STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING	X3) DATE SURVEY COMPLETED
	152585		05/01/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FRESENIUS MEDICAL CARE SHADELAND STATION	7155 SHADELAND STATION STE 130 INDIANAPOLIS, IN 46256

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V 000 Bldg. 00	This was a Federal ESRD [core] recertification survey. Survey Dates: 4-27-15, 4-29-15, 4-30-15, and 5-1-15 Facility #: 003483 Medicaid Vendor #: 200424460 FMC Shadeland Station was found to be out of compliance with Condition for Coverage 42 CFR 494.90 Patient Plan of Care. QR:JE 5/7/15	V 000		
V 113 Bldg. 00	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station. Based on observation, interview, and facility policy review, the facility failed to ensure staff had cleansed hands and changed gloves appropriately in 3 (#s 1, 2, and 3) of 14 infection control observations completed where hand hygiene and glove changes were indicated.	V 113	The Governing Body for the facility met on 5/11/15 to review the Statement of deficiencies and developed the plan of Correction. The Director of Operations reviewed the following policies “"Infection Control Overview" policy number FMS-CS-IC-II-155-060A, “Hand Hygiene Policy”	06/01/2015

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Any defiencystatement ending with an asterisk (*) denotes a deficency which the institution may be excused from correcting providing it is determined that other safegaurds 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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	The findings include: 1. Employee S, a patient care technician (PCT), was observed to perform central venous catheter (CVC) exit site care on patient number 5 on 4-28-15 at 11:00 AM. The PCT failed to cleanse his hands and change his gloves after removing the old dressing and cleansing the exit site. 2. Employee N, a PCT, was observed to initiate the dialysis treatment on patient number 14 on 4-30-15 at 8:50 AM. The patient was observed to have a fistula in the left arm that was wrapped in a clear plastic wrap. The patient indicated a "numbing cream" had been applied prior to arrival at the dialysis facility and the plastic wrap applied over the cream. The PCT was observed to remove the wrap and wipe the access site with a dry gauze. The PCT was not observed to cleanse his hands and change gloves prior to cleansing the needle insertion site with an antiseptic. 3. Employee Y, a registered nurse (RN), was observed to administer intravenous Epogen to patient number 14 on 4-28-15 at 12:10 PM. The RN prepared the medication at the medication preparation station and brought it to the dialysis station. The RN was then observed to		FMS-CS-IC-II-155-090A and "Cleaning and Disinfection" policy number FMS-CS-IC-II-155-110A with the Clinical Manager on 5/11/15 emphasizing his responsibility to ensure all staff members are educated on the policies, competency is assessed and staff understands the requirement to follow policies and procedures as written. All current staff will participate in a mandatory in-service by the Clinic Manager, Charge RN, and Director of Operations regarding Infection Control Practices the week of 5/4/15 and 5/15/15 specifically focusing on the policies listed above. In addition, the staff will be educated on their responsibility to ensure that all staff wears disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. The importance of hand sanitation before and after glove change will be reinforced. The "Infection Control Information Acknowledgment" form will be placed in each staff members personnel/education file. The Clinical Manager or designee will ensure that infection control audits utilizing the QAI Infection Control audit tool are done weekly for 4 weeks, monthly for 3 months, and then as determined by the QAI calendar. Any deficiencies noted during the audits will be referred immediately to the Clinical	

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	don clean gloves without first cleansing her hands. 4. The above-stated findings were presented to the clinic manager, employee B, and the charge nurse, employee G, on 4-30-15 at 12:25 PM. The manager and the charge nurse indicated the employees had not changed gloves and performed hand hygiene in accordance with facility policy. 5. The facility's 1-4-12 "Infection Control Overview" policy number FMS-CS-IC-II-155-060A states, "All infection control policies for patient care are consistent with recommendation of the Centers for Disease Control (CDC)." The Centers for Disease Control "Standards Precautions" states, "IV. Standard Precautions . . . IV.A. Hand Hygiene. IV.A.1. During the delivery of healthcare, avoid unnecessary touching of surfaces in close proximity to the patient to prevent both contamination of clean hands from environmental surfaces and transmission of pathogens from contaminated hands to surfaces . . . Perform hand hygiene: IV.A.3.a. Before having direct contact with patients. IV.A.3.b. After contact with blood, body fluids or excretions, mucous membranes, nonintact skin, or wound dressings.		Manager who is responsible to address the issue with each employee including corrective action as appropriate The Clinical Manager is responsible to evaluate and present the audit findings in the monthly QAI meeting/minutes. The QAI Committee is responsible to review, analyze and trend all monitoring results to ensure resolution is both occurring and is sustained.	

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	IV.A.3.c. After contact with a patient's intact skin (e.g., when taking a pulse or blood pressure or lifting a patient). IV.3.d. If hands will be moving from a contaminated-body site to a clean-body site during patient care. IV.A.3.e. After contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient. IV.A.3.f. After removing gloves . . . IV.F.5. Include multi-use electronic equipment in policies and procedures for preventing contamination and for cleaning and disinfection, especially those items that are used by patients, those used during delivery of patient care, and mobile devices that are moved in and out of patient rooms frequently . . . IV.B. Personal protective equipment (PPE) . . . IV.B.2. Gloves. IV.B.2.a. Wear gloves when it can be reasonably anticipated that contact with blood or potentially infectious materials, mucous membranes, nonintact skin, or potentially contaminated intact skin . . . could occur." 6. The facility's 3-20-13 "Hand Hygiene" policy number FMS-CS-IC-II-155-090A states, "Hand will be . . . Decontaminated using alcohol based hand rub or by washing hands with antimicrobial soap and water . . . Immediately after removing gloves . . . After contact with			

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	inanimate objects near the patient. When moving from a contaminated body site to a clean body site of the same patient." 7. The facility's 1-6-14 "Changing the Catheter Dressing" procedure number FMS-CS-IC-I-105-032C states, "Inspect and remove the old dressing . . . Discard dressing and remove gloves. Perform hand hygiene." 8. The facility's 9-25-13 "Assessment and Preparation of Internal Access for Needle Placement" procedure number FMS-CS-IC-I-115-006C states, "Perform hand hygiene and don gloves. Use an approved antiseptic to clean the insertion site following manufacturers' recommendation."			
V 122 Bldg. 00	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. Based on observation, interview, and facility policy review, the facility failed	V 122	The Director of Operations met with the Clinical Manager on	06/01/2015

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	to ensure staff had cleaned the dialysis station in accordance with facility policy in 3 (#s 1, 2, and 3) of 2 cleaning and disinfection of the dialysis station observations completed. The findings include: 1. Employee V, a patient care technician (PCT), was observed to clean the dialysis machine at station number 1 on 4-27-15 at 2:20 PM. The employee was not observed to clean the dialysate hoses or the Hansen connectors on the machine. 2. Employee R, a PCT, was observed to clean the dialysis machine at station number 14 on 4-28-15 at 10:00 AM. The employee was not observed to clean the intravenous (IV) pole, the dialysate hoses, or the prime waste bucket. The employee was also observed to clean the dialysis chair at station number 14. The employee was not observed to clean the fronts of the arms of the chair where the patient places his/her hands. 3. Employee S, a PCT, was observed to clean the dialysis machine at station number 5 on 4-28-15 at 10:50 AM. The PCT was not observed to clean the IV pole, the dialysate hoses, or the blood pressure cuff.		5/11/15 and emphasizing his responsibility to ensure all staff members are educated on the policy FMS-CS-IC-II-155-110A and FMS-CS-IC-II-155-122A and the requirement that staff follow policy and procedure as written. All current staff will be in-serviced by the Clinical Manager, Charge RN, and Director of Operations on disinfection and Infection Control Practices the week of 5/4/15 and 5/15/15, specifically focusing on the following policies: ·FMS-CS-IC-II-155-110A "Cleaning and Disinfection Policy In addition, the staff will be educated on their responsibility to ensure all equipment in the patient care station; including all sections of the dialysis machine, prime waste bucket, chair arms, computer, and counter top are properly disinfected per P&P. All areas must be considered potentially blood contaminated, and should be separated, handled with caution and either disinfected or discarded. The "Infection Control Information Acknowledgment" form will be placed in each staff members personnel/education file. The Clinical Manager or designee will ensure that infection control audits utilizing the QAI Infection Control audit tool are done weekly for 4 weeks, monthly for 3 months, and then as determined	

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	4. The above-stated findings were presented to the clinic manager, employee B, and the charge nurse, employee G, on 4-30-15 at 12:25 PM. The manager and the charge nurse indicated the employees had not cleaned the dialysis machine in accordance with facility policy. 5. The facility's 1-28-15 "Cleaning and Disinfection" policy number FMS-CS-IC-II-155-110A states, "All work surfaces shall be cleaned and disinfected with 1:100 bleach solution after completion of procedures . . . Non-disposable items such as blood pressure cuffs, IV poles . . . should be disinfected with 1:100 bleach solution after each treatment."		by the QAI calendar. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager who is responsible to address the issue with each employee including corrective action as appropriate The Clinical Manager is responsible to evaluate and present the audit findings in the monthly QAI meeting/minutes. The QAI Committee is responsible to review, analyze and trend all monitoring results to ensure resolution is both occurring and is sustained.	
V 147 Bldg. 00	494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE Recommendations for Placement of Intravascular Catheters in Adults and Children I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections.			

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	B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters. II. Surveillance A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site. Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients. VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].			
	Based on observation, interview, and facility policy review, the facility failed to ensure staff had discontinued the dialysis treatment on a patient with a central venous catheter (CVC) in accordance with facility policy in 2 (#s 1 and 2) of 2 discontinuation of dialysis with a CVC observations completed. The findings include: 1. Employee R, a patient care technician (PCT), was observed to discontinue the dialysis treatment on patient number 11 on 4-28-15 at 9:45 AM. The PCT was not observed to place a clean field under	V 147	The Director of Operations reviewed the following policy FMS-CS-IC-I-105-028C "Termination of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer" procedure with the Clinical Manager on 5/11/15 emphasizing his responsibility to ensure all staff members are educated on the policies and follow policy and procedure as written. All current staff will be in serviced by the Clinic Manager on Infection Control Practices the week of 5/15/15 specifically focusing on the policy listed above. In addition, the staff will be educated	06/01/2015

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	the CVC ports prior to starting the discontinuation procedure. 2. Employee P, a PCT, was observed to discontinue the dialysis treatment on patient number 12 on 4-30-15 at 10:20 AM. The PCT was not observed to place a clean field under the CVC ports prior to starting the discontinuation procedure. 3. The above-stated findings were presented to the clinic manager, employee B, and the charge nurse, employee G, on 4-30-15 at 12:25 PM. The manager and the charge nurse indicated the employees had not discontinued the dialysis treatment using a CVC in accordance with facility policy. 4. The facility's 1-6-14 "Termination of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer" procedure number FMS-CS-IC-I-105-028C states, "Ensure that a clean under pad is below the catheter limbs to protect the work area and the clothing."		on their responsibility to ensure that aseptic technique is maintained when providing catheter care dressing changes with placement of a clean under pad prior to discontinuation of treatment, and the importance of preventing cross contamination. The “Infection Control Information Acknowledgment” form will be placed in each staff members personnel/education file. The Clinical Manager or designee will ensure that infection control audits utilizing the QAI Infection Control audit tool are done weekly for 4 weeks, monthly for 3 months, and then as determined by the QAI calendar. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager who is responsible to address the issue with each employee including corrective action as appropriate. The specific area of focus during the monitoring will be proper aseptic technique is observed during Central Venous Catheter dressing changes The Clinical Manager is responsible to evaluate and present the audit findings in the monthly QAI meeting/minutes. The QAI Committee is responsible to review, analyze and trend all monitoring results to ensure resolution is both	

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			occurring and is sustained.	
V 407 Bldg. 00	494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement). Based on clinical record and facility policy review and interview, the facility failed to ensure vital signs and machine checks had been completed at least every 30 minutes in accordance with facility policy in 6 (#s 2, 3, 4, 6, 8, and 10) of 10 records reviewed. The findings include: 1. The facility's 8-20-14 "Patient Monitoring During Patient Treatment" policy number FMS-CS-IC-I-110-133A states, "Vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently, as needed . . . Observe and document at the initiation of dialysis and at every safety check that all connections are secure and visible . . . Check machine settings and measurements and document at the initiation of dialysis and at every safety check." 2. Clinical record number 2 failed to evidence vital signs and safety checks had been completed at least every 30	V 407	The Director of Operations (DO) met with the Clinical Manager (CM) on 5/11/15 and reviewed FMS-CS-IC-I-110-133A "Monitoring During Patient Treatment Policy", emphasizing his responsibility to ensure all staff members are educated on the policies, competency is assessed and staffs are required to follow policy and procedure as written. Staff will be reeducated by the DO and CM the week of 5/4/15 and 5/15/15 on the policy listed above, with an emphasis placed on the following responsibilities: • Vital signs will be monitored at initiation of treatment of dialysis and every 30 minutes, or more frequently as necessary. • Appropriate interventions in response to changes in vital signs, treatment parameters, or machine adjustments shall be documented in the treatment record including referral to the RN and assessment findings. The Clinical Manager or designee	06/01/2015

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	minutes. A. A hemodialysis treatment flow sheet dated 4-3-15 evidenced the patient had been checked at 4:00 PM and not again until 5:00 PM, a period of 1 hour between checks. B. A hemodialysis treatment flow sheet dated 4-10-15 evidenced the patient had been checked at 4:03 PM and not again until 5:01 PM, a period of 58 minutes between checks. C. A hemodialysis treatment flow sheet dated 4-13-15 evidenced the patient had been checked at 3:06 PM and not again until 4:30 PM, a period of 1 hour and 24 minutes between checks. D. A hemodialysis treatment flow sheet dated 4-15-15 evidenced the patient had been checked at 2:32 PM and not again until 3:34 PM, a period of 1 hour and 2 minutes between checks. E. A hemodialysis treatment flow sheet dated 4-17-15 evidenced the patient had been checked at 3:33 PM and not again until 4:32 PM, a period of 59 minutes between checks. F. A hemodialysis treatment flow sheet dated 4-24-15 evidenced the		will audit 10% of treatment sheets 3 random days per week for the next 4 weeks, if substantial compliance is achieved at 4 weeks, the medical record audits will be conducted monthly per the QAI calendar. The Clinical Manager is responsible to evaluate and present the treatment sheet audit findings in the monthly QAI meeting/minutes. The QAI Committee is responsible to review, analyze and trend all monitoring results to ensure resolution is both occurring and is sustained.	

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	treatment had been initiated at 3:13 PM and the patient had not been checked again until 4:02 PM, a period of 45 minutes between checks. 3. Clinical record number 3 failed to evidence vital signs and safety checks had been completed at least every 30 minutes. A. A hemodialysis treatment flow sheet dated 4-8-15 evidenced the patient had been checked at 3:31 PM and not again until 4:17 PM, a period of 46 minutes between treatment checks. The treatment sheet evidenced the patient had been checked at 4:31 PM and not again until 5:32 PM, a period of 1 hour and 1 minute between checks. B. A hemodialysis treatment flow sheet dated 4-10-15 evidenced the patient had been checked at 4:02 PM and not again until 5:01 PM, a period of 59 minutes between checks. The flow sheet evidenced the patient had been checked at 7:03 PM and not again until 8:05 PM, a period of 1 hour and 2 minutes between checks. C. A hemodialysis treatment flow sheet dated 4-13-15 evidenced the patient had been checked at 3:03 PM and not again until 4:34 PM, a period of 1 hour			

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	and 31 minutes between checks. D. A hemodialysis treatment flow sheet dated 4-22-15 evidenced the patient had been checked at 7:01 PM and not again until 7:52 PM, a period of 51 minutes between checks. 4. Clinical record number 4 failed to evidence vital signs and safety checks had been completed at least every 30 minutes. A hemodialysis treatment flow sheet dated 4-17-15 evidenced the patient had been checked at 6:30 PM and not again until 7:33 PM, a period of 1 hour and 3 minutes between checks. 5. Clinical record number 6 failed to evidence vital signs and safety checks had been completed at least every 30 minutes. A. A hemodialysis treatment flow sheet dated 4-9-15 evidenced the patient had been checked at 1:31 PM and not again until 2:31 PM, a period of 1 hour between checks. B. A hemodialysis treatment flow sheet dated 4-14-15 evidenced the patient had been checked at 10:59 AM and not again until 12:02 PM, a period of 1 hour			

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	and 3 minutes between checks. 6. Clinical record number 8 failed to evidence vital signs and safety checks had been completed at least every 30 minutes. A. A hemodialysis treatment flow sheet dated 4-9-15 evidenced the patient had been checked at 2:03 PM and not again until 3:01 PM, a period of 59 minutes between checks. B. A hemodialysis treatment flow sheet dated 4-23-15 evidenced the treatment had been initiated at 10:30 AM and the patient had not been checked again until 11:36 AM, a period of 1 hour and 6 minutes between checks. 7. Clinical record number 10 failed to evidence vital signs and safety checks had been completed at least every 30 minutes. A. A hemodialysis treatment flow sheet dated 4-10-15 evidenced the patient had been checked at 1:03 PM and not again until 2:03 PM, a period of 1 hour between checks. B. A hemodialysis treatment flow sheet dated 4-24-15 evidenced the patient had been checked at 1:33 PM and not			

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	again until 3:13 PM, a period of 1 hour and 41 minutes between checks. 8. The clinic manager, employee B, and the charge nurse, employee G, were unable to provide any additional documentation and/or information when asked on 5-1-15 at 10:00 AM The charge nurse indicated, on 5-1-15 at 2:10 PM vital signs and safety checks should be completed at least every 30 minutes.			
V 540 Bldg. 00	494.90 CFC-PATIENT PLAN OF CARE Based on clinical record and facility policy review and interview, it was determined the facility failed to ensure appropriate care and services had been provided in accordance with the plan of care by failing to ensure the necessary care and services had been provided to achieve estimated dry weights (EDW) in 4 of 10 records reviewed and failed to ensure medications for elevated blood pressure readings had been administered as ordered in 1 of 3 records reviewed of patients with medication orders for elevated blood pressure readings (See V 543); by failing to ensure it had maintained the prescribed dose of dialysis by failing to ensure intermittent heparin	V 540	V540 494.90 CFC-PATIENTS PLAN OF CARE The Governing Body acknowledges its responsibility to ensure this facility establishes and sustains a process by which each patient is reviewed monthly to determine health status and to ensure appropriate frequency of reassessments and modifications to the Plan of Care as warranted. The Governing Body met on5/11/15 to review the citations from the May 1 2015 survey and developed the Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. This	06/01/2015

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	had been administered as ordered in 1 of 1 record reviewed of patients with intermittent heparin orders and by failing to ensure bolus heparin had been administered as ordered in 1 of 7 records reviewed of patients with bolus heparin orders (See V 544); by failing to ensure dietary counseling services had been provided on a monthly basis to monitor patients' albumin levels in 6 of 6 records reviewed of patients that had received dialysis treatments for longer than 90 days; failed to ensure dietary supplements had been administered during the dialysis treatment as ordered in 8 of 8 records reviewed of patients with dietary supplement orders, and failed to ensure monthly albumin levels had been drawn in 3 of 10 records reviewed (See V 545); by failing to ensure dietary counseling services to manage mineral metabolism and renal bone disease had been provided on a monthly basis in 6 of 6 records reviewed of patients that had received dialysis treatments for longer than 90 days (See V 546); by failing to ensure access sites had been cleansed in 2 of 2 observations and failed to ensure access sites had been assessed in 1 of 2 access of arteriovenous fistula or graft initiations of dialysis observations and failed to ensure clean dressings had been applied to access sites after the treatment had been discontinued in 2 of post access site care		Body will meet weekly to monitor the progress of the Plan of Correction until the Condition level deficiencies are lifted. The Governing Body will meet monthly at minimum an additional 3 months to ensure that the corrective actions have resulted in sustained compliance. Once this is determined the Governing Body will return to quarterly or as needed meetings. As a result of the citations from the May 1 2015 survey and as part of the developed plan of correction, the following corrective actions have been implemented: · Reeducation and reinforcement with the DPC staff on the mandatory requirement to ensure that patient blood pressures out of range are addressed and interventions documented. Estimated Dry Weights (EDW) are regularly assessed and the Plan of Care is modified to achieve the ordered EDW. Please refer to V-543 · Reeducation and reinforcement with DPC staff of the mandatory requirement to follow physician's heparin orders. Please refer to V-544 · Reeducation and reinforcement with both the Clinical Manger and Dietitian of the mandatory requirement to ensure dietary counseling services are provided to every patient monthly. The counseling	

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	observations completed (See V 550); and by failing to ensure records included documentation of reasons for goals not being met and adjustments of plans of care to identify identified reasons in 2 of 10 records reviewed (See V 559). 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.		service must include monitoring albumin levels, interventions, dietary supplements and updating the Plan of Care Please refer to V545 · Reeducation and reinforcement with both the Clinical Manger and Dietitian of the mandatory requirement to ensure dietary counseling services are provided to every patient monthly. The counseling service must include monitoring of bone and mineral metabolism, interventions, and updating the Plan of Care Please refer to V546 · Reeducation and reinforcement with DPC staff of the mandatory requirement to comply with the facility's vascular assess policies. Please refer to V-550 · Reeducation and reinforcement with the DPC staff on the mandatory requirement to ensure that Estimated Dry Weights (EDW)are regularly assessed and the Plan of Care is modified to achieve the ordered EDW or documentation of reasons goal is not met. Please refer to V-559	
V 543 Bldg. 00	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;			

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	Based on clinical record and facility policy review and interview, the facility failed to ensure the necessary care and services had been provided to achieve estimated dry weights (EDW) in 4 (#s 2, 3, 4, and 6) of 10 records reviewed and failed to ensure medications for elevated blood pressure readings had been administered as ordered in 1 (# 9) of 3 records reviewed of patients with medication orders for elevated blood pressure readings. The findings include: Regarding EDW: 1. Clinical record number 2 included physician orders dated 2-4-15 that identified the EDW (the patient's desired weight at the end of the dialysis treatment) as 130 kilograms (kg). Hemodialysis treatment flow sheets evidenced the EDW had not been attained at the end of the treatments. A. A hemodialysis treatment flow sheet dated 4-3-15 evidenced the patient's weight at the end of the treatment was 143.5 kg. B. A hemodialysis treatment flow sheet dated 4-10-15 evidenced the patient's weight at the end of the	V 543	The Director of Operations reviewed the following policies FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care Policy" and FMS-CS-IC-I-110-133A "Monitoring During Patient Treatment" with the Clinical Manager on 5/11/15 emphasizing his responsibility to ensure all staff members are educated on the policies, competency is assessed and staff understands the requirement to follow policies and procedures as written. A mandatory in-service is scheduled for all staff the week of 5/4/15 and the clinic manager will review & re-educate the following policies: • FMS-CS-IC-I-110-133A "Monitoring During Patient Treatment" • FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care Policy" Special emphasis was placed on ensuring that the patient's EDW is addressed each treatment; prescribed dose of dialysis is sustained; hypertensive monitoring and interventions are delivered according to the physician's prescription and requirement to achieve adequate clearance. This will be monitored by the nurse using the rounding tool.	06/01/2015

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	treatment was 135.2 kg. C. A hemodialysis treatment flow sheet dated 4-13-15 evidenced the patient's weight at the end of the treatment was 138 kg. D. A hemodialysis treatment flow sheet dated 4-1515 evidenced the patient's weight at the end of the treatment was 139.9 kg. E. A hemodialysis treatment flow sheet dated 4-17-15 evidenced the patient's weight at the end of the treatment was 136.7 kg. F. A hemodialysis treatment flow sheet dated 4-20-15 evidenced the patient's weight at the end of the treatment was 133.3 kg. G. A hemodialysis treatment flow sheet dated 4-22-15 evidenced the patient's weight at the end of the treatment was 134.2 kg. H. A hemodialysis treatment flow sheet dated 4-24-15 evidenced the patient's weight at the end of the treatment was 134.1 kg. 2. Clinical record number 3 included physician orders dated 3-18-15 that		The Clinical Manager will hold a staff meeting on 5/15/15 to review and train all staff on proper administration of Clonidine, per physician order, for any blood pressure outside of parameters ordered per MD. The Clinical Manager will also meet with the interdisciplinary team to ensure any target weight issues and blood pressure issues are addressed on the POC. The Clinical Manager will review 10% of patient charts, flow sheets, and POC's each month to ensure Clonidine is given per physician order as well as all target weight and blood pressure issues are addressed on the patient's plan of care. The Clinical Manager is responsible to report a summary of findings monthly in QAI. If resolution is not evident, the QAI Committee will complete a root cause analysis and the Plan of Correction will be revised as necessary.	

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	identified the EDW as 46.5 kg. Physician orders dated 4-24-15 evidenced the EDW had been increased to 48 kg. Hemodialysis treatment flow sheets evidenced the EDW had not been attained at the end of the treatments. A. Hemodialysis treatment flow sheets, dated 4-6-15, 4-8-15, and 4-10-15, evidenced the patient's weight at the end of the treatment was 47.4 kg. B. A hemodialysis treatment flow sheet dated 4-13-15 evidenced the patient's weight at the end of the treatment was 48.5 kg. C. A hemodialysis treatment flow sheet dated 4-15-15 evidenced the patient's weight at the end of the treatment was 48.3 kg. D. A hemodialysis treatment flow sheet dated 4-17-15 evidenced the patient's weight at the end of the treatment was 48.7 kg. E. A hemodialysis treatment flow sheet dated 4-20-15 evidenced the patient's weight at the end of the treatment was 48.4 kg. F. A hemodialysis treatment flow sheet dated 4-22-15 evidenced the			

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	patient's weight at the end of the treatment was 48.6 kg. G. A hemodialysis treatment flow sheet dated 4-24-15 evidenced the patient's weight at the end of the treatment was 49 kg. 3. Clinical record number 4 included physician orders dated 3-9-15 that identified the EDW as 58.7 kg. Hemodialysis treatment flow sheets evidenced the EDW had not been attained at the end of the treatments. A. A hemodialysis treatment flow sheet dated 4-3-15 evidenced the patient's weight at the end of the treatment was 59.8 kg. B. A hemodialysis treatment flow sheet dated 4-6-15 evidenced the patient's weight at the end of the treatment was 59.3 kg. C. A hemodialysis treatment flow sheet dated 4-8-15 evidenced the patient's weight at the end of the treatment was 59.1 kg. D. A hemodialysis treatment flow sheet dated 4-22-15 evidenced the patient's weight at the end of the treatment was 60.7 kg.			

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	E. A hemodialysis treatment flow sheet dated 4-24-15 evidenced the patient's weight at the end of the treatment was 60 kg. 4. Clinical record number 6 included physician orders dated 4-7-15 that identified the EDW as 63 kg. Hemodialysis treatment flow sheets evidenced the EDW had not been attained at the end of the treatments. A. A hemodialysis treatment flow sheet dated 4-14-15 evidenced the patient's weight at the end of the treatment was 69.5 kg. B. A hemodialysis treatment flow sheet dated 4-21-15 evidenced the patient's weight at the end of the treatment was 64.5 kg. C. A hemodialysis treatment flow sheet dated 4-23-15 evidenced the patient's weight at the end of the treatment was 64.7 kg. 5. The charge nurse, employee G, and the clinic manager, employee B, were unable to provide any additional documentation and/or information when asked on 5-1-15 at 10:11 AM.			

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	Regarding medications for elevated blood pressure readings during treatment: 1. Clinical record number 9 included physician orders dated 2-9-15 that identified Clonidine HCl (hydrochloride) 0.1 milligrams (mg) was to be administered during dialysis for systolic blood pressure readings of greater than 170. A. A hemodialysis treatment flow sheet dated 4-13-15 evidenced a blood pressure reading of 181/49 at 5:03 PM and 179/57 at 7:35 PM, at the end of the treatment. The flow sheet failed to evidence any Clonidine had been administered. B. A hemodialysis treatment flow sheet dated 4-15-15 evidenced blood pressure readings of 191/108 at 4:18 AM, 215/53 at 4:36 PM, 215/61 at 5:03 PM, 206/62 at 5:32 PM, 201/52 at 6:03 PM, 184/107 at 6:34 PM, 177/58 at 7:02 PM, and 182/53 at 7:31 PM at the end of the treatment. The flow sheet failed to evidence any Clonidine had been administered during the treatment. C. A hemodialysis treatment flow sheet dated 4-17-15 evidenced blood pressure readings of 175/61 at 4:15 PM at the beginning of the treatment, 197/54 at			

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	4:34 PM, 177/47 at 6:06 PM, 184/57 at 6:32 PM, 182/56 at 7:02 PM, and 196/57 at 7:32 PM at the end of the treatment. The flow sheet failed to evidence any Clonidine had been administered during the treatment. D. A hemodialysis treatment flow sheet dated 4-20-15 evidenced blood pressure readings of 219/60 at 4:15 PM, 4 minutes after the initiation of treatment, 233/68 at 4:33 PM, 247/77 at 5:02 PM, 238/69 at 5:35 PM, 204/71 at 6:01 PM, 226/72 at 6:36 PM, 207/69 at 7:01 PM, 175/34 at 7:31 PM, and 209/67 at 7:45 PM at the end of the treatment. E. A hemodialysis treatment flow sheet dated 4-24-15 evidenced blood pressure readings of 177/58 at 11:38 AM, at the start of the treatment, 192/58 at 12:01 PM, 177/60 at 2:00 PM, 184/61 at 2:38 PM, at the end of the treatment. 2. The charge nurse, employee G, and the clinic manager, employee B, were unable to provide any additional documentation and/or information when asked on 5-1-15 at 10:11 AM. 3. The facility's 7-4-12 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The			

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	patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Dose of Dialysis. Sustain the prescribed dose of dialysis."			
V 544 Bldg. 00	494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. Based on clinical record and facility policy review and interview, the facility failed to ensure it had maintained the prescribed dose of dialysis by failing to ensure intermittent heparin had been administered as ordered in 1 (# 4) of 1 record reviewed of patients with intermittent heparin orders and by failing to ensure bolus heparin had been administered as ordered in 1 (# 10) of 7 records reviewed of patients with bolus heparin orders. The findings include: 1. Clinical record number 4 included physician orders dated 2-9-15 that identified 2000 units of heparin were to be administered half-way through every	V 544	The Director of Operations reviewed the following policies FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care Policy" and FMS-CS-IC-I-110-133A "Monitoring During Patient Treatment" with the Clinical Manager on 5/11/15 emphasizing his responsibility to ensure all staff members are educated on the policies, competency is assessed and staff understands the requirement to follow policies and procedures as written. A mandatory in-service is scheduled for all staff the week of 5/4/15 and 5/15/15 and the Clinic Manager will review & re-educate the following policies: • FMS-CS-IC-I-110-133A "Monitoring During Patient Treatment"	06/01/2015

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	treatment. A. A hemodialysis treatment flow sheet dated 4-24-15 failed to evidence any heparin had been administered half-way through the treatment. B. The charge nurse, employee G, stated, on 5-1-15 at 2:05 PM, "The patient did not receive the heparin half-way through the treatment as ordered." 2. Clinical record number 10 included physician orders dated 7-7-14 that identified 2000 units of bolus heparin were to be administered at the start of treatment. A. A hemodialysis treatment flow sheet dated 4-24-15 failed to evidence the bolus heparin had been administered. B. The charge nurse, employee G, and the clinic manager, employee B, were unable to provide any additional documentation and/or information when asked on 5-1-15 at 10:11 AM. 3. The facility's 7-4-12 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The patient's individualized comprehensive		• FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care Policy" Special emphasis was placed on ensuring that the patient's prescribed blood flow rate, dialyzer and heparinization is delivered according to the physician's prescription and requirement to achieve adequate clearance. This will be monitored daily by the nurse using the rounding tool. The Clinical Manager will monitor the results of the Rounding Tool audits weekly for 4 weeks and ongoing monitoring will be determined by the QAI Committee upon review of monitoring results and resolution of the issue. The Clinical Manager is responsible to report a summary of findings monthly in QAI. If resolution is not evident, the QAI Committee will complete a root cause analysis and the Plan of Correction will be revised as necessary.	

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	Plan of Care must include, but is not limited to the following: . . . Dose of Dialysis. Sustain the prescribed dose of dialysis."			
V 545 Bldg. 00	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. Based on clinical record and facility policy review and interview, the facility failed to ensure dietary counseling services had been provided on a monthly basis to monitor patients' albumin levels in 6 (#s 2, 4, 6, 8, 9, and 10) of 6 records reviewed of patients that had received dialysis treatments for longer than 90 days; failed to ensure dietary supplements had been administered during the dialysis treatment as ordered in 8 (#s 1, 2, 4, 5, 6, 7, 8, and 9) of 8 records reviewed of patients with dietary supplement orders, and failed to ensure monthly albumin levels had been drawn in 3 (#s 1, 8, and 10) of 10 records reviewed. The findings include: Regarding monthly dietary counseling:	V 545	The Director of Operations met with the Clinical Manager and RD on 5/11/15 emphasizing their responsibility to ensure all staff members are educated policies FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care Policy" & FMS-CS-IC-I-111-005C3 "Oral Nutritional Supplements Administration Procedure: "eCube Clinicals Procedure" and the requirement that staff follow policy and procedure as written. The Clinical Manager will educate and review with all staff policies at a mandatory staff in-service the week of 5/4/15 and 5/15/15: • FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care Policy" • FMS-CS-IC-I-111-005C3	06/01/2015

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE SHADELAND STATION		STREET ADDRESS, CITY, STATE, ZIP CODE 7155 SHADELAND STATION STE 130 INDIANAPOLIS, IN 46256	

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	1. The facility's 7-4-12 "Nutrition Services" policy number FMS-CS-IC-I-111-001A states, "Evidence-based professionally accepted nutrition related indicators will be reviewed monthly, or as is appropriate, to determine the patient's current nutritional status and response to the plan of care, and patients will be counseled accordingly . . . The monthly review of biochemical, adequacy and anthropometric data will be documented by the RD [registered dietitian] either as a progress note or, when indicated per the Comprehensive Patient Assessment and Plan of Care Policy, as part of the interdisciplinary assessment and plan of care form." 2. According to the Centers for Medicare and Medicaid Services (CMS) Measures Assessment Tool (MAT), the desired albumin level is equal to or greater than 4.0 grams per deciliter (g/dL). 3. Clinical record number 2 evidenced a dialysis start date at the facility of 10-31-14. The record failed to evidence any dietary counseling had been provided for November and December 2014 or January and February 2015. The record included laboratory results		"Oral Nutritional Supplements Administration Procedure: "eCube Clinicals Procedure" The education will specifically address monitoring administration of protein supplements. All patients are required to be offered the supplement per order and in the event that the patient refuses the supplement the staff will be directed to create a multi-disciplinary note of refusal. The Clinical Manager or designee will audit 10% of treatment sheets 3 random days per week for the next 4 weeks, if substantial compliance is achieved at 4 weeks, the medical record audits will be conducted monthly per the QAI calendar. The Clinical Manager is responsible to evaluate and present the treatment sheet audit findings in the monthly QAI meeting/minutes. The QAI Committee is responsible to review, analyze and trend all monitoring results to ensure resolution is both occurring and is sustained.	

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	that identified the albumin level had declined. The laboratory results evidenced the albumin level was 3.6 g/dL on 11-3-14, 3.5 g/dL on 12-1-14, and 3.4 g/dL on 1-5-15 and 2-2-15. 4. Clinical record number 4 evidenced a dialysis start date at the facility of 8-29-14. The record failed to evidence any dietary counseling had been provided for November and December 2014 or January and February 2015. The record included laboratory results that identified the albumin level had declined. The laboratory results evidenced the albumin level was 4.2 on 11-3-14, 3.9 on 12-1-14, 3.5 on 1-5-15, and 3.1 on 2-2-15. 5. Clinical record number 6 evidenced a dialysis start date at the facility of 9-12-13. The record failed to evidence any dietary counseling had been provided for November and December 2014 or January and February 2015. The record included laboratory results that identified the albumin had remained below the desired level during this timeframe. The laboratory results evidenced the albumin level was 2.9 on 11-6-15, 3.0 on 12-2-15, 3.2 on 1-6-15, and 3.4 on 2-3-15.			

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	6. Clinical record number 8 evidenced a dialysis start date of 12-3-13. The record failed to evidence any dietary counseling had been provided for November and December 2014 and January and February 2015. The record included laboratory results that identified the albumin level had declined. The laboratory results evidenced the albumin level was 3.8 on 11-4-14, 3.4 on 12-2-14, and 2.9 on 2-3-15. The record failed to evidence any albumin laboratory results for the month of January 2015. 7. Clinical record number 9 evidenced a dialysis start date of 6-6-14. The record failed to evidence any dietary counseling had been provided for November and December 2014 and January and February 2015. The record included laboratory results that identified the albumin level had declined and had remained below the desired level of 4.0. The laboratory results evidenced the albumin level was 3.0 on 11-3-14, 2.8 on 12-1-14, 2.7 on 1-5-15, and 3.1 on 2-2-15. 8. Clinical record number 10 evidenced a dialysis start date of 3-7-14. The record			

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	failed to evidence any dietary counseling had been provided for November and December 2014 and January and February 2015. 9. The regional dietitian, employee BB, indicated, on 4-30-15 at 10:10 AM, per telephone call, dietary services had been provided by other registered dietitians in the area. The dietitian indicated the other dietitians had ensured interdisciplinary assessments and plans of care had been completed and had been available for patient questions or for emergencies. The dietitian indicated the patients' physicians had reviewed the patients monthly laboratory results. 10. The Director of Operations, employee CC, indicated, on 5-1-15 at 12:30 PM, the facility had been without an RD since October 2014. The director indicated the current RD had been hired mid-February 2015. Regarding dietary supplement administration: 1. Clinical record number 1 included physician orders dated 3-2-15 that identified Nepro Carb Steady 8 ounces was to be administered by mouth during each dialysis treatment.			

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	Hemodialysis treatment flow sheets, dated 4-6-15, 4-8-15, 4-17-15, 4-20-15, 4-22-15, and 4-24-15, failed to evidence the Nepro had been administered as ordered. 2. Clinical record number 2 included physician orders dated 3-16-15 that identified Nepro Carb Steady 8 ounces was to be administered by mouth during each dialysis treatment. Hemodialysis treatment flow sheets, dated 4-3-15, 4-13-15, 4-17-15, 4-20-15, and 4-22-15, failed to evidence the Nepro had been administered as ordered. 3. Clinical record number 4 included physician orders dated 2-11-15 that identified a Zone Perfect Bar was to be administered during each dialysis treatment. Hemodialysis treatment flow sheets, dated 4-6-15, 4-8-15, 4-10-15, 4-15-15, 4-17-15, 4-20-15, 4-22-15, and 4-24-15, failed to evidence the Zone Perfect bar had been administered as ordered. 4. Clinical record number 5 included physician orders dated 4-18-15 that identified Nepro Carb Steady 8 ounces was to be administered during each dialysis treatment.			

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	Hemodialysis treatment flow sheets, dated 4-23-15 and 4-25-15, failed to evidence the Nepro had been administered as ordered. 5. Clinical record number 6 included physician orders dated 8-2-14 that identified Body Quest Ice Cream 4 ounces was to be administered during each dialysis treatment. Hemodialysis treatment flow sheets, dated 4-4-15 and 4-14-15, failed to evidence the Body Quest Ice Cream had been administered as ordered. 6. Clinical record number 7 included physician orders dated 4-7-15 that identified Nepro Carb Steady 8 ounces was to be administered during each dialysis treatment. A hemodialysis treatment flow sheet dated 4-16-15 failed to evidence the Nepro had been administered as ordered. 7. Clinical record number 8 included physician orders dated 2-28-15 that identified Nepro Carb Steady 8 ounces was to be administered during each dialysis treatment. A hemodialysis treatment flow sheet			

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	dated 4-18-15 failed to evidence the Nepro had been administered as ordered. 8. Clinical record number 9 included physician orders dated 6-25-14 that identified Nepro Carb Steady 8 ounces was to be administered during each dialysis treatment. Hemodialysis treatment flow sheets, dated 4-6-15, 4-8-15, 4-13-15, 4-17-15, and 4-24-15, failed to evidence the Nepro had been administered as ordered. 9. The charge nurse, employee G, indicated, on 5-1-15 at 2:10 PM, the dietary supplements had not been administered as ordered. The charge nurse stated, "The patients refused the supplements but it is not in the record as to why the supplements were not given." Regarding monthly albumin levels: 1. Clinical record number 1 included physician orders dated 12-28-14 that identified albumin levels were to be drawn monthly. A "Patient Labs" report, for 12-28-14 through 4-6-15, failed to evidence an albumin level had been drawn in March 2015. 2. Clinical record number 8 included physician orders dated 8-14-14 that			

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	identified albumin levels were to be drawn monthly. A "Patient Labs" report for 10-7-14 through 4-7-15 failed to evidence an albumin level had been drawn in January 2015. 3. Clinical record number 10 included physician orders dated 3-7-14 identified albumin levels were to be drawn monthly. A "Patient Labs" report for 10-6-14 through 4-6-15 failed to evidence albumin levels were drawn in February and March 2015. 4. The charge nurse, employee G, stated, on 5-1-15 at 2:10 PM. "The monthly albumin levels were not done on patients numbered 1, 8, and 10. 5. The facility's 7-4-12 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Nutritional Status . . . Albumin must be measured and dry body weight changes monitored monthly."			
V 546 Bldg. 00	494.90(a)(3) POC-MANAGE MINERAL METABOLISM Provide the necessary care to manage mineral metabolism and prevent or treat			

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	renal bone disease. Based on clinical record and facility policy review and interview, the facility failed to ensure dietary counseling services to manage mineral metabolism and renal bone disease had been provided on a monthly basis in 6 (#s 2, 4, 6, 8, 9, and 10) of 6 records reviewed of patients that had received dialysis treatments for longer than 90 days. The findings include: 1. The facility's 7-4-12 "Nutrition Services" policy number FMS-CS-IC-I-111-001A states, "Evidence-based professionally accepted nutrition related indicators will be reviewed monthly, or as is appropriate, to determine the patient's current nutritional status and response to the plan of care, and patients will be counseled accordingly. Such indicators of nutrition status include but are not limited to . . . bone mineral metabolism . . . The monthly review of biochemical, adequacy and anthropometric data will be documented by the RD [registered dietitian] either as a progress note or, when indicated per the Comprehensive Patient Assessment and Plan of Care Policy, as part of the interdisciplinary assessment and plan of care form."	V 546	· The Director of Operations met with the Clinical Manager and RD on 5/11/15 emphasizing their responsibility to ensure dietary counseling services are provided to every patient monthly. The counseling service must include monitoring of bone and mineral metabolism, interventions, and updating the Plan of Care policy FMS-CS-IC-I-111-001A “Nutrition Services ” and the requirement that staff follow policy and procedure as written. Evidenced-based professionally accepted nutrition related indicators will be reviewed monthly, or as appropriate, to determine the patient’s current nutritional status and response to the POC, and patients will be counseled accordingly. Such indicators of nutrition status include but are not limited to bone mineral metabolism. The review of biochemical, adequacy, and angthropometric data will be documented by the RD either as a progress note or, when indicated per the CIA/POC Policy as part of the IDT assessment and POC form. The Clinical Manager and RD are responsible to evaluate and present any BMM indicators in the monthly QAI meeting/minutes. The QAI Committee is responsible to review, analyze and trend all monitoring results to	06/01/2015

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	2. According to the Centers for Medicare and Medicaid Services (CMS) Measures Assessment Tool (MAT), the desired level for corrected calcium is less than 10.2 milligrams per deciliter (mg/dL) and the desired level for phosphorous is 3.5 to 5.5 gm/dL. 3. Clinical record number 2 evidenced a dialysis start date at the facility of 10-31-14. The record failed to evidence any dietary counseling had been provided for November and December 2014 or January and February 2015. The record included laboratory results that identified the patient's phosphorous levels were 4.2 on 11-3-14, 6.4 on 12-1-14, 7.0 on 1-5-15, 5.4 on 2-2-15, and 6.7 on 3-2-15. 4. Clinical record number 4 evidenced a dialysis start date at the facility of 8-29-14. The record failed to evidence any dietary counseling had been provided for November and December 2014 or January and February 2015. The record included laboratory results that identified the patient's phosphorous levels were 4.8 on 11-3-14, 5.6 on 12-1-14, 4.5 on 1-5-15, 6.0 on 2-2-15, and 5.8 on 3-2-15.		ensure resolution is both occurring and is sustained.	

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	5. Clinical record number 6 evidenced a dialysis start date at the facility of 9-12-13. The record failed to evidence any dietary counseling had been provided for November and December 2014 or January and February 2015. The record included laboratory results that identified the patient's phosphorous levels were 2.9 on 11-6-14, 3.7 on 12-9-14, 2.4 on 1-6-15, 3.4 on 2-3-15, and 2.8 on 3-3-15. 6. Clinical record number 8 evidenced a dialysis start date of 12-3-13. The record failed to evidence any dietary counseling had been provided for November and December 2014 and January and February 2015. The record included laboratory results that identified the patient's phosphorous levels was 6.1 on 11-14-14, 5.9 on 12-2-14, 2.9 on 1-22-15, 4.6 on 2-3-15, and 4.3 on 3-3-15. 7. Clinical record number 9 evidenced a dialysis start date of 6-6-14. The record failed to evidence any dietary counseling had been provided for November and December 2014 and January and February 2015. The record included laboratory results			

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	that identified the patient's phosphorous levels were 4.0 on 12-1-14, 2.4 on 1-5-15, 6.3 on 2-2-15, and 5.0 on 3-2-15. 8. Clinical record number 10 evidenced a dialysis start date of 3-7-14. The record failed to evidence any dietary counseling had been provided for November and December 2014 and January and February 2015. 9. The regional dietitian, employee BB, indicated, on 4-30-15 at 10:10 AM, per telephone call, dietary services had been provided by other registered dietitians in the area. The dietitian indicated the other dietitians had ensured interdisciplinary assessments and plans of care had been completed and had been available for patient questions or for emergencies. The dietitian indicated the patients' physicians had reviewed the patients monthly laboratory results. 10. The Director of Operations, employee CC, indicated, on 5-1-15 at 12:30 PM, the facility had been without an RD since October 2014. The director indicated the current RD had been hired mid-February 2015.			

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V 550 Bldg. 00	494.90(a)(5) POC-VASCULAR ACCESS-MONITOR/REFERRALS The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. Based on facility policy review, observation, and interview, the facility failed to ensure access sites had been cleansed in 2 (#s 1 and 2) of 2 observations and failed to ensure access sites had been assessed in 1 (# 2) of 2 access of arteriovenous fistula or graft initiations of dialysis observations and failed to ensure clean dressings had been applied to access sites after the treatment had been discontinued in 2 (#s 1 and 2) of post access site care observations completed. The findings include: Regarding washing the access prior to initiation of treatment 1. Employee AA, a patient care technician (PCT), was observed to initiate the dialysis treatment on patient number 13 on 4-28-15 at 11:50 AM using	V 550	The Director of Operations met with the Clinical Manager on 5/11/15 emphasizing his responsibility to ensure all staff members are educated on the policy FMS-CS-IC-I-115-006C "Assessment and Preparation of Internal Access of Needle Placement" FMS-CS-IC-I-115-013C "Post Treatment Fistula Needle Removal" and "Post Treatment Fistula Needle Removal" procedure and the requirement that staff follow policy and procedure as written. The Clinical Manager will educate and review with all staff the following policy at a mandatory staff in-service the week of 5/4/15 and 5/15/15 with emphasis on access assessment for patency – Look, Listen, Feel; and changing dressing after hemostasis has been achieved and access evaluation and assessment. ·FMS-CS-IC-I-115-006C	06/01/2015

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	an arteriovenous fistula (AVF). The PCT failed to wash the skin over the access, or ask the patient if the patient had washed the access, prior to evaluating the access and initiating the treatment. 2. Employee N, a PCT, was observed to initiate the dialysis treatment on patient number 14 on 4-30-15 at 8:50 AM using an AVF. The PCT failed to wash the skin over the access, or ask the patient if the patient had washed the access, prior to initiating the treatment. Observation noted the access was covered with plastic wrap. The patient stated a "numbing cream" had been applied to the patient's arrival at the facility. 3. The facility's 9-25-13 "Assessment and Preparation of Internal Access of Needle Placement" procedure number FMS-CS-IC-I-115-006C states, "Ask your patient to wash access area with liquid soap for one minute, rinsing well. Dry with clean paper towel." Regarding assessment of access sites: 1. Employee N, a PCT, was observed to initiate the dialysis treatment on patient number 14 on 4-30-15 at 8:50 AM. The PCT was not observed to evaluate the access or locate/palpate the cannulation sites prior to inserting the needles.		Assessment and Preparation of Internal Access of Needle Placement" ·FMS-CS-IC-115-013C "Post Treatment Fistula Needle Removal" procedure The Clinical Manager or designee will ensure that Access audits utilizing the QAI Infection Control audit tool are done weekly for 4 weeks, monthly for 3 months, and then as determined by the QAI calendar. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager who is responsible to address the issue with each employee including corrective action as appropriate The Clinical Manager is responsible to evaluate and present audit findings in the monthly QAI meeting/minutes. The QAI Committee is responsible to review, analyze and trend all monitoring results to ensure resolution is both occurring and is sustained.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152585	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING	(X3) DATE SURVEY COMPLETED 05/01/2015

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	2. The facility's 9-25-13 "Assessment and Preparation of Internal Access for Needle Placement" procedure number FMS-CS-IC-I-115-006C states, "The access must be assessed each treatment for patency, infection, and any abnormal findings . . . Look carefully for signs of infection . . . Listen: Staff who have been trained to auscultate vascular accesses should listen to the entire length of the access . . . Feel for thrill." Regarding post access site care: 1. Employee N, a PCT, was observed to discontinue the dialysis treatment on patient number 15 on 4-27-15 at 2:10 PM. The PCT removed both needles and placed gauze and tape over the needle removal sites. The PCT failed to replace the gauze over the needle removal sites when the bleeding had stopped. 2. Employee S was observed to discontinue the dialysis treatment on patient number 16 on 4-28-15 at 10:55 AM. The PCT removed both needles and placed gauze and tape over the needle removal sites. The PCT failed to replace the gauze over the needle removal sites when the bleeding had stopped. 3. The facility's 3-26-14 "Post Treatment			

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	Fistula Needle Removal" procedure number FMS-CS-IC-I-115-013C states, "Once hemostasis [bleeding has stopped] has been achieved, remove the gauze used for hemostasis and replace the sites with Band-Aids or adhesive dressing or clean tape with gauze." 4. All of the findings regarding the care of the access, both pre- and post-dialysis were discussed with the clinical manager, employee B, and the charge nurse, employee G, on 4-30-15 at 12:25 PM. The manager and the charge nurse indicated the employees had not provided pre- and post-access care in accordance with facility policy.			
V 559 Bldg. 00	494.90(b)(3) POC-OUTCOME NOT ACHIEVED-ADJUST POC 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- (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.			

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	Based on clinical record and facility policy review and interview, the facility failed to ensure records included documentation of reasons for goals not being met and adjustments of plans of care to identify identified reasons in 2 (#s 2 and 8) of 10 records reviewed. The findings include: 1. Clinical record number 2 failed to evidence possible reasons for the failure to attain the patient's estimated dry weight (EDW) had been addressed and the plan of care updated to address the potential reasons. A. The record included a "Hemodialysis Care Plan Update" dated 2-20-15 that states, "difficult wt [weight] d/t [due to] chair wt." B. The record included a "Hemodialysis Care Plan Update" dated 3-30-15 that states, "? EDW needs [changed] - difficult to weigh in chair." C. The updates failed to evidence changes to the plan of care had been implemented to address the identified reasons for the patient not reaching the EDW. 2. Clinical record number 8 evidenced	V 559	The Director of Operations reviewed the following policies FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care Policy" with the Clinical Manager on 5/11/15 emphasizing his responsibility to ensure all staff members are educated on the policies, competency is assessed and staff understands the requirement to follow policies and procedures as written. A mandatory in-service is scheduled for all staff the week of 5/4/15 and 5/15/15 and the clinic manager will review & re-educate the following policies: • FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care Policy" Education Department is offering formalized classes for POC/CIA on May 19th and 21st. Special emphasis was placed on ensuring that the patient's EDW is addressed with documentation in POC for root causes; recording of patient Absence and Hospitalizations; and documented AMA's. This will be monitored daily by the nurse using the rounding tool. The Clinical Manager will monitor the results of the Rounding Tool audits weekly for 4 weeks and ongoing monitoring will be determined by the QAI Committee upon review of	06/01/2015

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	the patient was "absent" on 4-14-15, 4-16-15, 4-21-15, and 4-25-15 and had signed off early on 4-18-15. The record failed to evidence the facility had identified any reasons for the missed treatments and had adjusted the plan of care to address the identified reasons. The facility's "Absence and Hospitalization Report" from 1-27-15 to 4-27-15 failed to include the patient's name or the reasons for the missed treatments. 3. The clinic manager, employee B, and the charge nurse, employee G, were unable to provide any additional documentation and/or information when asked on 5-1-15 at 10:00 AM. 4. The facility's 7-4-12 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "If the patient specific expected outcome as determined by the attending physician, IDT [interdisciplinary team] and patient for the Plan of Care is not achieved within the identified timeframe: Interdisciplinary team must adjust the patient's Plan of Care as described in the Plan of Care/Updates section of this policy in a effort to achieve the specified goal. If the patient is unable to achieve		monitoring results and resolution of the issue. The Clinical Manager is responsible to report a summary of findings monthly in QAI. If resolution is not evident, the QAI Committee will complete a root cause analysis and the Plan of Correction will be revised as necessary.	

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	the desired outcomes, the team must adjust the Plan of Care to reflect the patient's current condition, and Document in the medical record the reason(s) why the patient is unable to achieve the goal. Implement the Plan of Care changes to address the identified issues."			
V 638 Bldg. 00	494.110(b) QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time. Based on quality assessment and performance improvement (QAPI) documentation and facility policy review and interview, the facility failed to ensure it had implemented a performance improvement plan to address hemoglobin values of less than 10 in 4 (December 2014 and January, February, and March 2015) of 4 months reviewed. The findings include: 1. The facility's Quality Status Reports (QSR) identified an increasing percentage of patients with hemoglobin levels of less than 10 in December 2014, January, February, and March 2015.	V 638	The Director of Operations and the Clinic Manager participated in mandatory Quality Assessment and Performance Improvement Program training on 1/22/15. Education provided by the Regional Quality Manager, Regional Technical Operations Manager and Regional Education Manager. The Director of Operations met with the Clinical Manager on 5/11/15 emphasizing his responsibility to ensure "Quality Assessment and Performance Improvement Program (QAPI)" policy number FMS-CS-IC-I-101-001A and the requirement to follow policy and procedure as written. Special emphasis was placed on Anemia	06/01/2015

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	The QSR identified the percentage of patients with a hemoglobin of less than 10 was 15.6 for the period ending 12-31-14, 17% for the period ending 1-31-15, 18.3% for the period ending 2-28-15, and 24.1% for the period ending 3-31-15. 2. The clinic manager, employee B, indicated, on 5-1-15 at 1:45 PM, the facility initiates a performance improvement project for a particular area if there is a progressive deviation for at least 3 months. The manager stated, "We do not have a performance improvement project in place for anemia at this time." 3. The facility's QAPI meeting minutes, dated 4-28-15, failed to evidence the facility had addressed the progressive increase in the percentage of patients with hemoglobin values of less than 10. 4. The facility's 4-4-12 "Quality Assessment and Performance Improvement Program" policy number FMS-CS-IC-I-101-001A states, "QAI Program activities for each facility or program include: . . . Review of aggregate patient data by modality to identify opportunities for improvement for clinical outcomes, and track progress by: Evaluating clinical indicators monthly using the Quality Status Reports		Management and addressing sub 10 HGB's. The Director of Operations, Medical Director, and Clinic Manager will ensure that aggregate patient data is reviewed by modality to identify opportunities for improvement for clinical outcomes and track progress as determined by the QAI calendar. Any commonalities identified among patients who do not reach the minimum expected patient targets indicators identified during monthly QAPI will be addressed by the DO, Medical Director, and Clinic Manager. Action plan (s) will be developed to address those causes; plan to be implemented and monitored for effectiveness, with adjustments made to portions of plan that are not successful. The Clinical Manager is responsible to evaluate and Action Plans in the monthly QAI meeting/minutes. The QAI Committee is responsible to review, analyze and trend all monitoring results to ensure resolution is both occurring and is sustained. Governing Body oversight will ensure full compliance of the QAPI per policy.	

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	(QSR) . . . Identify commonalities among patients who do not reach the minimum expected patient targets, Develop a plan to address those causes, Implement the plan, Monitor the effectiveness of the plan, Adjust portions of the plan that are not successful."			
V 758 Bldg. 00	494.180(b)(1) GOV-RN, MSW, & RD AVAIL TO MEET PT NEEDS The governing body or designated person responsible must ensure that- The registered nurse, social worker and dietitian members of the interdisciplinary team are available to meet patient clinical needs; Based on clinical record and facility policy review and interview, the governing body failed to ensure a registered dietitian was available to provide dietary counseling services on a monthly basis to monitor patients' albumin levels and manage mineral metabolism and renal bone disease in 6 (#s 2, 4, 6, 8, 9, and 10) of 6 records reviewed of patients that had received dialysis treatments for longer than 90 days. The findings include: Regarding the monitoring of patients' albumin levels:	V 758	The Director of Operations and the Clinic Manager participated in mandatory Quality Assessment and Performance Improvement Program training on 1/22/15. Education provided by the Regional Quality Manager, Regional Technical Operations Manager and Regional Education Manager. This education included but was not limited to the following: •QAI processes including monthly analysis and trending. · Ensuring that the RN, MSW, and RD members of the IDT are available to meet patient clinical needs. · Ensuring Governing Body recognizes any vacancies on the IDT (RN, MSW, RD) and appoints appropriate staff members of the	06/01/2015

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	1. The facility's 7-4-12 "Nutrition Services" policy number FMS-CS-IC-I-111-001A states, "Evidence-based professionally accepted nutrition related indicators will be reviewed monthly, or as is appropriate, to determine the patient's current nutritional status and response to the plan of care, and patients will be counseled accordingly . . . The monthly review of biochemical, adequacy and anthropometric data will be documented by the RD [registered dietitian] either as a progress note or, when indicated per the Comprehensive Patient Assessment and Plan of Care Policy, as part of the interdisciplinary assessment and plan of care form." 2. According to the Centers for Medicare and Medicaid Services (CMS) Measures Assessment Tool (MAT), the desired albumin level is equal to or greater than 4.0 grams per deciliter (g/dL). 3. Clinical record number 2 evidenced a dialysis start date at the facility of 10-31-14. The record failed to evidence any dietary counseling had been provided for November and December 2014 or January and February 2015. The record included laboratory results that identified the albumin level had		professional staff during vacancy. The Director of Operations met with the Medical Director, RVP, and Clinic Manager on 5/11/15 emphasizing the Governing Body's responsibility to ensure the RN, MSW, and RD members of the IDT are available to meet patient clinical needs. "Quality Assessment and Performance Improvement Program (QAPI)" policy number FMS-CS-IC-I-101-001A and the requirement to follow policy and procedure as written. The Clinical Manager, Director of Operations are responsible to evaluate and present vacant IDT positions along with audit findings in the monthly QAI meeting/minutes. The QAI Committee/Governing Body is responsible to review, analyze and trend all monitoring results to ensure resolution is both occurring and is sustained. Governing Body oversight will ensure full compliance per policy	

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	declined. The laboratory results evidenced the albumin level was 3.6 g/dL on 11-3-14, 3.5 g/dL on 12-1-14, and 3.4 g/dL on 1-5-15 and 2-2-15. 4. Clinical record number 4 evidenced a dialysis start date at the facility of 8-29-14. The record failed to evidence any dietary counseling had been provided for November and December 2014 or January and February 2015. The record included laboratory results that identified the albumin level had declined. The laboratory results evidenced the albumin level was 4.2 on 11-3-14, 3.9 on 12-1-14, 3.5 on 1-5-15, and 3.1 on 2-2-15. 5. Clinical record number 6 evidenced a dialysis start date at the facility of 9-12-13. The record failed to evidence any dietary counseling had been provided for November and December 2014 or January and February 2015. The record included laboratory results that identified the albumin had remained below the desired level during this timeframe. The laboratory results evidenced the albumin level was 2.9 on 11-6-15, 3.0 on 12-2-15, 3.2 on 1-6-15, and 3.4 on 2-3-15.			

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	6. Clinical record number 8 evidenced a dialysis start date of 12-3-13. The record failed to evidence any dietary counseling had been provided for November and December 2014 and January and February 2015. The record included laboratory results that identified the albumin level had declined. The laboratory results evidenced the albumin level was 3.8 on 11-4-14, 3.4 on 12-2-14, and 2.9 on 2-3-15. The record failed to evidence any albumin laboratory results for the month of January 2015. 7. Clinical record number 9 evidenced a dialysis start date of 6-6-14. The record failed to evidence any dietary counseling had been provided for November and December 2014 and January and February 2015. The record included laboratory results that identified the albumin level had declined and had remained below the desired level of 4.0. The laboratory results evidenced the albumin level was 3.0 on 11-3-14, 2.8 on 12-1-14, 2.7 on 1-5-15, and 3.1 on 2-2-15. 8. Clinical record number 10 evidenced a dialysis start date of 3-7-14. The record failed to evidence any dietary counseling			

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	had been provided for November and December 2014 and January and February 2015. 9. The regional dietitian, employee BB, indicated, on 4-30-15 at 10:10 AM, per telephone call, dietary services had been provided by other registered dietitians in the area. The dietitian indicated the other dietitians had ensured interdisciplinary assessments and plans of care had been completed and had been available for patient questions or for emergencies. The dietitian indicated the patients' physicians had reviewed the patients' monthly laboratory results. Regarding the management of mineral metabolism and renal bone disease: 1. The facility's 7-4-12 "Nutrition Services" policy number FMS-CS-IC-I-111-001A states, "Evidence-based professionally accepted nutrition related indicators will be reviewed monthly, or as is appropriate, to determine the patient's current nutritional status and response to the plan of care, and patients will be counseled accordingly. Such indicators of nutrition status include but are not limited to . . . bone mineral metabolism . . . The monthly review of biochemical, adequacy and anthropometric data will be			

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	documented by the RD [registered dietitian] either as a progress note or, when indicated per the Comprehensive Patient Assessment and Plan of Care Policy, as part of the interdisciplinary assessment and plan of care form." 2. According to the Centers for Medicare and Medicaid Services (CMS) Measures Assessment Tool (MAT), the desired level for corrected calcium is less than 10.2 milligrams per deciliter (mg/dL) and the desired level for phosphorous is 3.5 to 5.5 gm/dL. 3. Clinical record number 2 evidenced a dialysis start date at the facility of 10-31-14. The record failed to evidence any dietary counseling had been provided for November and December 2014 or January and February 2015. The record included laboratory results that identified the patient's phosphorous levels were 4.2 on 11-3-14, 6.4 on 12-1-14, 7.0 on 1-5-15, 5.4 on 2-2-15, and 6.7 on 3-2-15. 4. Clinical record number 4 evidenced a dialysis start date at the facility of 8-29-14. The record failed to evidence any dietary counseling had been provided for November and December 2014 or January and February 2015.			

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	The record included laboratory results that identified the patient's phosphorous levels were 4.8 on 11-3-14, 5.6 on 12-1-14, 4.5 on 1-5-15, 6.0 on 2-2-15, and 5.8 on 3-2-15. 5. Clinical record number 6 evidenced a dialysis start date at the facility of 9-12-13. The record failed to evidence any dietary counseling had been provided for November and December 2014 or January and February 2015. The record included laboratory results that identified the patient's phosphorous levels were 2.9 on 11-6-14, 3.7 on 12-9-14, 2.4 on 1-6-15, 3.4 on 2-3-15, and 2.8 on 3-3-15. 6. Clinical record number 8 evidenced a dialysis start date of 12-3-13. The record failed to evidence any dietary counseling had been provided for November and December 2014 and January and February 2015. The record included laboratory results that identified the patient's phosphorous levels was 6.1 on 11-14-14, 5.9 on 12-2-14, 2.9 on 1-22-15, 4.6 on 2-3-15, and 4.3 on 3-3-15. 7. Clinical record number 9 evidenced a			

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE SHADELAND STATION		STREET ADDRESS, CITY, STATE, ZIP CODE 7155 SHADELAND STATION STE 130 INDIANAPOLIS, IN 46256	

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
	dialysis start date of 6-6-14. The record failed to evidence any dietary counseling had been provided for November and December 2014 and January and February 2015. The record included laboratory results that identified the patient's phosphorous levels were 4.0 on 12-1-14, 2.4 on 1-5-15, 6.3 on 2-2-15, and 5.0 on 3-2-15. 8. Clinical record number 10 evidenced a dialysis start date of 3-7-14. The record failed to evidence any dietary counseling had been provided for November and December 2014 and January and February 2015. 9. The regional dietitian, employee BB, indicated, on 4-30-15 at 10:10 AM, per telephone call, dietary services had been provided by other registered dietitians in the area. The dietitian indicated the other dietitians had ensured interdisciplinary assessments and plans of care had been completed and had been available for patient questions or for emergencies. The dietitian indicated the patients' physicians had reviewed the patients monthly laboratory results. 10. Governing body meeting minutes dated 10-30-14 failed to evidence any mention of the vacant registered dietitian			

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	(RD) position. A. Governing body meeting minutes dated 12-17-14 state, "The appointment of the following employees as members of the professional staff and thereby affirms the applicable privileges: . . . Renal Dietitian: open position, RD." B. Governing body meeting minutes dated 1-22-15 failed to evidence any mention of the vacant RD position. C. Governing body meeting minutes dated 2-26-15 failed to evidence any mention of the vacant RD position. 11. The Director of Operations, employee CC, indicated, on 5-1-15 at 12:30 PM, the facility had been without an RD since October 2014. The director indicated the current RD had been hired mid-February 2015.			