4/22/16 at 12:20 PM, Employee A indicated the patient's pain was not addressed or documented on the flow sheet.</p> <p>I. A post treatment flow sheet dated 11/5/14 evidenced low heart rate through the treatment. At the beginning of treatment at 2:37 PM, the heart rate was 45 beats per minutes and through the treatment the heart rate varied from 41 - 53. 53 beats per minutes was the final pulse rate at 5:54 PM.</p> <p>J. A post treatment flow sheet dated 11/7/14 evidenced low heart rates through the treatment. Heart rate varied from 36 beats per minute to 39 beats per minute through the treatment.</p> <p>During an interview on 4/22/16 at</p>			
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	<p>12:15 PM, Employee A, Registered Nurse, indicated the cuff had needed adjusting and was changed.</p> <p>K. A post treatment flow sheet on 11/21/14 evidenced the patient complained of generalized pain and signed an against medical advice document to leave early. This was documented by Employee L, Registered Nurse. The physician was not contacted about this generalized pain. The patient had a treatment order to dialyze 195 minutes. Treatment was terminated after 163 minutes.</p> <p>A. A clinical record document titled "Early Termination of Treatment" with a date of 11/21/14 evidenced the patient had terminated treatment 32 minutes early due to generalized pain.</p> <p>B. During an interview on 4/22/16 at 11 AM, Employee A, Registered Nurse, indicated the physician notes about this generalized pain incident should be in the falcon notes.</p> <p>L. A IDT Patient Plan of care Meeting report and assessment was labeled as unstable due to hospitalization.</p>			

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	<p>The goals were marked as stable. This plan of care / assessment was completed on 12/15/14 and signed by the physician, nurse, social worker, and dietician. This plan of care did not address the patient's issues of chest pain or missed treatments. The KDQOL results were not updated on this report. This assessment / plan of care evidenced the patient had a goal to meet or trend toward goal of interdialytic weight gain that was less than 5% of Estimated Dry Weight. This plan of care / comprehensive assessment document did not address any issues the patient had with pain, angina, or shortening treatments, missed treatments, or noncompliance with treatments.</p> <p>During an interview on 4/25/16 at 11:20 AM, Employee T, RN, indicated this was the care plan developed by the comprehensive assessment.</p> <p>M. A post treatment flow sheet on 1/5/15 evidenced the patient's blood pressure was high at the assessment checks. One blood pressure was documented at 202 / 102. There was no documentation that the physician was notified. Employee L, Registered Nurse, documented this blood pressure.</p> <p>N. A post treatment flow sheet on 1/9/15 evidenced the patient was over the</p>			

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	<p>estimated dry weight at the end of treatment and that the patient only dialyzed 175 minutes due to patient request to terminate treatment early. There was no documentation about why the patient wanted to discontinue treatment early.</p> <p>During an interview on 4/22/16 at 12:40 PM, Employee A indicated that stopping treatment 15 minutes early was not a cause for alarm.</p> <p>O. A post treatment flow sheet on 1/14/15 evidenced the patient was over the estimated dry weight at the end of the treatment. The estimated dry weight was to be 76 kilograms. The patient's pretreatment weight was 83.9 kilograms and post treatment weight was 78.5 kilograms.</p> <p>P. A post treatment flow sheet on 1/16/15 evidenced the patient was over the estimated dry weight at the end of the treatment. The estimated dry weight was to be 76 kilograms. The patient's pretreatment weight was 82.3 kilograms and post treatment weight was 77.5 kilograms.</p> <p>During an interview on 4/22/16 at 1:45 PM, Employee A, Registered Nurse, evidenced the patient's weight was not</p>			

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	<p>adjusted immediately especially after hospitalizations.</p> <p>2. The records of Patient #3 were obtained from the hospital where several inpatient hospital stays and the patient's death occurred. Below is a summary of these occurrences with a brief synopsis of the dates, diagnoses, and other information from these stays:</p> <p>A. 10/22/14 -10/26/14. A hospital encounter occurred on 10/22/14 with a discharge date of 10/26/16. The patient entered the hospital through the emergency room with an admitting diagnosis of acute coronary syndrome, chest pain, and chronic renal failure. The emergency room nurse documented, "Pt [patient] presents to ED [emergency department] with CP onset last noc [night]. + SOB [shortness of breath]. +accessory muscle use. Pt actively vomiting in triage. + dizziness. Lab values on 10/22/14 evidenced the following: Potassium level was 5.8. Phosphorus level was 8.5. The chest X-ray on 10/22/14 showed cardiomegaly. The patient's physician, Employee R, was notified and consulted for medication use including nitroglycerin, heparin, and morphine. Myocardial damage was detected on 10/22/14. The discharge diagnoses included acute myocardial</p>			

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	<p>infarction, end stage renal disease, acute on chronic combined systolic and diastolic heart failure, hypertensive heart and kidney disease, and chronic respiratory failure. Procedure: On 10/22/14, hemodialysis per Dr. [employee R]. An EKG report dated 10/22/14 documented sinus tachycardia and left bundle branch block. On 10/23/14, the physician documented the patient had hyperkalemia or high potassium level in the blood. A document on 10/23/14 at 8:29 AM, evidenced after hemodialysis in hospital, the patient improved when 3 liters of fluid were removed.</p> <p>B. 11/3/14. A hospital emergency room visit on 11/3/14 evidenced Patient #3 entered the ED on 11/3/14 with complaint of blister -like wound to left great medial toe for the past two days. Encounter diagnosis on 11/3/14 included a blister on the left great toe, toe fracture closed, initial encounter, and left foot fracture, closed. Discharge occurred the same day.</p> <p>C. 11/10/14 - 11/14/14. A hospital emergency room visit on 11/10/14 evidenced Patient #3 entered the emergency room via car from home. Diagnoses found at this visit included bradycardia, other second degree</p>			

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	<p>atrioventricular block, end stage renal disease, unspecified hypertensive heart and kidney disease with heart failure and chronic kidney disease stage V, other ascites, diabetes mellitus, and hyperkalemia. Upon admission into the ER, patient was complaining of chest pain, abdominal pain, and vomiting for 3 days. The patient's informal caregiver reported heart rate had been in the 30's for several days and this was a new symptom. An EKG strip showed the patient had a bradycardiac rhythm or slow heart heart in the upper 30's and low 40s. The final diagnoses from this visit included second degree atrioventricular block. The patient had a pacemaker implanted on 11/11/14. The patient's lab draw on 11/10/14 showed high levels of phosphorus, potassium, and calcium. The history and physical conducted by the physician evidenced the patient was noncompliant with ESRD dialysis treatment regimen.</p> <p>D. 11/20/14 - 11/20/14 A hospital admit occurred on 11/20/14 with a referral from the physician. Labs were conducted on this date. The potassium level was within the reference range with a diagnosis of other complications due to renal dialysis device, implant, or graft and discharge diagnosis was ESRD. There was an X-ray of a nonfunctioning</p>			

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	<p>tunneled HD (hemodialysis) catheter.</p> <p>E. 11/21/14 - 11/21/14. A hospital admit occurred on 11/21/14 with a referral from a physician. One admitting diagnosis was other complications due to renal dialysis device, implant, and graft. Discharge diagnosis was ESRD and to receive follow - up care at the HD center. The history and physical showed a nonfunctioning HD catheter. The patient received a hemodialysis catheter exchange procedure on this day.</p> <p>F. 11/22/14 - 11/26/14. The patient was admitted through the emergency room and had come from home via care with a diagnosis of acute coronary syndrome. Hospital documentation on 11/20/14 7:40 AM from the emergency room nurse stated, "PT. states has had chest pain since dialysis yesterday - much worse tonight - diaphoretic, nauseated, mid chest pressure skin is ashen in color, [oxygen saturation rate] 81% ra [room air]. The discharge summary from the physician evidenced discharge diagnoses of acute coronary syndrome, chronic kidney disease requiring hemodialysis, acute exacerbation of congestive heart failure, acute respiratory failure with hypoxia secondary to fluid overload - better after dialysis. Potassium level on 11/22 and 11/23/14 were normal.</p>			

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	<p>Calcium levels were also normal. Phosphorus levels were elevated. Hemoglobin levels were low on 11/22/14 and 11/23/14.</p> <p>G. 12/5/14 - 12/8/14. The patient was admitted through the emergency room via car from home with vomiting, abdominal pain, shortness of breath, and diarrhea. The patient's admitting diagnoses were pulmonary edema and dyspnea, and gastrointestinal concerns. On 12/5/14 and 12/6/14, the potassium levels were normal. Calcium levels were elevated on 12/5/14 and normal on 12/6/14. Hemoglobin levels were lower than the normal range. The physician's impression at the end of this hospital stay on 12/7/14 stated, "Nausea, vomiting, and diarrhea which seems to have resolved, 2. Probably diabetic gastroparesis ... prior pacemaker implantation."</p> <p>H. 1/20/15. The patient was admitted through the emergency room at 7:06 AM and expired at 10:34 AM with final diagnoses of cardiac arrest, cardiac dysrhythmia, hyperpotassemia, unspecified essential hypertension, Type 2 Diabetes, Congestive heart failure, hyperlipidemia, and coronary atherosclerosis.</p>			

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V 0502 Bldg. 00	<p>3. The policy titled "Patient Assessment and Plan of Care when utilizing Falcon Dialysis" with a date of October 2015 stated, "The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment documenting his / her needs. The comprehensive assessment will be used to develop the patient's treatment plan and expectations for care ... assessment criteria will include, but not be limited to, evaluation of current health status and medical condition, including co - morbid conditions, dialysis prescription, blood pressure, and fluid management needs ... A comprehensive re - assessment of each patient and a revision in the plan of care will be conducted ... at least monthly for unstable patients including ... extended or frequent hospitalizations, marked deterioration in health status."</p> <p>494.80(a)(1) PA-ASSESS CURRENT HEALTH STATUS/COMORBIDS The patient's comprehensive assessment must include, but is not limited to, the</p>			

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	<p>following:</p> <p>(1) Evaluation of current health status and medical condition, including co-morbid conditions.</p> <p>Based on record review and interview, the facility failed to ensure the comprehensive assessment accurately and comprehensively addressed the patient's current health status in 1 of 7 records reviewed (#3).</p> <p>The findings include:</p> <p>1. Clinical record #3 failed to evidence the comprehensive assessment dated 12/15/14 accurately addressed the patient's current health status for the months prior the completion of this assessment and the last assessment prior which was dated 6/24/14. The patient missed many treatments from 10 /1 - 12/15/14. The patient had episodes of chest pain, shoulder pain, generalized pain, a blister on the left great toe, and diarrhea during this time. Several treatments were shortened due to the patient's complaints of pain / discomfort. The patient took nitroglycerin. Hospital records show the patient had a heart attack, pacemaker implantation, and other hospitalizations. These concerns were not discussed on the comprehensive</p>	V 0502	<p>V502</p> <p>FA held mandatory in-service for all clinical TMs beginning on 5/10/2016. In-service included but was not limited to: review of Policy & Procedure #1-03-09: Intradialytic Treatment Monitoring and Policy # 1-01-02 Patient Pain Assessment. TMs instructed: 1) Significant changes inpatient condition must reported to the licensed nurse and documented; 2) Appropriate action must be taken and documented including licensed nurse assessing/evaluating patients current health status, contact physician if warranted, and follow physician orders; 3) All findings, interventions and patient response must be documented in the patient's medical record; 4) All patients must be assessed for pain each time they dialyze. Monthly, all patients must receive a formalized pain screening as part of the dialysis patient assessment and documented in patient medical record. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA held mandatory in-service for IDT by 05/24/2016. In-service included but was not limited to: review of Policy & Procedure</p>	05/25/2016

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	<p>assessment in December 2014. This is evidenced by the following flow sheets, comprehensive assessment and hospitalization records.</p> <p>A. A hemodialysis flow sheet dated 10/1/14 evidenced the patient wanted to discontinue treatment early due to shoulder cramping and treatment was discontinued after 116 minutes instead of the ordered 195 minutes.</p> <p>B. Missed visits were documented including 10/3/14, 10/4/14, 10/13/14, 10/15/14, 10/17/14, 10/22/14, 10/31/14, 11/3/14, 11/10/14, 11/17/14, 11/25/14, 11/28/14, and 12/5/14.</p> <p>C. A hemodialysis flow sheet dated 10/14/14 evidenced the patient had severe chest pain and received 2 nitroglycerin tablets under the tongue during the treatment time.</p> <p>D. A hemodialysis flowsheet dated 10/20/14 evidenced the patient had requested to discontinue treatment early. The treatment was stopped after 148 minutes of the ordered 195 minutes of treatment. The pain documented on the following document was not on this flow sheet:</p> <p>1. A clinical record document</p>		<p>#1-14-02 Patient Assessment and Plan of Care when Utilizing Falcon Dialysis emphasizing IDT is responsible for providing each patient with an individualized and comprehensive assessment documenting his/her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care. Assessment must include evaluation of current health status and medical conditions including evaluation of pain, fluid volume status, blood pressure, and psychosocial status as measured by KDQOL, compliance with treatment regimen, frequent/extended hospitalization, and implement plan of care to address issues to achieve specified goals and meet patient needs. Verification of attendance to in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA or designee to conduct daily audits on 50% of patient post treatment flow sheets x 1 month, then 10% of patient post treatment sheets monthly to ensure TMs are obtaining and documenting pre/post patient data collection, intradialytic treatment monitoring, documentation is present to support any significant changes are reported to licensed nurse, and appropriate action is taken. FA or designee will conduct a Medical Record Audit for 100% of new admissions, 100% patients deemed unstable and 10% of current patients monthly to ensure current</p>	

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	<p>titled "Early Termination of Treatment" with a date of 10/20/14 and signature of Employee U, Registered Nurse, evidenced the following statement written by this nurse: "Prescribed treatment time: 195 minutes, Shortened Treatment time: 52 minutes, Reason ... Pain in Shoulder Blades - angina."</p> <p>2. During an interview on 4/22/16 at 12:20 PM, Employee A indicated the patient's pain was not addressed or documented on the flow sheet and the physician was not notified.</p> <p>E. A physician's physical exam dated 10/29/14 evidenced the patient had a recent hospitalization with acute coronary syndrome, hyperkalemia, and congestive heart failure.</p> <p>F. A hemodialysis flowsheet dated 11/5/14 evidenced the patient had a very low pulse rate: 41 - 53 beats per minute during the hemodialysis treatment.</p> <p>G. A hemodialysis flow sheet dated 11/21/14 evidenced the patient asked to discontinue treatment early.</p> <p>H. A clinical record document titled "Early Termination of Treatment" with a date of 11/21/14 evidenced the patient left treatment early due to generalized</p>		<p>individualized Comprehensive Assessments and Plan of Care are in place, up-to-date, and documentation appropriate. FA will review results of all audits with TMs during home room meetings and with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p> <p>Completion date: 05/25/2016</p>		

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	<p>pain.</p> <p>I. A clinical record document titled "Early Termination of Treatment" with a date of 11/29/14 evidenced the patient left treatment early to go home due to diarrhea.</p> <p>J. A document titled "IDT [Interdisciplinary] Patient Plan of Care [plan of care] meeting report ... Assessment" with a date of 12/15/14 failed to evidence comprehensive assessment assessed the patient's hospitalizations, cardiac conditions including a recent pacemaker implantation, wound on toe, diarrhea, and pain including cardiac pain that occurred in October and November. The patient had missed treatments due to hospitalizations and also shortened treatments due to leaving early and these reasons for these hospitalizations and shortened treatments were not addressed on the comprehensive assessment.</p> <p>Hospital Stay Records K - Q</p> <p>K. 10/22/14 -10/26/14. A hospital encounter occurred on 10/22/14 with a discharge date of 10/26/16. The patient entered the hospital through the emergency room with an admitting diagnosis of acute coronary syndrome,</p>			

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	<p>chest pain, and chronic renal failure. The emergency room nurse documented, "Pt [patient] presents to ED [emergency department] with CP onset last noc [night]. + SOB [shortness of breath]. +accessory muscle use. Pt actively vomiting in triage. + dizziness. Lab values on 10/22/14 evidenced the following: Potassium level was 5.8. Phosphorus level was 8.5. The chest X-ray on 10/22/14 showed cardiomegaly. The patient's physician, Employee R, was notified and consulted for medication use including nitroglycerin, heparin, and morphine. Myocardial damage was detected on 10/22/14. The discharge diagnoses included acute myocardial infarction, end stage renal disease, acute on chronic combined systolic and diastolic heart failure, hypertensive heart and kidney disease, and chronic respiratory failure. Procedure: On 10/22/14, hemodialysis per Dr. [employee R]. An EKG report dated 10/22/14 documented sinus tachycardia and left bundle branch block. On 10/23/14, the physician documented the patient had hyperkalemia or high potassium level in the blood. A document on 10/23/14 at 8:29 AM, evidenced after hemodialysis in hospital, the patient improved when 3 liters of fluid were removed.</p>			

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	<p>L 11/3/14. A hospital emergency room visit on 11/3/14 evidenced Patient #3 entered the ED on 11/3/14 with complaint of blister -like wound to left great medial toe for the past two days. Encounter diagnosis on 11/3/14 included a blister on the left great toe, toe fracture closed, initial encounter, and left foot fracture, closed. Discharge occurred the same day.</p> <p>M. 11/10/14 - 11/14/14. A hospital emergency room visit on 11/10/14 evidenced Patient #3 entered the emergency room via car from home. Diagnoses found at this visit included bradycardia, other second degree atrioventricular block, end stage renal disease, unspecified hypertensive heart and kidney disease with heart failure and chronic kidney disease stage V, other ascites, diabetes mellitus, and hyperkalemia. Upon admission into the ER, patient was complaining of chest pain, abdominal pain, and vomiting for 3 days. The patient's informal caregiver reported heart rate had been in the 30's for several days and this was a new symptom. An EKG strip showed the patient had a bradycardiac rhythm or slow heart heart in the upper 30's and low 40's. The final diagnoses from this visit included second degree atrioventricular block. The patient had a pacemaker</p>			

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	<p>implanted on 11/11/14. The patient's lab draw on 11/10/14 showed high levels of phosphorus, potassium, and calcium. The history and physical conducted by the physician evidenced the patient was noncompliant with ESRD dialysis treatment regimen.</p> <p>N. 11/20/14 - 11/20/14 A hospital admit occurred on 11/20/14 with a referral from the physician. Labs were conducted on this date. The potassium level was within the reference range with a diagnosis of other complications due to renal dialysis device, implant, or graft and discharge diagnosis was ESRD. There was an X-ray of a nonfunctioning tunneled HD (hemodialysis) catheter.</p> <p>O. 11/21/14 - 11/21/14. A hospital admit occurred on 11/21/14 with a referral from a physician. One admitting diagnosis was other complications due to renal dialysis device, implant, and graft. Discharge diagnosis was ESRD and to receive follow - up care at the HD center. The history and physical showed a nonfunctioning HD catheter. The patient received a hemodialysis catheter exchange procedure on this day.</p> <p>P. 11/22/14 - 11/26/14. The patient was admitted through the emergency room and had come from home via care</p>			

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	<p>with a diagnosis of acute coronary syndrome. Hospital documentation on 11/20/14 7:40 AM from the emergency room nurse stated, "PT. states has had chest pain since dialysis yesterday - much worse tonight - diaphoretic, nauseated, mid chest pressure skin is ashen in color, [oxygen saturation rate] 81% ra [room air]. The discharge summary from the physician evidenced discharge diagnoses of acute coronary syndrome, chronic kidney disease requiring hemodialysis, acute exacerbation of congestive heart failure, acute respiratory failure with hypoxia secondary to fluid overload - better after dialysis. Potassium level on 11/22 and 11/23/14 were normal. Calcium levels were also normal. Phosphorus levels were elevated. Hemoglobin levels were low on 11/22/14 and 11/23/14.</p> <p>Q. 12/5/14 - 12/8/14. The patient was admitted through the emergency room via car from home with vomiting, abdominal pain, shortness of breath, and diarrhea. The patient's admitting diagnoses were pulmonary edema and dyspnea, and gastrointestinal concerns. On 12/5/14 and 12/6/14, the potassium levels were normal. Calcium levels were elevated on 12/5/14 and normal on 12/6/14. Hemoglobin levels were lower than the normal range. The physician's</p>			

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	<p>impression at the end of this hospital stay on 12/7/14 stated, "Nausea, vomiting, and diarrhea which seems to have resolved, 2. Probably diabetic gastroparesis ... prior pacemaker implantation."</p> <p>2. During an interview on 4/25/16 at 3:15 PM, Employee A, Registered Nurse, indicated the comprehensive assessment should be a reflection of the patient's current health status.</p> <p>3. The policy titled "Patient Assessment and Plan of Care when utilizing Falcon Dialysis" with a date of October 2015 stated, "The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment documenting his / her needs. The comprehensive assessment will be used to develop the patient's treatment plan and expectations for care ... assessment criteria will include, but not be limited to, evaluation of current health status and medical condition, including co - morbid conditions, dialysis prescription, blood pressure, and fluid management needs ... A comprehensive re - assessment of each patient and a revision in the plan of care will be conducted ... at least monthly for unstable patients including ... extended or</p>			

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V 0520 Bldg. 00	<p>frequent hospitalizations, marked deterioration in health status."</p> <p>494.80(d)(2) PA-FREQUENCY REASSESSMENT-UNSTABLE Q MO In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted-</p> <p>At least monthly for unstable patients including, but not limited to, patients with the following: (i) Extended or frequent hospitalizations; (ii) Marked deterioration in health status; (iii) Significant change in psychosocial needs; or (iv) Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis. Based on record review and interview, the facility failed to ensure comprehensive assessments had been completed monthly in 1 of 2 unstable patient records reviewed (#3).</p> <p>The findings include:</p> <p>1. Clinical record #3 evidenced the date of first dialysis as 7/26/11. The patient's plans of care were listed as unstable on 4/24/14, 6/24/14, and 12/15/14. There</p>	V 0520	V520 FA held mandatory in-service for IDT by 05/24/2016. In-service includedbut was not limited to: review of Policy & Procedure #1-14-02 PatientAssessment and Plan of Care when Utilizing Falcon Dialysis emphasizing 1) IDTis responsible for providing each patient with an individualized andcomprehensive assessment documenting his/her needs, 2) the comprehensive assessmentmust be	05/25/2016	

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	<p>were no other unstable or stable care plans completed for May 2014 or July - November 2014 despite the patient's hospitalizations listed below:</p> <p>A. 10/22/14 -10/26/14. A hospital encounter occurred on 10/22/14 with a discharge date of 10/26/16. The patient entered the hospital through the emergency room with an admitting diagnosis of acute coronary syndrome, chest pain, and chronic renal failure. The emergency room nurse documented, "Pt [patient] presents to ED [emergency department] with CP onset last noc [night]. + SOB [shortness of breath]. +accessory muscle use. Pt actively vomiting in triage. + dizziness. Lab values on 10/22/14 evidenced the following: Potassium level was 5.8. Phosphorus level was 8.5. The chest X-ray on 10/22/14 showed cardiomegaly. The patient's physician, Employee R, was notified and consulted for medication use including nitroglycerin, heparin, and morphine. Myocardial damage was detected on 10/22/14. The discharge diagnoses included acute myocardial infarction, end stage renal disease, acute on chronic combined systolic and diastolic heart failure, hypertensive heart and kidney disease, and chronic respiratory failure. Procedure: On 10/22/14, hemodialysis per Dr.</p>		<p>used to develop the patient's treatment plan and expectations for care;3) The plan of care must specify the services necessary to address patients' needs as identified in the comprehensive assessment and changes in thepatient's condition, 4) the plan of care must include measureable and expectedoutcomes and estimated timetables to achieve those outcomes identified, 5)review of unstable criteria, 6) patients deemed unstable must have comprehensive assessment followedby a Plan of Care completed monthly until deemed stable; 7) stable comprehensive assessment and plan ofcare must reflect resolution of unstable issues. Verification of attendance toin-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA or designee will audit 100% patient census current IDT Assessment andPlan of Care to ensure unstable patientshave current individualized comprehensive assessment and plan of care thatinclude changes in condition, measureable outcomes, estimated timetables andresolution of any identified unstable issues. Governing Body approved additionof unstable criteria on 05/27/2016 that includes patients must be deemedunstable if meeting the following criteria: Greater than 1 missed treatment and1 hospitalization monthly or greater than 2 missed treatments monthly, minutesreflect.</p>	

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	<p>[employee R]. An EKG report dated 10/22/14 documented sinus tachycardia and left bundle branch block. On 10/23/14, the physician documented the patient had hyperkalemia or high potassium level in the blood. A document on 10/23/14 at 8:29 AM, evidenced after hemodialysis in hospital, the patient improved when 3 liters of fluid were removed.</p> <p>B. 11/3/14. A hospital emergency room visit on 11/3/14 evidenced Patient #3 entered the ED on 11/3/14 with complaint of blister -like wound to left great medial toe for the past two days. Encounter diagnosis on 11/3/14 included a blister on the left great toe, toe fracture closed, initial encounter, and left foot fracture, closed. Discharge occurred the same day.</p> <p>C. 11/10/14 - 11/14/14. A hospital emergency room visit on 11/10/14 evidenced Patient #3 entered the emergency room via car from home. Diagnoses found at this visit included bradycardia, other second degree atrioventricular block, end stage renal disease, unspecified hypertensive heart and kidney disease with heart failure and chronic kidney disease stage V, other ascites, diabetes mellitus, and hyperkalemia. Upon admission into the</p>		<p>FA or designee will conduct a Medical Record Audit for 100% of newadmissions, 100% patients deemed unstable and 10% of current patients monthly to ensure current individualized Comprehensive Assessments and Plan of Care are in place, up-to-date, and documentation appropriate. FA will review results of audits with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p> <p>Completion date: 05/25/2016</p>	

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	<p>ER, patient was complaining of chest pain, abdominal pain, and vomiting for 3 days. The patient's informal caregiver reported heart rate had been in the 30's for several days and this was a new symptom. An EKG strip showed the patient had a bradycardiac rhythm or slow heart heart in the upper 30's and low 40s. The final diagnoses from this visit included second degree atrioventricular block. The patient had a pacemaker implanted on 11/11/14. The patient's lab draw on 11/10/14 showed high levels of phosphorus, potassium, and calcium. The history and physical conducted by the physician evidenced the patient was noncompliant with ESRD dialysis treatment regimen.</p> <p>D. 11/20/14 - 11/20/14 A hospital admit occurred on 11/20/14 with a referral from the physician. Labs were conducted on this date. The potassium level was within the reference range with a diagnosis of other complications due to renal dialysis device, implant, or graft and discharge diagnosis was ESRD. There was an X-ray of a nonfunctioning tunneled HD (hemodialysis) catheter.</p> <p>E. 11/21/14 - 11/21/14. A hospital admit occurred on 11/21/14 with a referral from a physician. One admitting diagnosis was other complications due to</p>			

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	<p>renal dialysis device, implant, and graft. Discharge diagnosis was ESRD and to receive follow - up care at the HD center. The history and physical showed a nonfunctioning HD catheter. The patient received a hemodialysis catheter exchange procedure on this day.</p> <p>F. 11/22/14 - 11/26/14. The patient was admitted through the emergency room and had come from home via care with a diagnosis of acute coronary syndrome. Hospital documentation on 11/20/14 7:40 AM from the emergency room nurse stated, "PT. states has had chest pain since dialysis yesterday - much worse tonight - diaphoretic, nauseated, mid chest pressure skin is ashen in color, [oxygen saturation rate] 81% ra [room air]. The discharge summary from the physician evidenced discharge diagnoses of acute coronary syndrome, chronic kidney disease requiring hemodialysis, acute exacerbation of congestive heart failure, acute respiratory failure with hypoxia secondary to fluid overload - better after dialysis. Potassium level on 11/22 and 11/23/14 were normal. Calcium levels were also normal. Phosphorus levels were elevated. Hemoglobin levels were low on 11/22/14 and 11/23/14.</p> <p>G. 12/5/14 - 12/8/14. The patient</p>			

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	<p>was admitted through the emergency room via car from home with vomiting, abdominal pain, shortness of breath, and diarrhea. The patient's admitting diagnoses were pulmonary edema and dyspnea, and gastrointestinal concerns. On 12/5/14 and 12/6/14, the potassium levels were normal. Calcium levels were elevated on 12/5/14 and normal on 12/6/14. Hemoglobin levels were lower than the normal range. The physician's impression at the end of this hospital stay on 12/7/14 stated, "Nausea, vomiting, and diarrhea which seems to have resolved, 2. Probably diabetic gastroparesis ... prior pacemaker implantation."</p> <p>H. 1/20/15. The patient was admitted through the emergency room at 7:06 AM and expired at 10:34 AM with final diagnoses of cardiac arrest, cardiac dysrhythmia, hyperpotassemia, unspecified essential hypertension, Type 2 Diabetes, Congestive heart failure, hyperlipidemia, and coronary atherosclerosis.</p> <p>2. During an interview on 4/25/16 at 1 PM, Employee A, Registered Nurse, indicated the comprehensive assessment should be a reflection of the patient's current health status and that an unstable care plan should have been written when</p>			

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	<p>the patient had recurrent hospitalizations and serious cardiac issues.</p> <p>3. During an interview on 4/25/16 at 1:15 PM, Employee U, the medical director, indicated patient #3 should have been documented as unstable and had an updated comprehensive assessment / plan of care for an unstable patient with the chest pain, hospitalization, and cardiac concerns.</p> <p>4. The policy titled "Patient Assessment and Plan of Care When Utilizing Falcon Dialysis" with a date of October 2015 stated, "A comprehensive re - assessment of each patient and a revision in the plan of care will be conducted at least annually ... for stable patients, at last monthly for unstable patients including but not limited to patients with the following: extended or frequent hospitalizations, marked deterioration in health status, significant changes in psychosocial needs, concurrent poor nutritional status, unmanaged anemia, and inadequate dialysis."</p>			

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V 0540 Bldg. 00	494.90 CFC-PATIENT PLAN OF CARE Based on record review and interview, it was determined the facility failed to ensure plans of care were individualized to address the patients needs for 1 of 7 records reviewed including changes in the patient's condition or goals for these changes in patient's condition (see V 541); to ensure it had provided the necessary care and services to manage the patients' blood pressure and fluid volume status in 3 of 7 incenter hemodialysis records reviewed and monitored the patient's blood pressures every 30 minutes for 1 of 7 incenter hemodialysis patients (see V 543); to ensure the prescribed dialysate was used in 1 of 7 incenter hemodialysis records reviewed and the prescribed treatment time was achieved in 1 of 7 incenter hemodialysis records reviewed (See V 544); to ensure it had provided the necessary nutritional counseling services in 1 of 7 records reviewed (see V 545); and to ensure the plan of care had been updated to address identified barriers to the patient completing dialysis treatments in 1 of 7 records reviewed (see V 559).	V 0540	Condition V540 DaVita Munster takes the conditions of coverage very seriously; immediate steps were taken to ensure facility continuously assesses patient outcomes, and updates individualized patient plan of care to meet goals. These actions are outlined in depth in the POC for V541, V543, V544, V545, and V559. Governing Body (GB) meeting was held on 05/27/2016 to review the deficiencies received as a result of a survey concluded on 04/25/2016. Members of the GB including the Medical Director, FA, and Regional Operations Director (ROD) have agreed to meet weekly to monitor the facility's ongoing progress towards compliance including but not limited to: 1) IDT implements individualized plan of care with regard to dialysis prescription, assesses patient outcomes, identifies need for adjustment of patient plan of care when goals are not met, and implements changes based on patients current health status; 2) All patients BP and fluid management needs are monitored and assessed during treatment; 3) Facility process in place to safely provide patients appropriate prescribed treatment per physician orders; 4) Facility provides necessary nutritional counseling services; 5)	05/27/2016	

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V 0541 Bldg. 00	<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>494.90 POC-GOALS=COMMUNITY-BASED STANDARDS 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 record review and interview, the facility failed to ensure plans of care were individualized to address the patients needs for 1 of 7 records reviewed</p>	V 0541	<p>IDT updates plan of care to address identified barriers to patient completing dialysis treatments. GB will review FHM minutes to ensure action plans are evaluated for effectiveness, new plans developed as applicable. Once compliance is achieved, POC will be monitored during GB meeting at a minimum of quarterly. This POC will also be reviewed during FHM and the FA will report progress, as well as any barriers to maintaining compliance, with supporting documentation included in the meeting minutes. _ Completion date: 05/27/2016</p> <p>V541 FA held mandatory in-service for IDT by 05/24/2016. In-service included but was not limited to: review of Policy & Procedure</p>	05/25/2016

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	<p>(#3) including changes in the patient's condition or goals for these changes in patient's condition.</p> <p>The findings include:</p> <p>1. Clinical record #3 included a "IDT [Interdisciplinary] Patient POC Meeting Report" with a date of 12/15/14. This plan of care failed to evidence the development of any goals for the chest pain, shoulder cramping, angina, low heart rate and diagnosis of acute coronary syndrome and congestive heart failure identified on treatment flow sheets and other clinical record documents in October and November 2014.</p> <p>A. A hemodialysis flow sheet dated 10/1/14 evidenced the patient wanted to discontinue treatment early due to shoulder cramping and treatment was discontinued after 116 minutes instead of the ordered 195 minutes.</p> <p>B. Missed visits were documented including 10/3/14, 10/4/14, 10/13/14, 10/15/14, 10/17/14, 10/22/14, 10/31/14, 11/3/14, 11/10/14, 11/17/14, 11/25/14, 11/28/14, and 12/5/14.</p> <p>C. A hemodialysis flow sheet dated</p>		<p>#1-14-02 Patient Assessment and Plan of Care when Utilizing Falcon Dialysis emphasizing 1) IDT is responsible for providing each patient with an individualized and comprehensive assessment documenting his/her needs; 2) the comprehensive assessment must be used to develop the patient's treatment plan and expectations for care; 3) The plan of care must specify the services necessary to address patients' needs as identified in the comprehensive assessment and changes in the patient's condition including pain management, fluid volume status, blood pressure management, compliance with treatment regimen, frequent/extended hospitalization, and implement plan of care to address issues to achieve specified goals and meet patient needs; 4) the plan of care must include measurable and expected outcomes and estimated time tables to achieve those outcomes identified; 5) review of unstable criteria; 6) patients deemed unstable must have comprehensive assessment followed by a plan of care completed monthly until deemed stable, IDT must follow-up and readjust plan of care to address changes in patient condition, and needs; 7) stable comprehensive assessment and plan of care must reflect resolution of unstable issues. Verification of attendance to in-service will be evidenced by TMs signature on in-service sheet.</p>				

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	<p>10/14/14 evidenced the patient had severe chest pain and received 2 nitroglycerin tablets under the tongue during the treatment time.</p> <p>D. A hemodialysis flowsheet dated 10/20/14 evidenced the patient had requested to discontinue treatment early. The treatment was stopped after 148 minutes of the ordered 195 minutes of treatment. The pain documented on the following document was not on this flow sheet:</p> <p>1. A clinical record document titled "Early Termination of Treatment" with a date of 10/20/14 and signature of Employee U, Registered Nurse, evidenced the following statement written by this nurse: "Prescribed treatment time: 195 minutes, Shortened Treatment time: 52 minutes, Reason ... Pain in Shoulder Blades - angina."</p> <p>2. During an interview on 4/22/16 at 12:20 PM, Employee A indicated the patient's pain was not addressed or documented on the flow sheet and the physician was not notified.</p> <p>E. A physician's physical exam dated 10/29/14 evidenced the patient had a recent hospitalization with acute coronary syndrome, hyperkalemia, and congestive</p>		<p>FA or designee will audit 100% patient census current IDT Assessment and Plan of Care to ensure unstable patients have current individualized comprehensive assessment and plan of care that include changes in condition, measureable outcomes, estimated timetables and resolution of any identified unstable issues. Governing Body approved addition of unstable criteria on 05/27/2016 that includes patients must be deemed unstable if meeting the following criteria: Greater than 1 missed treatment and 1 hospitalization monthly or greater than 2 missed treatments monthly, minutes reflect.</p> <p>FA or designee will conduct a Medical Record Audit for 100% of new admissions, 100% patients deemed unstable and 10% of current patients monthly to ensure current individualized Comprehensive Assessments and Plan of Care are in place, up-to-date, and documentation appropriate. FA will review results of audits with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p> <p>Completion date: 05/25/2016</p>		

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	<p>heart failure.</p> <p>F. A hemodialysis flowsheet dated 11/5/14 evidenced the patient had a very low pulse rate: 41 - 53 beats per minute during the hemodialysis treatment.</p> <p>G. A hemodialysis flow sheet dated 11/21/14 evidenced the patient asked to discontinue treatment early.</p> <p>H. A clinical record document titled "Early Termination of Treatment" with a date of 11/21/14 evidenced the patient left treatment early due to generalized pain.</p> <p>2. During an interview on 4/25/16 at 1 PM, Employee A, Registered Nurse, indicated the plan of care was to assess the patient's current health needs.</p> <p>3. The policy titled "Patient Assessment and Plan of Care when Utilizing Falcon Dialysis" with a date of October 2015 stated, "The facility's interdisciplinary team will develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified in the comprehensive assessment and changes in the patient's condition and will include measurable and expected outcomes and estimated</p>			

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V 0543 Bldg. 00	<p>time tables to achieve these outcomes."</p> <p>494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status;</p> <p>Based on record review and interview, the facility failed to ensure it had provided the necessary care and services to manage the patients' blood pressure and fluid volume status in 3 (#3, #4, #6) of 7 incenter hemodialysis records reviewed and monitored the patient's blood pressures every 30 minutes for 1 of 7 incenter hemodialysis patients (#3).</p> <p>The findings include:</p> <p>Regarding the management of the patient's fluid status</p> <p>1. Clinical record #3 included physician orders dated 8/29/14 that identified the desired weight at the end of the treatment, the estimated dry weight</p>	V 0543	<p>V543</p> <p>FA held mandatory in-service for all clinical TMs beginning on 5/10/2016. In-service included review of Policy & Procedure #1-03-09 Intradialytic Treatment Monitoring, emphasizing 1) TMs must verify patient dialysis prescription, and set all treatments as prescribed. Nurses are responsible for ensuring patients receive prescribed dose of dialysis and physician orders are followed; 2) Treatment monitoring must be completed at a minimum of every 30 minutes, evaluation and documentation must include at a minimum patient's blood pressure, heart rate, blood and dialysate flows, arterial & venous pressures, fluid removal and/or replacement, vascular access status, line connections, patient status and subjective wellbeing; 3) TMs must report and document any significant changes</p>	05/25/2016

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NAME OF PROVIDER OR SUPPLIER COMPREHENSIVE RENAL CARE MUNSTER			STREET ADDRESS, CITY, STATE, ZIP CODE 9100 CALUMET AVE MUNSTER, IN 46321		
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	<p>(EDW), was 73 kilograms (kg)for flow sheets in October 2014. Hemodialysis treatment flow sheets evidenced the patient's weight was above the estimated dry weight at the end of the treatment and these EDWs had not been adjusted.</p> <p>A. A hemodialysis flow sheet dated 10/1/14 evidenced the patient's weights were 82.7 kg. at preweight at the beginning of treatment and 80.7 kg post weight at the end of treatment. The patient did not reach the desired weight at the end of the treatment.</p> <p>B. A hemodialysis flow sheet dated 10/6/14 evidenced the patient's weights were 83.3 kg. at preweight at the beginning of treatment and 79.1 kg post weight at the end of treatment. The patient did not reach the desired weight at the end of the treatment.</p> <p>C. A hemodialysis flow sheet dated 10/8/14 evidenced the patient's weights were 83.5 kg. at preweight at the beginning of treatment and 79 kg post weight at the end of treatment. The patient did not reach the desired weight at the end of the treatment.</p> <p>D. A hemodialysis flow sheet dated 10/10/14 evidenced the patient's weights were 82 kg. at preweight at the beginning</p>		<p>or indicators outside of ordered parameters to licensed nurse, licensed nurse must take appropriate action, contact physician if warranted, and follow physician orders. All findings, interventions and patient response will be documented in patient's medical record. Verification of attendance at in-service will be evidenced by TMs signature on in-servicesheet.</p> <p>FA or designee to conduct daily audits on 50% of patient post treatment flow sheets x 1 month, then 10% of patient post treatment sheets monthly to ensure TMs are obtaining and documenting pre/post patient data collection, intradialytic treatment monitoring, documentation is present to support any significant changes are reported to licensed nurse, and appropriate action is taken. FA will review results of audits with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p> <p>Completion date: 05/25/2016</p>		

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	<p>of treatment and 76.3 kg post weight at the end of treatment. The patient did not reach the desired weight at the end of the treatment.</p> <p>E. On 4/22/16 at 11:45 AM, Employee A, Registered Nurse, indicated the estimated dry weight needed an adjustment.</p> <p>2. Clinical record #4 included physician orders dated 1/15/16 that identified the desired weight at the end of the treatment, the estimated dry weight (EDW), was 47.5 kilograms (kg). Hemodialysis treatment flow sheets evidenced the patient's weight was above the estimated dry weight at the end of the treatment and these EDWs had not been adjusted.</p> <p>A. A hemodialysis flow sheet dated 4/11/16 evidenced the patient's weights were 52.2 kg at preweight at the beginning of treatment and 50.1 kg post weight at the end of treatment. The patient did not reach the desired weight at the end of the treatment.</p> <p>B. A hemodialysis flow sheet dated 4/13/16 evidenced the patient's weights were 52.2 kg at preweight at the beginning of treatment and 50.1 kg post weight at the end of treatment. The</p>			

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	<p>patient did not reach the desired weight at the end of the treatment.</p> <p>C. A hemodialysis flow sheet dated 4/15/16 evidenced the patient's weights were 52.3 kg at preweight at the beginning of treatment and 49.4 kg post weight at the end of treatment. The patient did not reach the desired weight at the end of the treatment.</p> <p>D. A hemodialysis flow sheet dated 4/18/16 evidenced the patient's weights were 52.9 kg at preweight at the beginning of treatment and 50.3 kg. post weight at the end of treatment. The patient did not reach the desired weight at the end of the treatment.</p> <p>E. A hemodialysis flow sheet dated 4/20/16 evidenced the patient's weights were 52.4 kg at preweight at the beginning of treatment and 50.5 kg post weight at the end of treatment. The patient did not reach the desired weigh at the end of the treatment.</p> <p>F. On 4/22/16 at 2:45 PM, Employee A, Registered Nurse, indicated the dry weight needed adjusted for this patient.</p> <p>3. Clinical record #6 evidenced high blood pressures on post treatment flow sheets. The doctor was not notified of</p>			

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	<p>these high blood pressures on the days that the high blood pressures occurred. The plan of care follow up notes with a trigger date of 12/11/14 evidenced the patient's goal was to to meet or trend toward goal of pre - dialysis blood pressure of less than or equal 140 / 90. This was signed and dated by the nurse on 12/11/14.</p> <p>A. A hemodialysis flow sheet dated 12/18/14 evidenced the patient had a blood pressure of 212/91, 206/99, and 208 / 98 during the patient's treatment. The physician and registered nurse were not notified of these high blood pressures.</p> <p>B. A hemodialysis flow sheet dated 12/27/14 evidenced the patient had a blood pressure of 208/104 at 10:21 AM at the time of treatment initiation. The physician was not notified and the registered nurse was not notified. At the end of treatment at 1:58 PM, the patient's blood pressure was 250 / 116. There was no documentation the physician or nurse were contacted.</p> <p>C. A hemodialysis flow sheet dated 12/29/14 evidenced the patient had a blood pressure of 215/ 110 at 9:30 AM at the time of treatment initiation. The physician was not notified. The blood</p>			

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	<p>pressure at the end of treatment was 197 / 105 at 12:57 PM. The physician was not notified.</p> <p>A progress note for the registered nurse on 12/29/14 evidenced the Employee X, Registered Nurse, had offered blood pressure to the patient at 1:20 PM. The patient had refused. There was no documentation the physician was contacted.</p> <p>D. A hemodialysis flow sheet dated 12/31/14 evidenced the patient had a blood pressure of 225/106 at 10:28 AM. The registered nurse and the physician were not notified. The blood pressure at the end of treatment was 218 / 93 at 2 PM. The registered nurse and the physician were not notified.</p> <p>E. A hemodialysis flow sheet dated 1/3/15 evidenced the patient had a blood pressure of 229/106 at 10:25 AM. The registered nurse and the physician were not notified. The blood pressure at the end of treatment was 192 /105 at 1:54 PM. The registered nurse and the physician were not notified.</p> <p>Regarding checking the blood pressure and patient status every 30 minutes</p> <p>4. Clinical record #3 failed to evidence</p>			

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	<p>the patient's blood pressure and patient statistics were assessed every 30 minutes.</p> <p>A. A hemodialysis flow sheet dated 10/10/14 evidenced the patient's blood pressure was checked at 6:35 PM. The next check was completed at 8:06 PM.</p> <p>B. During an interview on 4/22/15 at 12:10 PM, Employee A, Registered Nurse, indicated the blood pressure was not checked every 30 minutes.</p> <p>5. The agency policy titled "Patient Assessment and Plan of Care when utilizing Falcon Dialysis" with a date of October 15 stated, "The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment documenting his / her needs. The comprehensive assessment will be used to develop the patient's treatment plan and expectations for care ... The facility's interdisciplinary team will 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."</p> <p>6. The agency policy titled "Intradialytic Treatment Monitoring" with a date of</p>			

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V 0544 Bldg. 00	<p>December 2015 stated, "Treatment checks should be completed at least every 30 minutes ... The licensed nurse notifies the physician as needed of changes in patient's status."</p> <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 record review and interview, the facility failed to ensure the prescribed dialysate was used in 1 of 7 incenter hemodialysis records reviewed (#1) and the prescribed treatment time was achieved in 1 of 7 incenter hemodialysis records reviewed (#3).</p> <p>The findings include:</p> <p>1. Clinical record #1 evidenced a physician order dated 10/12/15 for the patient's dialysate to be K [potassium] 3.25 Calcium HCO3 [bicarbonate]. A post treatment flowsheet evidenced this order was not followed.</p> <p>A. A post treatment flowsheet on 4/4/16 with a treatment initiation time of 10:38 AM included a treatment note written by Employee S, Patient Care</p>	V 0544	<p>V544</p> <p>FA will hold mandatory in-service for all clinical TMs beginning 5/10/16. In-service will include review of Policy & Procedure #1-03-09 Intradialytic Treatment Monitoring, emphasizing 1) TMs must verify patient dialysis prescription, and set all treatments as prescribed. Nurses are responsible for ensuring patients receive prescribed dose of dialysis and physician orders are followed; 2) Treatment monitoring must be completed at a minimum of every 30 minutes, evaluation and documentation must include at a minimum patient's blood pressure, heart rate, blood and dialysate flows, arterial & venous pressures, fluid removal and/or replacement, vascular access status, line connections, patient status and subjective wellbeing. TMs must report</p>	05/25/2016

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	<p>Technician, stated, "Treatment initiated, 200 ml [milliliters] normal saline prime given pt [patient] on 2 K [potassium] 2.25 CA [calcium] bath. Lines are secure."</p> <p>B. A clinical record document titled "Kardex" with a print date of 4/18/16 evidenced a physician order dated 10/12/15 for the patient's dialysate to be K [potassium] 3.25 Calcium HCO₃ [bicarbonate].</p> <p>C. On 4/25/16 at 3:05 PM, Employee B, Registered Nurse, indicated the dialysate order was not followed.</p> <p>2. Clinical record #3 failed to evidence the prescribed treatment time of 195 minutes followed at a treatment on 12/10/14.</p> <p>A. A post treatment flowsheet on 12/10/16 with a treatment initiation at 4:51 PM and discontinuation at 8:28 PM evidenced the patient's treatment was 217 minutes instead of the prescribed 195 minutes.</p> <p>B. During an interview on 4/25/16 at 11:05 AM, Employee C, Registered Nurse, stated, "I am not sure why that treatment was too long."</p>		<p>and document any significant changes or indicators outside of ordered parameters and report prescribed time variances to licensed nurse, licensed nurse must take appropriate action, contact physician if warranted, and follow physician orders. All findings, interventions and patient response will be documented in patient's medical record. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA or designee to conduct daily audits on 50% of patient post treatment flow sheets x 1 month, then 10% of patient post treatment sheets monthly to ensure TMs are obtaining and documenting pre/post patient data collection, intradialytic treatment monitoring, documentation is present to support any significant changes are reported to licensed nurse, and appropriate action is taken. FA will review results of audits with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p> <p>Completion date: 05/25/2016</p>		

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V 0545 Bldg. 00	<p>3. The policy dated "Intradialytic Treatment Monitoring " dated December 2015 stated, "To provide an effective, safe and comfortable dialysis treatment to every patient in accordance with his / her individual plan of care."</p> <p>494.90(a)(2) POC-EFFECTIVE NUTRITIONAL STATUS The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate.</p> <p>Based on record review and interview, the facility failed to ensure it had provided the necessary nutritional counseling services in 1 (#5) of 7 records reviewed.</p> <p>The findings include:</p> <p>1. Clinical record #5 included plan of care follow up notes for the registered dietician on 12/23/15, 1/22/16, 2/22/16 and 2/24/16 concerning the patient's low albumin and included plan of care follow up notes for the registered dietician on 2/22/16 concerning the patient's high</p>	V 0545	<p>V545</p> <p>FA or designee will audit 100% of RD progress notes to ensure nutrition& metabolic notes are completed, up to date, and appropriate interventions are documented to meet patient needs for indicators not meeting goal.</p> <p>FA held mandatory in-service for all clinical Teammates (TMs) including Renal Dietician beginning on 05/24/2016. In-service reviewed Policy & Procedure #1-14-04 Provision of Nutrition Services, emphasizing 1) A comprehensive assessment and re-assessment of nutritional status; 2) Review of individual laboratory</p>	05/25/2016

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	<p>phosphorus. There were no other notes about the patient's nutritional status after 2/24/16.</p> <p>On 4/25/16 at 2:40 PM, Employee M, Registered Dietician, indicated there were no further progress notes after February of this year.</p> <p>2. The agency policy titled "Provision of Nutrition Services" with a date of March 2016 stated, "Review of individual laboratory nutrition report with each patient and / or caregiver at least monthly."</p>		<p>report of each patient and or caregiver at least monthly; 3) Monitor nutritional status and laboratory values to assess adherence and response to prescribed nutrition therapy and prescribed nutrition related medications; 4) Individualized education of patient and or caregiver on diet guidelines, nutrition related issues and nutrition related medications; 5) Documentation of nutritional interventions and the patients nutritional progress monthly or more frequently as needed. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA or designee will conduct falcon audits on 25% of patients monthly to ensure nutritional progress note are completed and appropriate interventions are documented to meet patient needs for indicators not meeting goal. FA will review results of audits with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p> <p>Completion date: 05/25/2016</p>	

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V 0559 Bldg. 00	<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 record review and interview, the facility failed to ensure the plan of care had been updated to address identified barriers to the patient completing dialysis treatments in 1 (# 3) of 7 records reviewed.</p> <p>The findings include:</p> <p>A. A hemodialysis flow sheet dated 10/1/14 evidenced the patient wanted to discontinue treatment early due to shoulder cramping and treatment was discontinued after 116 minutes instead of the ordered 195 minutes.</p> <p>B. Missed visits were documented including 10/3/14, 10/4/14, 10/13/14, 10/15/14, 10/17/14, 10/22/14, 10/31/14,</p>	V 0559	V559 FA will hold mandatory in-service for IDT by 05/24/2016. In-service included but was not limited to:review of Policy & Procedure #1-14-02 Patient Assessment and Plan of Carewhen Utilizing Falcon Dialysis emphasizing IDT must follow-up and readjust planof care to reflect patient's current condition, changes in patient condition,document reasons why patient unable to achieve goals, and implement changes toplan of care to address issues, and achieve specified goals. IDT must completecomprehensive reassessment, and an updated plan of care monthly on unstablepatients until deemed stable. Stable comprehensive assessment and plan of carewill reflect resolution of unstable issues. Examples given	05/25/2016	

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	<p>11/3/14, 11/10/14, 11/17/14, 11/25/14, 11/28/14, and 12/5/14.</p> <p>C. A hemodialysis flowsheet dated 10/20/14 evidenced the patient had requested to discontinue treatment early. The treatment was stopped after 148 minutes of the ordered 195 minutes of treatment. The pain documented on the following document was not on this flow sheet:</p> <p>A clinical record document titled "Early Termination of Treatment" with a date of 10/20/14 and signature of Employee U, Registered Nurse, evidenced the following statement written by this nurse: "Prescribed treatment time: 195 minutes, Shortened Treatment time: 52 minutes, Reason ... Pain in Shoulder Blades - angina."</p> <p>D. A hemodialysis flow sheet dated 11/21/14 evidenced the patient asked to discontinue treatment early. Duration of dialysis was 163 minutes.</p> <p>E. A clinical record document titled "Early Termination of Treatment" with a date of 11/21/14 evidenced the patient left treatment early due to generalized pain. The patient shortened the treatment by 32 minutes.</p>		<p>using surveyor observations of patient having ongoing non-compliance with treatment regimen by continuously signing off treatment early and plan of care did not address causative factors for early termination, barriers for patient completing dialysis treatments or interventions to increase compliance. Verification of attendance to in-service will be evidenced by TMs signature on in-servicesheet.</p> <p>FA or designee will audit 100% patient census current IDT Assessment and Plan of Care to ensure unstable patients have current individualized comprehensive assessment and plan of care that include changes in condition, measureable outcomes, estimated timetables and resolution of any identified unstable issues. Governing Body approved addition of unstable criteria on 05/27/2016 that includes patients must be deemed unstable if meeting the following criteria: Greater than 1 missed treatment and 1 hospitalization monthly or greater than 2 missed treatments monthly, minutes reflect.</p> <p>FA or designee will conduct a Medical Record Audit for 100% of new admissions, 100% patients deemed unstable and 10% of current patients monthly to ensure current individualized Comprehensive Assessments and Plan of Care are in place, up-to-date, and documentation appropriate. FA will review results</p>				

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	<p>F. A clinical record document titled "Early Termination of Treatment" with a date of 11/29/14 evidenced the patient left treatment early to go home due to diarrhea. The treatment time was shortened by 60 minutes.</p> <p>2. Clinical record #2 failed to evidence coordination and collaboration among the interdisciplinary team to implement changes to the plan of care to address the identified issues of multiple missed or shortened treatments.</p> <p>3. During an interview on 4/25/16 at 1 PM, Employee A, Registered Nurse, indicated the plan of care was to reflect the patient's current health needs.</p> <p>4. The policy titled "Patient Assessment and Plan of Care when Utilizing Falcon Dialysis" with a date of October 2015 stated, "The facility's interdisciplinary team will develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified in the comprehensive assessment and changes in the patient's condition and will include measurable and expected outcomes and estimated time tables to achieve these outcomes."</p>		<p>of audits with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p> <p>Completion date: 05/25/2016</p>	

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V 0710 Bldg. 00	<p>Based on record review and interview, it was determined the medical director failed to ensure all personnel had adhered to facility policies and procedures relative to changes in patient condition for 1 of 7 records reviewed and relative to dialysis treatment prescription delivery in 1 of 7 incenter hemodialysis records reviewed (see V 713) and to ensure the Registered Dieticians acted within the scope of the Indiana Registered Dietician Practice Act in 6 of 7 records reviewed, the physicians signed orders within 30 days as required by policy for 3 of 7 records reviewed, and the timing of Hectoral administration followed policy and pharmacy recommendations for 5 of 5 records reviewed of patients receiving hectoral and 1 of 4 Registered Dieticians had a license in Indiana (See V 715).</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to meet the requirements of this</p>	V 0710	<p>Condition V710</p> <p>DaVita Munster takes the conditions of coverage very seriously; immediate steps were taken to ensure Medical Director's active involvement and oversight regarding safe provision of care, facility processes and monitoring of ESRD services to its patients. These actions are outlined in depth in the POC for V713 and V715.</p> <p>GB meeting was held on 05/27/2016 to review the deficiencies received as a result of a survey concluded on 04/25/2016. Members of the GB including the Medical Director, FA, and ROD have agreed to meet weekly to monitor the facility's ongoing progress towards compliance including but not limited to: 1) Ensuring all TMs adhere to policies and procedures relative to changes in patient condition and dialysis treatment prescription delivery; 2) Registered Dietician (RD) is licensed and acts within scope of the Indiana Registered Dietician Practice Act; 3) Physician orders are signed within</p>	05/27/2016

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V 0713 Bldg. 00	<p>Condition for Coverage 494.150: Responsibilities of the Medical Director.</p> <p>494.150(b) MD RESP-STAFF ED, TRAINING & PERFORM Medical director responsibilities include, but are not limited to, the following: (b) Staff education, training, and performance.</p> <p>Based on record review and interview, the medical director failed to ensure all personnel had adhered to facility policies and procedures relative to changes in patient condition for 1 of 7 records reviewed (#3) and relative to dialysis treatment prescription delivery in 1 of 7 incenter hemodialysis records reviewed (#1).</p> <p>The findings include:</p>	V 0713	<p>30days; 4) Medications are administered per policy andmanufacturer package insert. GB willreview FHM minutes to ensure action plans are evaluated for effectiveness, newplans developed as applicable. Once compliance is achieved, POC will bemonitored during GB meeting at a minimum of quarterly. This POC will also be reviewed during FHM andthe FA will report progress, as well as any barriers to maintaining compliance,with supporting documentation included in the meeting minutes.</p> <p>Completion date: 05/27/2016</p> <p>V713</p> <p>FA held mandatory in-service for all clinical TMs beginning 5/10/2016.In-service included review of Policy & Procedure #1-03-09 IntradialyticTreatment Monitoring, emphasizing 1) TMs must verify patient dialysisprescription, and set all treatments as prescribed. Nurses are responsible forensuring patients receive prescribed dose of dialysis and physician orders arefollowed; 2) Treatment monitoring must be</p>	05/25/2016	

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	<p>Regarding a change in patient condition</p> <ol style="list-style-type: none"> 1. A review of patient #3's record failed to evidence patient #3's reports of chest pain which occurred on 10/14/14 and 10/20/14 were reported to the physician. 2. A post treatment flow sheet dated 10/14/14 evidenced the patient received Nitroglycerin 0.4 milligrams under the tongue for complaints of chest pain by Employee I, Registered Nurse. This medication for relief of chest pain was given at 7:27 AM and 7:45 AM. The doctor was not notified. At the end of treatment at 8:24 AM, Employee I assessed the patient and documented, "No complaints of ." During this treatment, no oxygen was administered. The blood flow rate continued at 400. 3. During an interview on 4/22/16 at 12:11 PM, Employee A, Registered Nurse, indicated the physician was not contacted about the patient's chest pain. 4. A hemodialysis flowsheet dated 10/20/14 evidenced the patient had requested to discontinue treatment early. The treatment was stopped after 148 minutes of the ordered 195 minutes of treatment. The pain documented on the following document was not on this flow 		<p>completed at a minimum of every 30minutes during, evaluation and documentation must include at a minimumpatient's blood pressure, heart rate, blood and dialysate flows, arterial & venous pressures, fluid removal and/or replacement, vascular access status, line connections, patient status and subjective wellbeing; 3) TMs must reportand document any significant changes or indicators outside of orderedparameters to licensed nurse, licensed nurse must take appropriate action, contact physician if warranted, and follow physician orders. All TMs in-service on Policy #3-02-11 Chest Pain/Angina by 5/25/2016 emphasizing a re-evaluationof caring for a patient with chest pain, documentation, and notification ofphysician. Verification of attendance at in-service will be evidenced by TMssignature on in-service sheet.</p> <p>FA or designee to conduct daily audits on 50% of patient post treatmentflow sheets x 1 month, then 10% of patient post treatment sheets monthly toensure TMs are obtaining and documenting pre/post patient data collection, intradialytic treatment monitoring, documentation is present to support anysignificant changes are reported to licensed nurse, and appropriate action istaken. FA will review results of all audits with TMs during home room meetingsand with Medical Director during monthly FHM, minutes will reflect. FHM</p>	

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	<p>sheet (see Finding #5). During this treatment, no oxygen was administered. The blood flow rate was reduced to 350 and 200 but not to 150.</p> <p>5. A clinical record document titled "Early Termination of Treatment" with a date of 10/20/14 and signature of Employee U, Registered Nurse, evidenced the following statement written by this nurse: "Prescribed treatment time: 195 minutes, Shortened Treatment time: 52 minutes, Reason ... Pain in Shoulder Blades - angina."</p> <p>6. During an interview on 4/22/16 at 12:20 PM, Employee A indicated the patient's pain was not addressed or documented on the flow sheet, and the physician was not notified.</p> <p>7. The policy titled "Intradialytic Treatment Monitoring" with a date of December 2015, "Significant changes are reported to the licensed nurse and documented. 8. Appropriate action is taken and documented, including patient response ... the licensed nurse notifies the physician as needed of changes in the patient's status. All findings will be documented in the patient's medical record."</p> <p>8. The facility procedure titled "Chest</p>		<p>minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p> <p>Completion date: 05/25/2016</p>				

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	<p>Pain / Angina" with a date of September 2014 stated, "1. Licensed Nurse Teammate assesses patient. 2. Decrease blood flow rate to 150 ml / min. 3. Administer oxygen per physician order [not to exceed 2 liters per minute]. 4. Decrease UFR ... Attach to cardiac monitor, if available. 7. Notify the physician for further orders. 8. Medicated as prescribed. 9. If pain persists, after above measures, notify the physician, discontinue treatment and arrange transport to emergency room. Notify physician if patient is transported to emergency room. 10. Reevaluate dry weight if indicated. 11. Document event, action taken, and patient response to treatment in record."</p> <p>Regarding a failure to follow the patient's prescription as ordered</p> <p>9. Clinical record #1 evidenced a physician order dated 10/12/15 for the patient's dialysate to be K [potassium] 3.25 Calcium HCO3 [bicarbonate]. A post treatment flowsheet evidenced this order was not followed.</p> <p>A. A post treatment flowsheet on 4/4/16 with a treatment initiation time of 10:38 AM included a treatment note written by Employee S, Patient Care</p>			

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V 0715 Bldg. 00	<p>Technician, stated, "Treatment initiated, 200 ml [milliliters] normal saline prime given pt [patient] on 2 K [potassium] 2.25 CA [calcium] bath. Lines are secure."</p> <p>B. A clinical record document titled "Kardex" with a print date of 4/18/16 evidenced a physician order dated 10/12/15 for the patient's dialysate to be K [potassium] 3.25 Calcium HCO3 [bicarbonate].</p> <p>10. On 4/25/16 at 3:05 PM, Employee B, Registered Nurse, indicated the dialysate order was not followed.</p> <p>11. The policy dated "Intradialytic Treatment Monitoring " dated December 2015 stated, "To provide an effective, safe and comfortable dialysis treatment to every patient in accordance with his / her individual plan of care."</p> <p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility,</p>			

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	<p>including attending physicians and nonphysician providers;</p> <p>Based on record review and interview, the medical director failed to ensure the Registered Dietician (Employees # J, K, M, P) acted within the scope of the Indiana Registered Dietician Practice Act in 6 of 7 records reviewed (#2, #3, #4, #5, #6, #7), the physicians signed orders within 30 days as required by policy for 3 of 7 records reviewed (#2, #3, #4), the timing of Hectoral administration followed policy and pharmacy recommendations for 5 of 5 records reviewed (#1, #2, #3, #5, #6) of patients receiving hectoral, and 1 of 4 Registered Dieticians had a license in Indiana (Employee J, Registered Dietician) when completing verbal orders for the facility.</p> <p>The findings include:</p> <p>Regarding Registered Dieticians acting within the scope of the Indiana Registered Dietician Practice Act</p> <p>1. On 4/22/16 at 10:45 AM (EST), an attorney from the Indiana Professional Licensing indicated it was not in the scope of practice of a RD (Registered Dietician) to accept verbal orders from physicians for medications.</p>	V 0715	<p>V715</p> <p>Indiana Registered Dietician License placed in personnel file. RegisteredDietician (RD) immediately in-serviced on 4/22/2016 concerning scope ofpractice and understands entering medication and laboratory orders are out ofthe RD scope per The Indiana Registered Dietician Practice Act. Verification ofattendance at in-service will be evidenced by TMs signature on in-servicesheet.</p> <p>All physician orders will be verified as signed and up to date;Physicians with unsigned orders will be contacted if orders are not signed. Allcredentialed physicians rounding at the Munster facility will abide by Policy#3-02-10 Physician Order Policy stating all credentialed physicians arerequired to validate their orders no later than the end of the month followingthe month that the order was given. Physicians out of compliance with thispolicy will be given a letter signed by the FA and the Medical Directorconcerning compliance with unsigned orders.</p> <p>We respectfully disagree with the deficiency cited under V715 forfailure to give Hectoral per policy and manufacturer package insert. TheHectorol® (doxercalciferol) package insert requires that doxercalciferolinjection be</p>	05/25/2016			

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	<p>2. A state of Indiana document titled "Indiana Code 25 - 14.5 Dieticians" with a date of January 2013 retrieved on 4/24/16 5 PM at http://www.in.gov/pla/files/IDCB_2013_Edition.pdf failed to evidence Registered Dietician in the state of Indiana may accept verbal orders from physicians.</p> <p>3. A policy titled "Provision of Nutrition Services" with a date of March 2016 stated, "Nutrition Services and diet counseling will be provided by a Registered Dietician." The policy did not evidence the acceptance of verbal orders by the RD.</p> <p>4. A policy titled "Teammate qualifications, licensure, and Adequate Teammate Staffing" with a date of December 2012, stated, "All dialysis facility teammates will meet the applicable scope of practice, board, and licensure requirements in effect in the State in which they are employed."</p> <p>5. A policy titled "Physician Order Policy" with a date of March 2016 stated, "Verbal orders may only be taken by registered dieticians authorized by state regulations to accept physician verbal orders."</p>		<p>administered intravenously as a bolus dose three times weekly at the end of dialysis. The package insert and the 2010 Dialysis of Drugs reference note that doxercalciferol is not removed from blood during hemodialysis. This suggests that doxercalciferol may be given anytime during dialysis. FA will hold mandatory in-service for all licensed nurses on 04/19/2016. In-service will include but will not be limited to: review of Policy & Procedure # 1-06-01A: Preparation and Administration of Parenteral Medications (Non-Epo) with all Dialyzer Types emphasizing TMs must administer IV Parenteral Medication per manufacturer specifications on package insert. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA will audit 100% of physician orders monthly to ensure orders are assigned timely. FA or designee will conduct observational audits daily x 2 weeks, weekly x 2 weeks, and then monthly. FA will review results of all audits with TMs during home room meetings and with Medical Director during monthly FHM, continued frequency of audits will be determined by team, minutes will reflect. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with</p>				

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	<p>6. Clinical record #2 evidenced verbal orders written / accepted by a Registered Dietician.</p> <p>A. The clinical record order titled "Lab Order PTH Intact" evidenced a verbal order for PTH (parathyroid hormone) Intact to be done monthly with a start date of 11/29/13 and entered by Employee K, Registered Dietician. This order was signed by Employee R, Medical Director, on 12/30/13.</p> <p>B. The clinical record order titled "Medication: Hectoral Dose 14 mcg [micrograms] with order source verbal / phone Route IV [intravenous] Push Frequency Specified by Nephrologist: 3 times a week " was entered by Employee K, Registered Dietician on 5/8/15. This was signed by Employee R, Medical Director, on 7/10/15.</p> <p>C. The clinical record order titled "Medication: Hectoral Dose 15 mcg [micrograms] with order source verbal / phone Route IV [intravenous] Push Frequency Specified by Nephrologist: 3 times a week " was entered by Employee K, Registered Dietician on 6/19/15. This was signed by Employee R, Medical Director, on 7/10/15.</p> <p>D. The clinical record order titled "Lab Order Phosphorus" with a frequency of one - time, admit and date of 6/17/15 and entered and noted by Employee K, Registered Dietician. Employee R,</p>		<p>this plan of correction</p> <p>Completion date: 05/25/2016</p>				

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	<p>Medical Director, signed this order on 7/10/15.</p> <p>E. The clinical record order titled "Medication: Hectoral Dose 16 mcg [micrograms] with order source verbal / phone Route IV [intravenous] Push Frequency Specified by Nephrologist: 3 times a week " was entered by Employee K, Registered Dietician on 10/9/15. This was signed by Employee R, Medical Director, on 10/23/15.</p> <p>F. The clinical record order titled "Lab Order Phosphorus" evidenced a verbal order for this lab draw once on 11/9/15 and entered by Employee K, Registered Dietician. This order was signed by the physician on 12/8/15.</p> <p>G. The clinical record order titled "Lab Order Phosphorus" evidenced a one time / admit order on 12/18/15 with the order entered by Employee P, Registered Dietician. This order was signed by the physician on 12/19/15.</p> <p>H. The clinical record order titled "Lab Order Calcium" evidenced a one - time, admit order on 12/18/15 entered by Employee P, Registered Dietician. This order was signed by the physician on 12/19/15.</p> <p>I. The clinical record order titled "Medication: Hectoral Dose 12 mcg [micrograms] with order source verbal / phone Route IV [intravenous] Push Frequency Specified by Nephrologist: 3</p>			

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	<p>times a week " was entered by Employee M, Registered Dietician on 3/14/16. This was signed by the physician on 3/22/16.</p> <p>7. Clinical record #3, closed record, evidenced verbal orders written / accepted by a Registered Dietician.</p> <p>A. The clinical record order titled "Protocol HD Liquacel Oral Nutrition Supplement ... Protocol ... drug: Liquacel 1 oz [ounce]" evidenced a start date of 5/20/14. This order was written / accepted by Employee K, Registered Dietician on 5/20/14 and signed by the physician on 5/30/14.</p> <p>B. The clinical record order titled "Phosphorus ... frequency one - time admit evidence a verbal order accepted and written by Employee K, Registered Dietician on 9/12/14. This was signed electronically by the physician on 9/16/14.</p> <p>C. The clinical record order titled "Medication: Hectoral Dose 4 mcg Order Source: Verbal / phone Route: IV Push Frequency specified by Nephrologist" with a start date of 8/22/14 and discontinue date of 11/8/14 evidenced a verbal order written / accepted by Employee K, Registered Dietician. This was signed by the physician on 8/11/14.</p> <p>D. The clinical record order titled "Medication: Hectoral Dose 3 mcg Order Source: Protocol Route: IV Push Frequency specified by Nephrologist"</p>			

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	<p>with a start date of 11/8/14 and discontinue date of 12/6/14 evidenced a verbal order written / accepted by Employee K, Registered Dietician. This was signed by the physician on 11/24/14.</p> <p>E. The clinical record order titled "Medication: Hectoral Dose 3.5 mcg Order Source: Protocol Route: IV Push Frequency specified by Nephrologist" with a start date of 12/7/14 and discontinue date of 1/21/15 evidenced a verbal order written / accepted by Employee K, Registered Dietician. This was signed by the physician on 12/22/14.</p> <p>8. Clinical record #4, an active record, evidenced verbal orders written / accepted by a Registered Dietician.</p> <p>A. The clinical record order titled "Hectoral 10 mcg order source: Protocol Route IV Push Frequency specified by a nephrologist 3 times per week with a start date of 2/10/16 and discontinue date of 3/11/16 evidenced a verbal order written / accepted by Employee J, Registered Dietician on 2/10/16.</p> <p>B. The clinical record order titled "Hectoral 7 mcg order source: Protocol Route IV Push Frequency specified by a nephrologist 3 times per week with a start date of 3/11/16 and discontinue date of 3/29/16 evidenced a verbal order written / accepted by Employee M, Registered Dietician on 3/11/16.</p> <p>9. Clinical record #5, active record,</p>			

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	<p>evidenced verbal orders written / accepted by a Registered Dietician.</p> <p>A. The clinical record order titled "Lab Order Glucose" with a frequency of monthly was written / entered by Employee K, Registered Dietician, on 1/14/14 and signed by the physician on 2/18/14.</p> <p>B. The clinical record order titled "Hectoral Dose 1 mcg Order source: Verbal / Phone Route: IV Push Frequency Specified by Nephrologist 3 times per week" was written / entered by Employee K, Registered Dietician on 8/7/15 and signed by the physician on 8/11/15.</p> <p>C. The clinical record order titled "Hectoral Dose 1 mcg Order Source: Protocol Route: IV Push Frequency Specified by Nephrologist 3 times per week" was written / entered by Employee K, Registered Dietician on 12/5/14 and signed by the physician on 1/15/15.</p> <p>D. The clinical record order titled "Hectoral Dose 0.5 mcg Order Source: Protocol Route: IV Push Frequency Specified by Nephrologist 3 times per week" was written / entered by Employee K, Registered Dietician on 1/10/15 and signed by the physician on 1/15/15. This had a start date of 1/10/15 and stop date of 1/14/15 and discontinue date of 1/14/15.</p> <p>E. The clinical record order titled</p>			

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	<p>"Hectoral Dose 1 mcg Order Source: Protocol Route: IV Push Frequency Specified by Nephrologist 3 times per week" was written / entered by Employee K, Registered Dietician on 8/7/15 and signed by the physician on 8/11/15. This had a start date of 8/8/15 and stop date of 1/18/16 and discontinue date of 2/18/16.</p> <p>F. The clinical record order titled "Hectoral Dose 2 mcg Order Source: Protocol Route: IV Push Frequency Specified by Nephrologist 3 times per week" was written / entered by Employee M, Registered Dietician on 2/18/16 and signed by the physician on 2/23/16. This had a start date of 2/20/16 and no stop date.</p> <p>G. The clinical record order titled "Medication: Dose: 2.5 mcg Order source: Protocol Route: IV Push Frequency Specified by a Nephrologist 3 times per week ... Order entered by Employee M, Registered Dietician on 4/21/16 ... and is not signed by the physician.</p> <p>10. Clinical record #6, closed record, evidenced verbal orders written / accepted by a Registered Dietician.</p> <p>The clinical record order titled "Hectoral Dose: 4.5 mcg Order source: Verbal / phone Route: IV push Frequency ... 3 times per week " was written / entered by Employee K,</p>			

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	<p>Registered Dietician, on 6/9/14 and signed by the physician on 6/26/14.</p> <p>11. Clinical record #7, active record, evidenced verbal orders written / accepted by a Registered Dietician.</p> <p>A. The clinical record order titled "Iron Panel " was written / entered by Employee J, Registered Dietician, on 2/16/16 and signed by the physician on 2/23/16.</p> <p>B. The clinical record order titled "Ferritin" was written / entered by Employee J, Registered Dietician on 2/15/16 and signed by physician on 2/23/16.</p> <p>12. During an interview on 4/19/16 at 3:20 PM, Employee C, Clinical services specialist, presented the following document:</p> <p>The document titled "Details" with no date stated, "Osteodystrophy Management. The renal dietician may write verbal orders within the guideline of the following standing orders: 1.) IV Vitamin D per facility protocol. 2.) Phosphorus binders: Initiation and dose adjustments in accordance to laboratory parameters and patient tolerance ... 4.) Laboratory orders: Renal osteodystrophy blood work ... Justification: Osteodystrophy Management."</p> <p>13. During an interview on 4/20/16 at 3:05 PM, Employee C, Clinical Services Specialist, indicated the state's scope of</p>			

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	<p>practice for registered dieticians should be followed and indicated concern if the registered dietician could accept verbal orders in the state.</p> <p>14. During an interview on 4/25/16 at 2:20 PM, Employee M, Registered Dietician, stated, "DaVita has a protocol for the dietician."</p> <p>Regarding physician's orders signed within 30 days</p> <p>15. Clinical record #2 evidenced orders not signed by the physician within 30 days.</p> <p>A. An order inquiry report with an order for the medication Hectoral dose 14 mcg order source verbal phone Route: IV (intravenous) Push, Frequency specified by the nephrologist with a start date of 5/8/15 and stop date of 6/19/15 was written / accepted by Employee K, Registered Dietician. This was signed by the physician on 7/10/15.</p> <p>B. An order inquiry report with an order for the medication Hectoral dose 15 mcg order source verbal phone Route: IV (intravenous) Push, Frequency specified by the nephrologist with a start date of 1/14/16 and stop date of 2/19/16 was written / accepted by Employee A, RN.</p>			

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	<p>This was signed by the physician on 3/22/16.</p> <p>16. Clinical record #3 evidenced orders not signed by the physician within 30 days.</p> <p>A. An order inquiry report with an order for "PRN [as needed] Engerix 40 mcg Route: intramuscular Start Date: 12/5/11 and discontinue date 1/21/15 with instruction to give 40 mcg IM [intramuscular] for hepatitis vaccination series of 3 at 0, 1, and 6 months and for booster as indicated by lab results" was entered and noted by Employee I, Registered Nurse, on 12/5/11. This was signed by the physician on 5/5/13 and 4/28/14.</p> <p>B. An order inquiry report with an order for PRN Nitroglycerin dose 0.4 mg Route sublingual with a start date of 12/5/11 and discontinue date of 1/21/15 and instruction for 1/150 grain prn for chest pain, may repeat X 2 for total of 3 doses. Call physician. was entered by Employee I, Registered Nurse, on 12/5/11 and signed by the physician on 5/5/13 and 4/28/14.</p> <p>C. An order inquiry report with an order for Epogen 3300 units per protocol IV push 3 times per week with a start</p>			

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	<p>date of 9/29/12 and discontinue date of 10/22/12 was written by Employee I, Registered Nurse, on 9/28/12. The physician signed this order on 5/15/13.</p> <p>D. An order inquiry report with an order for Venofer / Iron Sucrose 100 mg (milligrams) with a start date of 10/8/12 and discontinue date of 11/17/12 was signed by Employee I on 9/28/12 and the physician on 5/15/13.</p> <p>E. An order inquiry report with an order for Hectoral 1.5 mcg IV push 3 times per week with a start date of 10/8/12 and stop date of 1/1/13 was written by Employee K, Registered Dietician, on 10/8/12 and signed by the physician on 5/5/13.</p> <p>F. An order inquiry report with an order for Epogen 4400 units IV push 3 times per week with a start date of 10/22/12 and stop date of 12/10/12 by Employee I, Registered Nurse, on 10/22/12 and signed by the physician on 5/15/13.</p> <p>G. An order inquiry report with an order for Vancomycin 500 mg by IV infusion at every treatment with a start date of 10/28/12 and discontinue date of 11/5/12 was accepted by Employee T, Registered Nurse on 10/27/12 and signed</p>			

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	<p>by the physician on 5/5/13.</p> <p>H. An order inquiry report with an order for Vancomycin 750 mg by IV infusion at every treatment with a start date of 11/9/12 and discontinue date of 12/6/12 was accepted by Employee Z, Registered Nurse on 11/9/12 and signed by the physician on 5/5/13.</p> <p>17. Clinical record #4, an active record, evidenced a verbal order signed by the registered dietician which had not been signed by the physician. The clinical record order titled "Hectoral 10 mcg order source: Protocol Route IV Push Frequency specified by a nephrologist 3 times per week with a start date of 2/10/16 and discontinue date of 3/11/16 evidenced a verbal order written / accepted by Employee J, Registered Dietician on 2/10/16. This was not signed by the physician.</p> <p>18. During an interview on 4/22/15 at 1 PM, Employee B, Registered Nurse, indicated the physician orders were late.</p> <p>19. The policy titled "Physician Order Policy" with a date of March 2016 stated, "Verbal orders and orders via secure message are to be signed and dated ... on an unsigned orders report no later than the end of the following month in which</p>			

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	<p>the order was given."</p> <p>Regarding timing of Hectoral dosing as recommended by the pharmacy manufacturer and policy</p> <p>19. Clinical record #1 evidenced post treatment flow sheets for incenter hemodialysis treatments from 3/21/16 - 4/18/16. Runs in this time period failed to evidence the administration of hectoral was at the end of treatment as recommended by the pharmacy manufacturer.</p> <p>A. A post treatment flow sheet on 3/30/16 with an initiation of dialysis at 10:32 AM and discontinuation of dialysis at 1:48 PM. Hectoral 3 mcg [micrograms] IVP (intravenous push) was administered at 11:43 AM by Employee V, Registered Nurse. A 10 ml (milliliter) NS (normal saline) flush for medication was also administered.</p> <p>B. A post treatment flow sheet on 4/1/16 with an initiation of dialysis at 10:29 AM and discontinuation of dialysis at 1:48 PM. Hectoral 3 mcg IVP was administered at 10:45 AM by Employee W, Registered Nurse. A 10 ml NS flush for medication was also administered.</p>			

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	<p>C. A post treatment flow sheet on 4/4/16 with an initiation of dialysis at 10:38 AM and discontinuation of dialysis at 2:04 PM. Hectoral 3 mcg IVP was administered at 11:50 AM by Employee V, Registered Nurse. A 10 ml NS flush for medication was also administered.</p> <p>D. A post treatment flow sheet on 4/11/16 with an initiation of dialysis at 10:26 AM and discontinuation of dialysis at 1:48 PM. Hectoral 3 mcg IVP was administered at 10:38 AM by Employee X, Registered Nurse. A 10 ml NS flush for medication was also administered.</p> <p>20. Clinical record #2 evidenced post treatment flow sheets for incenter hemodialysis treatments from 3/21/16 - 4/18/16. Runs in this time period failed to evidence the administration of hectoral was at the end of treatment as recommended by the pharmacy manufacturer.</p> <p>A. A post treatment flow sheet on 3/21/16 with an initiation of dialysis at 8:57 AM and discontinuation of dialysis at 11:35 AM. Hectoral 12 mcg IVP (intravenous push) was administered at 9:33 AM by Employee V, Registered Nurse. A 10 ml NS flush for medication was also administered.</p>			

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	<p>B. A post treatment flow sheet on 3/23/16 with an initiation of dialysis at 8:36 AM and discontinuation of dialysis at 11:37 AM. Hectoral 12 mcg IVP was administered at 9:21 AM by Employee A, Registered Nurse. A 10 ml NS flush for medication was also administered.</p> <p>21. Clinical record #3 evidenced post treatment flow sheets for incenter hemodialysis treatments from 10 / 1/ 14 - 1/20/15. Runs in this time period failed to evidence the administration of hectoral was at the end of treatment as recommended by the pharmacy manufacturer.</p> <p>A. A post treatment flow sheet on 10/14/14 with an initiation of dialysis on 5:09 AM and discontinuation of dialysis at 8:24 AM. Hectoral 4 mcg IVP was given at 7:29 AM by Employee I, Registered Nurse. A 10 ml NS flush for medication was also administered.</p> <p>B. A post treatment flow sheet on 11/7/14 with an initiation of dialysis on 4:51 PM and discontinuation of dialysis at 8:17 PM. Hectoral 4 mcg IVP was given at 5:49 PM by Employee L, Registered Nurse. A 10 ml NS flush for medication was also administered.</p>			

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	<p>C. A post treatment flow sheet on 12/12/14 with an initiation of dialysis on 4:56 PM and discontinuation of dialysis at 8:17 PM. Hectoral 4 mcg IVP was given at 5:34 PM by Employee U, Registered Nurse. A 10 ml NS flush for medication was also administered.</p> <p>22. Clinical record #5 evidenced post treatment flow sheets for incenter hemodialysis treatments from 3/21/16 - 4/18/16. Runs in this time period failed to evidence the administration of hectoral was at the end of treatment as recommended by the pharmacy manufacturer.</p> <p>A. A post treatment flow sheet on 3/21/16 with an initiation of dialysis on 10:12 AM and discontinuation of dialysis at 2:03 PM. Hectoral 2 mcg IVP was given at 10:32 AM by Employee V, Registered Nurse. A 10 ml NS flush for medication was also administered.</p> <p>B. A post treatment flow sheet on 3/30/16 with an initiation of dialysis on 10:10 AM and discontinuation of dialysis at 2:13 PM. Hectoral 2 mcg IVP was given at 10:25 AM by Employee X, Registered Nurse. A 10 ml NS flush for medication was also administered.</p>			

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	<p>C. A post treatment flow sheet on 4/14/16 with an initiation of dialysis on 10:03 AM and discontinuation of dialysis at 2:08 PM. Hectoral 2 mcg IVP was given at 10:44 AM by Employee W, Registered Nurse. A 10 ml NS flush for medication was also administered.</p> <p>23. Clinical record #6 evidenced post treatment flow sheets for incenter hemodialysis treatments from 12/22/14 - 1/3/15. Runs in this time period failed to evidence the administration of hectoral was at the end of treatment as recommended by the pharmacy manufacturer.</p> <p>A post treatment flow sheet on 12/22/14 with an initiation of dialysis on 10:08 AM and discontinuation of dialysis at 1:39 PM. Hectoral 3 mcg IVP was given at 10:34 AM by Employee X, Registered Nurse. A 50 ml NS flush for medication was also administered.</p> <p>24. On 4/25/16 at 1:30 PM, the medical director indicated agreement that the package insert from the Hectoral pharmacy manufacturer stated to give Hectoral at the end of treatment.</p> <p>25. A Genzyme pharmacy manufacturer document with a date of 4/2012 and titled</p>			

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	<p>"Hectoral [doxercalciferal injection] 4 mcg / 2 ml ... 2 mcg / ml stated, "Clinical studies ... Dosing of Hectoral injection was initiated at the rate of 4 mcg administered at the end of each dialysis session ... The recommended initial dose of Hectoral is 4 mcg administered intravenously as a bolus dose three times weekly at the end of dialysis."</p> <p>26. During a phone call interview, on 5/3/16 at 5 PM, a pharmacist at Genzyme indicated there have no studies related to dosing Hectoral at other times except at the end of treatment. The package insert refers to how the drug was studied at the clinical trials.</p> <p>Regarding a Registered Dietician without a license in the state</p> <p>27. Employee J, Registered Dietician, evidenced a license pending in the state and no current registered dietician license in Indiana.</p> <p>A. A document titled "Indiana Online Licensing" with a print date of 5/11/16 failed to evidence a current licence for this employee.</p> <p>B. A policy titled "Teammate qualifications, licensure, and Adequate Teammate Staffing" with a date of</p>			

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V 0726	<p>December 2012, stated, "All dialysis facility teammates will meet the applicable scope of practice, board, and licensure requirements in effect in the State in which they are employed."</p> <p>C. Clinical record #7, active record, evidenced verbal orders written / accepted by a Registered Dietician without a license in the state.</p> <p>1. The clinical record order titled "Iron Panel " was written / entered by Employee J, Registered Dietician, on 2/16/16 and signed by the physician on 2/23/16.</p> <p>2. The clinical record order titled "Ferritin" was written / entered by Employee J, Registered Dietician on 2/15/16 and signed by physician on 2/23/16.</p>			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152549	X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	X3) DATE SURVEY COMPLETED 04/25/2016
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NAME OF PROVIDER OR SUPPLIER COMPREHENSIVE RENAL CARE MUNSTER	STREET ADDRESS, CITY, STATE, ZIP CODE 9100 CALUMET AVE MUNSTER, IN 46321
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Bldg. 00	<p>MR-COMPLETE, ACCURATE, ACCESSIBLE</p> <p>The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.</p> <p>Based on record review and interview, the facility failed to maintain pertinent and up to date records regarding two adverse events in 1 of 7 incenter hemodialysis records reviewed (#3) and charting was accurate for 1 of 7 incenter hemodialysis records reviewed (#3)</p> <p>Findings include:</p> <p>Regarding adverse events not being documented and in the record</p> <p>1. A review of patient #3's record failed to evidence patient #3's adverse events which occurred on 10/14/14 and 10/20/14 were documented as adverse events after the patient experienced chest pain followed the agency policy. Documentation was lacking for these adverse events and the physician was not notified of the incidents.</p> <p>2. A post treatment flow sheet dated 10/14/14 evidenced the patient received</p>	V 0726	<p>V726</p> <p>FA will hold mandatory in-service for all clinical TMs beginning 5/10/2016. In-service will include review of Policy & Procedure #1-03-09 Intradialytic Treatment Monitoring and Policy # 1-01-02 Patient Pain Assessment, emphasizing treatment monitoring must be completed at a minimum of every 30 minutes, evaluation and documentation must include at a minimum patient's blood pressure, heart rate, blood and dialysate flows, arterial & venous pressures, fluid removal and/or replacement, vascular access status, line connections, patient status and subjective wellbeing. All patients must be assessed for pain each time they dialyze. TMs must report and document any significant changes or indicators outside of ordered parameters and report prescribed time variance to licensed nurse, licensed nurse must take appropriate action, contact physician if warranted, and follow physician orders. All findings, interventions and patient response will be documented in</p>	05/25/2016

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	<p>Nitroglycerin 0.4 milligrams under the tongue for complaints of chest pain by Employee I, Registered Nurse. This medication for relief of chest pain was given at 7:27 AM and 7:45 AM. The doctor was not notified. At the end of treatment at 8:24 AM, Employee I assessed the patient and documented, "No complaints of ." There was no note that the family was notified of the patient's chest pain or use of nitroglycerin.</p> <p>3. During an interview on 4/22/16 at 12:11 PM, Employee A, Registered Nurse, indicated the physician was not contacted about the patient's chest pain.</p> <p>4. A hemodialysis flowsheet dated 10/20/14 evidenced the patient had requested to discontinue treatment early. The treatment was stopped after 148 minutes of the ordered 195 minutes of treatment. The pain documented on the following document was not on this flow sheet (see Finding #5).</p> <p>5. A clinical record document titled "Early Termination of Treatment" with a date of 10/20/14 and signature of Employee U, Registered Nurse, evidenced the following statement written by this nurse: "Prescribed treatment time: 195 minutes, Shortened</p>		<p>patient's medical record. Verification of attendance at in-service will be evidenced by TM signature on in-service sheet.</p> <p>FA will hold mandatory in-service for all clinical TMs beginning on 5/10/2016. In-service will include review of Policy & Procedure #13-01-02 Adverse Occurrence Reporting Policy. Education included detailed review of what events qualify as an Adverse Occurrence Report (AOR), and proper documentation of an AOR. Reinforcing that any unexpected event that is inconsistent with the routine operation of a dialysis facility may be classified as an adverse occurrence, complete list reviewed. TMs will be instructed that the AOR does not take place of documenting in the patient medical record all pertinent information that is objective information directly relevant to the care and treatment of the patient. 1) All adverse occurrences must be promptly reported to the FA; 2) The TM involved must complete the AOR as soon after the occurrence as reasonably possible but no later than at the completion of the TMs shift; 3) The TM must describe the details of the occurrence that the TM has observed and will not report opinions as to fault or liabilities or details reported to him or her by third parties; 4) The FA or designee will notify in a reasonably timely manner the patient physician and Medical</p>	

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	<p>Treatment time: 52 minutes, Reason ... Pain in Shoulder Blades - angina."</p> <p>6. During an interview on 4/22/16 at 12:20 PM, Employee A indicated the patient's pain was not addressed or documented on the flow sheet, and the physician was not notified.</p> <p>7. The policy titled "Adverse Occurrence Reporting Policy [Non teammate related]" with a date of September 2015 stated, "Any unexpected event that is inconsistent with the routine operation of a dialysis facility, routine provision of acute dialysis or ancillary renal - related services may be an adverse occurrence ... additional examples are set forth in Exhibit A ... Exhibit A Examples of Reportable Occurrences Known or suspected ... chest pain."</p> <p>8. The policy titled "Intradialytic Treatment Monitoring" with a date of December 2015, "Significant changes are reported to the licensed nurse and documented. 8. Appropriate action is taken and documented, including patient response ... the licensed nurse notifies the physician as needed of changes in the patient's status. All findings will be documented in the patient's medical record."</p>		<p>Director as applicable; 5) AORs are to be trended and reviewed at FHM. Team must review any identified underperformance and analyze to identify root causes and have action plan identified that includes a timeline and result in performance improvement, and will track change in performance over time to ensure improvements are sustained. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA or designee to conduct audits on 100% of AORs monthly. FA will gather trends for health outcomes including incidence of adverse occurrences to present in FHM. Team will investigate potential causes, contributing factors; relationship to care received at dialysis, and ensure all documentation of such investigation and resulting corrective actions are kept on file. Any identified trends will be reviewed to identify root causes, and with the identification of an action plan geared toward performance improvement. Team will track change in performance over time to ensure improvements are sustained. FA or designee to conduct daily audits on 50% of patient post treatment flow sheets x 1 month, then 10% of patient post treatment sheets monthly to ensure TMs are obtaining and documenting pre/post patient data collection, intradialytic treatment monitoring, documentation is present to support any significant changes</p>	

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	<p>Regarding accurate charting / documenting</p> <p>9. Patient #3's flowsheet for 1/9/15 evidenced bleeding location with the word, "Arterial" at the post treatment documentation.</p> <p>10. On 4/22/16 at 12:40 PM, Employee A indicated this was a typo and did not happen.</p>		<p>are reported to licensed nurse, and appropriate action is taken. FA will review results of audits with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction Completion date: 05/25/2016</p>		